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15 KASOWITZ, BENSON, TORRES & FRIEDMAN LLP

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

16 UNITED STATES OF AMERICA,
17 *Ex rel.* KASOWITZ, BENSON, TORRES &
FRIEDMAN LLP,

18 Plaintiff,

19 v.

20 BASF CORPORATION;
21 BAYER MATERIALSCIENCE, LLC, f/k/a/ MILES,
22 INC. f/k/a MOBAY CHEMICAL COMPANY;
THE DOW CHEMICAL COMPANY; and
23 HUNTSMAN INTERNATIONAL LLC, f/k/a
24 IMPERIAL CHEMICAL INDUSTRIES PLC and f/k/a
ICI AMERICAS, INC.

25 Defendants.
26
27
28

SEALED BY ORDER
OF THE COURT

FILED

SEP 24 2015

SUSAN Y. SOONG
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND

CIVIL ACTION NO. CV 15 2262-DMR

AMENDED *QUI TAM* COMPLAINT

DEMAND FOR JURY TRIAL

FILED IN CAMERA AND
UNDER SEAL PER
31 U.S.C. § 3730(b)(2)

KASOWITZ, BENSON, TORRES & FRIEDMAN LLP
101 CALIFORNIA STREET, SUITE 2300
SAN FRANCISCO, CALIFORNIA 94111

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

1 UNITED STATES OF AMERICA,)
2 *Ex rel.* KASOWITZ, BENSON, TORRES &)
3 FRIEDMAN LLP,) CIVIL ACTION NO. CV 15 2262-DMR
4)
5 Plaintiff,)
6 v.) AMENDED *QUI TAM* COMPLAINT
7) DEMAND FOR JURY TRIAL
8 BASF CORPORATION;)
9 BAYER MATERIALSCIENCE, LLC, f/k/a/ MILES,)
10 INC. f/k/a MOBAY CHEMICAL COMPANY;) FILED IN CAMERA AND
11 THE DOW CHEMICAL COMPANY; and) UNDER SEAL PER
12 HUNTSMAN INTERNATIONAL LLC, f/k/a) 31 U.S.C. § 3730(b)(2)
13 IMPERIAL CHEMICAL INDUSTRIES PLC and f/k/a)
14 ICI AMERICAS, INC.)
15 Defendants.)

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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

1	UNITED STATES OF AMERICA,	)	
2	<i>Ex rel.</i> KASOWITZ, BENSON, TORRES &	)	
3	FRIEDMAN LLP,	)	CIVIL ACTION NO. 15-2262-DMR
4		)	
5	Plaintiff,	)	
6	v.	)	AMENDED <i>QUI TAM</i> COMPLAINT
7		)	DEMAND FOR JURY TRIAL
8	BASF CORPORATION;	)	
9	BAYER MATERIALSCIENCE, LLC, f/k/a/ MILES,	)	FILED IN CAMERA AND
10	INC. f/k/a MOBAY CHEMICAL COMPANY;	)	UNDER SEAL PER
11	THE DOW CHEMICAL COMPANY; and	)	31 U.S.C. § 3730(b)(2)
12	HUNTSMAN INTERNATIONAL LLC, f/k/a	)	
13	IMPERIAL CHEMICAL INDUSTRIES PLC and f/k/a	)	
14	ICI AMERICAS, INC.	)	
15		)	
16	Defendants.	)	

AMENDED QUI TAM COMPLAINT

Qui tam plaintiff and relator Kasowitz, Benson, Torres & Friedman LLP (KBT&F), on behalf of itself and the United States of America (United States), amends its original complaint to allege four additional claims against Huntsman, based on newly-discovered and previously-unavailable evidence, and to amend the factual allegations in the complaint to reflect this newly-discovered evidence. KBT&F complains and alleges as follows:

I. OVERVIEW

1. Over the past several decades, defendants BASF, Bayer, Dow, and Huntsman have sold billions of dollars worth of isocyanate chemicals while concealing from consumers and the EPA that merely touching those chemicals, or inhaling their vapors at concentrations thought (incorrectly) to be safe, can cause and has caused permanent pulmonary injury in humans. These chemical companies have deliberately violated their statutory and contractual duties to report to the EPA the extensive, non-public evidence they have obtained about these unexpected hazards, and have instead vigorously concealed that evidence to protect their substantial profits and to

1 avoid or deflect regulatory scrutiny. These companies have thus callously caused injury to many
2 unsuspecting consumers and workers, and have obstructed the EPA's hazard identification and
3 risk assessment activities. Each of these companies is separately liable to the United States
4 Government for billions of dollars in civil reporting penalties, which continue to accumulate by
5 tens of thousands of dollars daily, and for billions of dollars in similarly increasing breach of
6 contract damages.

7 2. For decades, each defendant, individually and in conspiracy with the others, has
8 aggressively concealed from the EPA its statutory and contractual violations, as well as its
9 liability for civil penalties and breach of contract damages, and has knowingly and improperly
10 concealed and avoided paying those penalties and damages. Similarly, each defendant has
11 concealed its multiple obligations to transmit to the government property (the multiple separate
12 items of concealed hazard information) that is worth billions of dollars. Each defendant's active
13 concealment tolled the applicable statutes of limitations on the underlying reporting and breach
14 of contract claims against it.

15 3. On May 20, 2009, the effective date of the 2009 amendments to the False Claims
16 Act, each defendant had multiple continuing and increasing obligations to pay money and
17 transmit property to the EPA, and their continuing concealment and avoidance of those
18 obligations began also to violate the False Claims Act. Each day since May 20, 2009, these
19 companies have continued actively and knowingly to conceal and avoid their individual
20 obligations, which have continued to increase, and are therefore liable under the False Claims
21 Act to the United States Government for three times the amount of those obligations, plus a
22 penalty for each separate violation of the False Claims Act.

23 4. As authorized by 31 U.S.C. § 3730(b)(1), KBT&F brings this action on behalf of
24 itself and the United States to recover treble damages and penalties under the False Claims Act
25 (FCA), 31 U.S.C. §§ 3729-3733.

26 5. As required by 31 U.S.C. § 3730(b)(2), KBT&F filed its original complaint under
27 seal and served on the United States Government, in accordance with Federal Rule of Civil
28

1 Procedure 4, a copy of that complaint and a written disclosure of substantially all material
2 evidence and information that KBT&F then possessed. As required by 31 U.S.C. § 3730(b)(2),
3 KBT&F files this amended complaint under seal and serves on the United States Government, in
4 accordance with Federal Rule of Civil Procedure 5(b)(1), a copy of this amended complaint and
5 a supplemental disclosure of the material evidence and information that KBT&F possesses in
6 support of its additional claims against Huntsman.

7 6. Concurrently with filing of its original complaint, and in accordance with 31
8 U.S.C. § 3730(e)(4)(B), KBT&F voluntarily disclosed to the United States Government the
9 information on which it based the claims in that complaint. Prior to seeking leave of court to file
10 this amended complaint, and in accordance with 31 U.S.C. § 3730(e)(4)(B), KBT&F voluntarily
11 disclosed to the United States Government the information on which it bases the additional
12 claims it alleges against Huntsman in this amended complaint.

13 7. The defendants manufacture and sell isocyanate chemicals, including methylene
14 diphenyl diisocyanate (MDI), polymeric MDI (PMDI), and toluene diisocyanate (TDI). When
15 reacted with polyol chemicals, isocyanates form polyurethane. By varying the type of isocyanate
16 and polyol reacted, the manufacturer can produce a variety of polyurethane materials, including
17 liquid coatings, paints, and adhesives; flexible foam used in mattresses and cushions; rigid foam
18 used as insulation; and elastomers used to make automotive interiors. These isocyanates, and
19 particularly PMDI, are increasingly being used in environments that create the possibility for
20 “by-stander” exposures, and are also being incorporated into consumer-level products, thus
21 increasing the opportunities for exposure and resulting injury.

22 8. Individually and in conspiracy, and in conscious violation of its reporting and
23 disclosure obligations imposed by Section 8(e) of the Toxic Substances Control Act (TSCA),
24 each defendant intentionally withheld from the Environmental Protection Agency (EPA)
25 numerous discrete items of non-public information, obtained or developed by it separately over
26 many years, that reasonably support the conclusion that its isocyanate chemicals present a
27
28

1 substantial risk of injury to health. Such information is commonly called “substantial risk
2 information.”

3 9. As described more specifically below, between at least 1979 and 2003, each
4 defendant obtained and developed discrete and separate items of scientific and medical
5 information that MDI and PMDI can cause and had caused permanent respiratory injury in
6 humans as a result of skin exposure. Defendants knew that this information reasonably
7 supported the conclusion that MDI and PMDI, as well as the similar chemical TDI, presented a
8 substantial risk of injury to health, that the EPA was not adequately informed of that information,
9 and that TSCA therefore required that they (each defendant) immediately report the substantial
10 risk information to the EPA.

11 10. Each defendant also knew during this time period that a very small quantity of
12 TDI, MDI, or PMDI on the skin—as little as one drop or 50 microliters—could cause permanent
13 respiratory injury in humans.

14 11. Moreover, between at least 1979 and 2003, each defendant obtained and
15 developed discrete and separate items of scientific and medical information that TDI, MDI, and
16 PMDI can cause and had caused permanent respiratory injury in humans when inhaled at levels
17 below applicable inhalation exposure limits (low-level inhalation). Defendants knew that this
18 information reasonably supported the conclusion that TDI, MDI, and PMDI presented a
19 substantial risk of injury to health, that the EPA was not adequately informed of that information,
20 and that TSCA therefore required that they (each defendant) immediately report the substantial
21 risk information to the EPA.

22 12. The defendants, the isocyanate industry, and the EPA have long known that
23 inhalation of isocyanates, including MDI, PMDI, and TDI, can cause respiratory injury, if the
24 inhalation exposure exceeds the applicable inhalation exposure limits. But the EPA, unaware of
25 the defendants’ concealed substantial risk information, continues to consider the dermal
26 induction of respiratory injury only a possibility. Indeed, in direct contradiction of their
27 extensive, concealed evidence that confirms the dermal induction route, the defendants have
28

1 publicly disputed the potential for dermal induction of respiratory injury. By concealing their
2 cache of extensive human evidence, the defendants have enabled themselves to deride the scant
3 human evidence that is publicly available as “anecdotal” and “inconclusive,” and have thereby
4 misled the EPA and shielded their isocyanate products from increased regulatory scrutiny or
5 action.

6 13. Moreover, unaware of the defendants’ concealed substantial risk information, the
7 EPA also continues to consider the low-level-inhalation induction of respiratory injury only a
8 possibility. Indeed, in direct contradiction of their extensive concealed evidence that confirms
9 respiratory injury from low-level inhalation, the defendants have publicly disputed the potential
10 for such an injury. By concealing their substantial risk information, the defendants have misled
11 the EPA and shielded their isocyanate products from increased regulatory scrutiny or action.

12 14. Rather than rectify their reporting and disclosure violations, defendants have
13 instead continued both to conceal the hazards and risks indicated by the information they were
14 required to report, and to falsely represent to the United States Government, including the EPA,
15 that those hazards and risks are non-existent or, at a minimum, that there is no reliable evidence
16 of those hazards and risks.

17 15. Because of their numerous reporting and disclosure evasions, which have
18 continued over many years, defendants have accumulated billions of dollars in civil penalties
19 under TSCA Section 8(e).

20 16. Defendants have knowingly concealed or knowingly and improperly avoided or
21 decreased their obligation to transmit property (the substantial risk information about their
22 isocyanate products) and/or money (the accumulated TSCA reporting penalties) to the United
23 States. Each defendant’s knowing concealment and avoidance violates the FCA and makes it
24 individually liable for three times the damages to the United States plus FCA penalties or
25 forfeitures in the amount of \$5,500 to \$11,000 for each of its FCA violation.

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II. PARTIES

17. KBT&F, a limited liability partnership, is a law firm with its principal office located at 1633 Broadway, New York, New York 10019.

18. As alleged more fully below, while KBT&F was prosecuting product liability, fraud, and conspiracy claims against many different companies, including defendants BASF, Bayer, and Dow, in the consolidated actions *Bice, et al. v. Micon, Inc., et al.*, Circuit Court of Tuscaloosa County, Alabama, Civil Action File Nos. CV-07-325, 07-326, and 07-327 (*Bice*), KBT&F, through an aggressive and targeted discovery effort, uncovered evidence showing defendants' TSCA reporting violations, as well as evidence showing their ongoing individual and conspiratorial fraud to conceal from the EPA and others the existence of the reportable information.

19. After the resolution of that litigation, KBT&F conducted additional investigation and discovered that these companies' reporting failures also violated their contracts with the EPA. KBT&F has direct and independent knowledge of the information on which these FCA allegations are based.

20. None of the evidence concerning the defendants' receipt of the reportable substantial risk information, or their individual and conspiratorial concealment of that information, was ever "publicly disclosed" as "public disclosure" was defined under the terms of the FCA's governing public disclosure bar.

21. BASF Corporation (BASF) is a Delaware corporation with its principal office in Florham Park, New Jersey. BASF manufactures MDI, PMDI, and/or TDI in various locations in the United States, and sells MDI, PMDI, and/or TDI throughout the United States, including in the State of California.

22. Since at least 1988, BASF has manufactured and sold MDI, PMDI, and TDI in the United States.

1 23. Since at least 1988, BASF has been a member of and has participated in the
2 business of the International Isocyanate Institute (III), an industry association of isocyanate
3 manufacturers.

4 24. Since at least 1988, BASF has been a member of and has participated in the
5 business of the Diisocyanates Panel of the American Chemistry Council (ACC) or its
6 predecessor, the Chemical Manufacturers' Association (CMA).

7 25. Bayer MaterialScience LLC (Bayer) is a Delaware limited liability company with
8 its principal office in Pittsburgh, Pennsylvania. Bayer manufactures MDI, PMDI, and/or TDI in
9 various locations in the United States, and sells MDI, PMDI, and/or TDI throughout the United
10 States, including in the State of California.

11 26. Mobay Chemical Company (Mobay) was a joint venture between Monsanto
12 Company, a United States corporation, and Bayer AG, a company organized under the laws of
13 Germany, to market isocyanates/polyurethanes in the United States. During the 1970s, Bayer
14 AG bought out Monsanto's share of the Mobay joint venture. In 1992, Bayer AG, having
15 previously acquired Miles Laboratories, Inc., consolidated Mobay and Miles Laboratories, Inc.
16 into Miles, Inc. (Miles). Both Mobay and Miles manufactured and sold MDI, PMDI, and TDI
17 and were members of and participated in the business of the International Isocyanate Institute
18 (III), an industry association of isocyanate manufacturers. Bayer MaterialScience LLC is the
19 successor-in-interest to Mobay and Miles. As used in this complaint, "Bayer" means Bayer
20 MaterialScience and its predecessors-in-interest Mobay and Miles.

21 27. Since at least 1979, Bayer, either itself or through its predecessors-in-interest
22 Mobay and/or Miles, has manufactured and sold MDI, PMDI, and TDI in the United States.

23 28. Since at least 1979, Bayer, either itself or through its predecessors-in-interest
24 Mobay and/or Miles, has been a member of and has participated in the business of the III.

25 29. Since at least 1979, Bayer, either itself or through its predecessors-in-interest
26 Mobay and/or Miles, has been a member of and has participated in the business of the
27 Diisocyanates Panel of the ACC or its predecessor, the CMA.

1 30. The Dow Chemical Company (Dow) is a Delaware corporation with its principal
2 office in Midland, Michigan. Dow manufactures MDI, PMDI, and/or TDI in various locations in
3 the United States, and sells MDI, PMDI, and/or TDI throughout the United States, including in
4 the State of California.

5 31. Since at least 1982, Dow has manufactured and sold TDI in the United States.

6 32. Since at least 1986, Dow has manufactured and sold MDI and PMDI in the
7 United States.

8 33. Since at least 1982, Dow has been a member of and has participated in the
9 business of the III.

10 34. Since at least 1982, Dow has been a member of and has participated in the
11 business of the Diisocyanates Panel of the ACC or its predecessor, the CMA.

12 35. Huntsman International LLC (Huntsman) is a Delaware limited liability company
13 with its principal office in Salt Lake City, Utah. Huntsman manufactures MDI, PMDI, and/or
14 TDI in various locations in the United States, and sells MDI, PMDI, and/or TDI throughout the
15 United States, including in the State of California.

16 36. Imperial Chemical Industries plc (ICI plc) was a public limited company
17 organized under the laws of the United Kingdom. ICI Americas, Inc. (ICI Americas) was a
18 Delaware corporation and a subsidiary of ICI plc. Both ICI plc and ICI Americas manufactured
19 and sold MDI, PMDI, and TDI and were members of and participated in the business of the
20 International Isocyanate Institute (III), an industry association of isocyanate manufacturers. In
21 1999, a holding company formed by Huntsman acquired ICI plc's isocyanate/polyurethanes
22 business, including the isocyanate/polyurethanes business of ICI America. Huntsman is now the
23 successor-in-interest to the isocyanate/polyurethanes businesses of ICI plc and ICI Americas. As
24 used in this complaint, "Huntsman" means Huntsman International LLC and its predecessors-in-
25 interest ICI plc and ICI Americas.

37. Since at least 1988, Huntsman, either itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has manufactured and sold MDI, PMDI, and TDI in the United States.

38. Since at least 1988, Huntsman, either itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has been a member of and has participated in the business of the III.

39. Since at least 1988, Huntsman, either itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has been a member of and has participated in the business of the Diisocyanates Panel of the ACC or its predecessor, the CMA.

III. JURISDICTION AND VENUE

40. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331, which confers original jurisdiction over actions arising under the laws of the United States, and under 31 U.S.C. § 3732(a), which confers jurisdiction over claims arising under the FCA.

41. This Court has personal jurisdiction over each defendant under 31 U.S.C. § 3732(a), because one or more of the defendants BASF, Bayer, Dow, or Huntsman can be found, resides, or transacts business in this judicial district.

42. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because one or more of the defendants BASF, Bayer, Dow, or Huntsman can be found, resides, or transacts business in this judicial district.

IV. DEFENDANTS' UNDERLYING FCA OBLIGATIONS

A. Overview of FCA provisions relevant to defendants' underlying obligations.

43. As amended effective May 20, 2009, the FCA prohibits "knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

44. As amended effective May 20, 2009, the FCA defines the type of "obligation" whose concealment or avoidance violates the FCA: "[T]he term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-

1 grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or
2 regulation, or from the retention of any overpayment.” 31 U.S.C. § 3729(b)(3).

3 45. Here, each defendant’s FCA obligations arose in two contexts. First, each
4 defendant’s obligations arose “from statute or regulation,” specifically the continuing TSCA
5 reporting (Section IV.B, ¶¶ 46-173 below) and penalty (Section IV.D, ¶¶ 801-895 below)
6 obligations. Second each defendant’s obligations arose from the “express . . . contractual . . .
7 relationship” alleged in Sections IV.E and F, paragraphs 896-930 below, and include both the
8 obligation to report information and the obligation to pay damages for breach of the contractual
9 reporting obligation.

10 **B. Defendants’ TSCA Section 8(e) reporting obligation.**

11 **1. Overview of TSCA Section 8(e).**

12 46. Finding that some chemical substances and mixtures “may present an
13 unreasonable risk of injury to health or the environment” (15 U.S.C. § 2601(a)(2)), Congress
14 enacted TSCA with the policy that
15 adequate authority should exist to regulate chemical substances and mixtures
16 which present an unreasonable risk of injury to health of the environment, and to
17 take action with respect to chemical substances and mixtures which are imminent
18 hazards.

19 15 U.S.C. § 2601(b)(2).

20 47. Congress therefore granted the EPA broad authority to regulate chemicals,
21 including the authority to prohibit, limit, or restrict the production or sale of any chemical that
22 the EPA reasonably concludes “will present an unreasonable risk of injury to health or the
23 environment.” 15 U.S.C. § 2605(a).

24 48. Recognizing that the EPA needs information about the risks of these chemicals to
25 exercise its authority to regulate the privilege to manufacture or sell chemicals, Congress
26 declared as “the policy of the United States” that
27 adequate data should be developed with respect to the effect of chemical
28 substances and mixtures on health and environment and that the development of
such data should be the responsibility of those who manufacture and those who
process such chemical substances and mixtures.

1 15 U.S.C. § 2610(b)(2).

2 49. To execute that policy, Congress authorized the EPA to require chemical
3 manufacturing and processing companies to develop risk information about their chemicals,
4 should the EPA find that the existing data is insufficient reasonably to determine or predict those
5 risks. 15 U.S.C. § 2603.

6 50. To execute that policy, Congress also required in Section 8(e) of TSCA that
7 chemical manufacturers, processors, and distributors “immediately” disclose to the EPA any
8 information they obtain “which reasonably supports the conclusion” that “a chemical substance
9 or mixture” that the company manufactures, processes, or distributes “presents a substantial risk
10 of injury to health or the environment,” unless the company “has actual knowledge that the
11 [EPA] has been adequately informed of such information.” 15 U.S.C. § 2607(e).

12 51. After Congress enacted the TSCA, the Chemical Manufacturers’ Association
13 (CMA) (of which each defendant or its predecessor was a member) formed the TSCA Regulation
14 Advisory Committee Recording and Reporting Task Group to work with the EPA to develop
15 guidance for compliance with Section 8(e). That group worked with EPA for more than one year
16 to develop the EPA’s 1978 policy statement, which reflected the chemical industry’s input as to
17 how Section 8(e) should work. That policy statement is “Toxic Substances Control Act,
18 Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk,” 43 Fed.
19 Reg. 11110, March 16, 1978 (“1978 Policy Statement”).

20 52. In June 1991, the EPA issued the “TSCA Section 8(e) Reporting Guide” (the
21 “1991 Reporting Guide”), which can be found on the EPA’s website at
22 <http://www.epa.gov/oppt/tsca8e/pubs/1991guidance.pdf> (last visited May 5, 2015). The EPA’s
23 1991 Reporting Guide reaffirmed and expanded on the 1978 Policy Statement.

24 53. In July 1993, the EPA proposed clarifications and amendments to its 1978 Policy
25 Statement, in “TSCA Section 8(e); Notice of Clarification and Solicitation of Public Comment,”
26 58 Fed. Reg. 37735, July 13, 1993 (“1993 Proposed Policy Clarification”).
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1 54. In June 2003, the EPA formally revised certain parts of the 1978 Policy Statement
2 in a document entitled “TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification
3 and Reporting Guidance,” 68 Fed. Reg. 33129, June 3, 2003 (“2003 TSCA Guidance
4 Revisions”). As to reporting policies material to the claims in this complaint, the 2003 TSCA
5 Guidance Revisions are virtually identical to those it announced ten years earlier in its 1993
6 Proposed Policy Clarification.

7 55. The EPA’s 1978 Policy Statement provides that “a person has ‘immediately
8 informed’ the Administrator if information is received by EPA not later than the 15th working
9 day after the date the person obtained such information.” 1978 Policy Statement, 43 Fed. Reg. at
10 11111, Unit IV. The EPA affirmed that policy in its 1991 Reporting Guide. 1991 Reporting
11 Guide at 11.

12 56. On July 13, 1993, the EPA announced its intention “to change the current 15-
13 working day reporting deadline for the submission of written reports containing substantial risk
14 information to 30 calendar days.” 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37736. In
15 its 2003 TSCA Guidance Revisions, the EPA formally revised the reporting period to “the 30th
16 calendar day after the date the subject person obtained such information.” 2003 TSCA Guidance
17 Revisions at 33138, Section VIII, Unit IV.

18 57. Under TSCA, a “business organization is considered to have obtained any
19 information which any officer or employee capable of appreciating the significance of that
20 information has obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II. The EPA
21 left that provision unchanged by the 2003 TSCA Guidance Revisions. See 2003 TSCA
22 Guidance Revisions at 33137, Section VIII, Unit III.

23 58. To emphasize that the timely reporting of substantial risk information is
24 indispensable to the EPA’s ability to regulate the privilege to manufacture or sell chemicals,
25 Congress imposed significant daily penalties for reporting violations. TSCA originally imposed
26 a “civil penalty” of up to \$25,000 for each TSCA violation (since adjusted upward, as detailed
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below), and specified that “[e]ach day such a violation continues shall . . . constitute a separate violation.” 15 U.S.C. § 2615(a)(1).

59. Not only are TSCA violations assessed separately for each day that a TSCA violation continues, “TSCA § 8(e) violations are assessed per type of effect per chemical not reported.” The Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12 and 13, U.S. Environmental Protection Agency, at 26 (1999) (“TSCA Enforcement Response Policy”). “Multiple violations are to be assessed whenever more than one rule is violated and for each violation within a rule.” TSCA Enforcement Response Policy, at 26. Thus, a regulated company’s failure to report a particular piece of substantial risk information may constitute multiple separate TSCA violations and may therefore subject the company to multiple civil penalties for each day that the reporting violation continues.

60. In accordance with Congressional instruction, the EPA has adjusted TSCA’s civil penalty from time to time for inflation, as reflected in the following chart:

Adjustments to TSCA Civil Penalty			
01/01/77 - 1/30/97	01/31/97 – 3/15/04	03/16/04 – 1/12/09	01/13/09 - Present
\$25,000 per violation	\$27,500 per violation	\$32,500 per violation	\$37,500 per violation

Civil Monetary Penalty Inflation Adjustment Rule, 73 Fed. Reg. 75340, 75345 (Dec. 11, 2008).

2. Each defendant is and has been at all material times subject to Section 8(e)’s reporting requirement.

61. Section 8(e)’s requirement to report “substantial risk information” reads in full as follows:

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e).

62. As used in Section 8(e) and elsewhere in TSCA, the term “Administrator” means the Administrator of the EPA. 15 U.S.C. § 2602(1).

63. TSCA defines “chemical substance” to mean “any organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical,” with exceptions not material here. 15 U.S.C. § 2602(2).

64. TSCA defines “mixture” to mean:
any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

15 U.S.C. § 2602(8).

65. Methylene diphenyl diisocyanate (MDI) is and has been since at least 1979 a “chemical substance or mixture” as defined in TSCA.

66. Polymeric MDI (PMDI) is and has been since at least 1979 a “chemical substance or mixture” as defined in TSCA.

67. Indeed, as each defendant has acknowledged, PMDI is “a mixture of MDI and higher molecular weight oligomers of MDI,” with MDI representing “[a]pproximately 50%” of that mixture. *Initial Submission: Letter from International Isocyanate Institute to U.S. EPA submitting information on Monomeric and Polymeric MDI*, Submitted March 14, 1984, EPA Document ID: FYI-OTS-0794-1027, EPA00609-00626 at 00615, Exh. 1. Thus, because it is the primary component of PMDI, substantial risk information about MDI (a “substance”) is necessarily substantial risk information about PMDI (a “mixture” comprised primarily of MDI).

68. Each defendant has acknowledged that substantial risk information reportable for MDI is also reportable for PMDI. On March 14, 1984, the III responded to a request for information about MDI from the TSCA Interagency Testing Committee (ITC). Although the

1 ITC had requested information about MDI (CAS numbers 101-68-8 and 26447-40-5), the III also
 2 believed it necessary to make a PMDI submission of its MDI information: “However, since
 3 MDI is mostly manufactured and sold in its polymeric form, we are also submitting information
 4 on this third chemical group [identifying PMDI].” *Id.*, Exh.1 at EPA00613.

5 69. Further, because PMDI consists primarily of MDI, substantial risk information
 6 about PMDI (a “mixture”) is necessarily substantial risk information about MDI, the “substance”
 7 that is the primary constituent of PMDI.

8 70. Toluene diisocyanate (TDI) is and has been since at least 1979 a “chemical
 9 substance or mixture” as defined in TSCA.

10 71. Each defendant has acknowledged that, in terms of human health risks, MDI and
 11 TDI are “closely related.” *Id.*, Exh. 1 at EPA00621.

12 72. The term “person” as used in TSCA Section 8(e) includes “corporations,
 13 companies, associations, firms, partnerships, societies, and joint stock companies.” 1 U.S.C. § 1.
 14 In its 1978 Policy Statement, the EPA indicates that the term “person” also includes sole
 15 proprietorships, associations, or any other business entity. 1978 Policy Statement, 43 Fed. Reg.
 16 at 11111, Unit I. The 1978 Policy Statement further provides that the “[p]ersons subject to
 17 section 8(e) reporting include both natural persons and business entities engaged in
 18 manufacturing, processing, or distributing in commerce a chemical substance or mixture.” 1978
 19 Policy Statement at 11111, Unit II. That provision is unchanged by the 2003 TSCA Guidance
 20 Revisions. See 2003 TSCA Guidance Revisions at 33137, Unit II. Defendants BASF, Bayer,
 21 Dow, and Huntsman are each “persons” subject to TSCA Section 8(e).

22 73. As used in TSCA, “[t]he term ‘commerce’ means trade, traffic, transportation, or
 23 other commerce (A) between a place in a State and any place outside of such State, or (b) which
 24 affects trade, traffic, transportation, or commerce described in clause (A).” 15 U.S.C. § 2602(3).

25 74. TSCA provides that “[t]he term ‘manufacture’ means to import into the customs
 26 territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of
 27 the United States), produce, or manufacture.” 15 U.S.C. § 2602(7).

1 75. TSCA Section 8(e) further provides that, for purposes of that section,
2 “manufacture” means to manufacture “for commercial purposes.” 15 U.S.C. § 2607(f).

3 76. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
4 “manufacture[d]” MDI “in commerce,”

5 77. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
6 “manufacture[d]” PMDI “in commerce.”

7 78. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
8 “manufacture[d]” TDI “in commerce.”

9 79. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
10 or through its predecessors-in-interest Mobay and/or Miles, has “manufacture[d]” MDI “in
11 commerce.”

12 80. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
13 or through its predecessors-in-interest Mobay and/or Miles, has “manufacture[d]” PMDI “in
14 commerce.”

15 81. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
16 or through its predecessors-in-interest Mobay and/or Miles, has “manufacture[d]” TDI “in
17 commerce.”

18 82. Since at least 1986, within the meaning of TSCA Section 8(e), Dow has
19 “manufacture[d]” MDI “in commerce.”

20 83. Since at least 1986, within the meaning of TSCA Section 8(e), Dow has
21 “manufacture[d]” PMDI “in commerce.”

22 84. Since at least 1982, within the meaning of TSCA Section 8(e), Dow has
23 “manufacture[d]” TDI “in commerce.”

24 85. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
25 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “manufacture[d]”
26 MDI “in commerce.”
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1 86. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
2 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “manufacture[d]”
3 PMDI “in commerce.”

4 87. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
5 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “manufacture[d]”
6 TDI “in commerce.”

7 88. TSCA defines “process” as follows:

8 The term “process” means the preparation of a chemical substance of mixture,
9 after its manufacture, for distribution in commerce—

- 10 (A) in the same form or physical state as, or in a different form or physical state from,
11 that in which it was received by the person so preparing such substance or
12 mixture, or
13 (B) as part of an article containing the chemical substance or mixture.

14 15 U.S.C. § 2602(10).

15 89. TSCA Section 8(e) further provides that, for purposes of that section, “process”
16 means to process “for commercial purposes.” 15 U.S.C. § 2607(f).

17 90. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
18 “processe[d]” MDI “in commerce.”

19 91. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
20 “processe[d]” PMDI “in commerce.”

21 92. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
22 “processe[d]” TDI “in commerce.”

23 93. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
24 or through its predecessors-in-interest Mobay and/or Miles, has “processe[d]” MDI “in
25 commerce.”

26 94. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
27 or through its predecessors-in-interest Mobay and/or Miles, has “processe[d]” PMDI “in
28 commerce.”

1 95. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
2 or through its predecessors-in-interest Mobay and/or Miles, has “processe[d]” TDI “in
3 commerce.”

4 96. Since at least 1986, within the meaning of TSCA Section 8(e), Dow has
5 “processe[d]” MDI “in commerce.”

6 97. Since at least 1986, within the meaning of TSCA Section 8(e), Dow has
7 “processe[d]” PMDI “in commerce.”

8 98. Since at least 1982, within the meaning of TSCA Section 8(e), Dow has
9 “processe[d]” TDI “in commerce.”

10 99. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
11 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “processe[d]” MDI
12 “in commerce.”

13 100. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
14 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “processe[d]”
15 PMDI “in commerce.”

16 101. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
17 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “processe[d]” TDI
18 “in commerce.”

19 102. TSCA defines “distribute” as follows:

20 The terms “distribute in commerce” and “distribution in commerce” when used to
21 describe an action taken with respect to a chemical substance or mixture or article
22 containing a substance or mixture mean to sell, or the sale of, the substance,
23 mixture, or article in commerce; to introduce or deliver for introduction into
24 commerce, or the introduction or delivery for introduction into commerce of, the
25 substance, mixture, or article; or to hold, or the holding of, the substance, mixture,
26 or article after its introduction into commerce.

27 15 U.S.C. § 2602(4).

28 103. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
“distribute[d]” MDI “in commerce.”

1 104. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
2 “distribute[d]” PMDI “in commerce.”

3 105. Since at least 1988, within the meaning of TSCA Section 8(e), BASF has
4 “distribute[d]” TDI “in commerce.”

5 106. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
6 or through its predecessors-in-interest Mobay and/or Miles, has “distribute[d]” MDI “in
7 commerce.”

8 107. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
9 or through its predecessors-in-interest Mobay and/or Miles, has “distribute[d]” PMDI “in
10 commerce.”

11 108. Since at least 1979, within the meaning of TSCA Section 8(e), Bayer either itself
12 or through its predecessors-in-interest Mobay and/or Miles, has “distribute[d]” TDI “in
13 commerce.”

14 109. Since at least 1986, within the meaning of TSCA Section 8(e), Dow has
15 “distribute[d]” MDI “in commerce.”

16 110. Since at least 1986, within the meaning of TSCA Section 8(e), Dow has
17 “distribute[d]” PMDI “in commerce.”

18 111. Since at least 1982, within the meaning of TSCA Section 8(e), Dow has
19 “distribute[d]” TDI “in commerce.”

20 112. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
21 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “distribute[d]”
22 MDI “in commerce.”

23 113. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
24 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “distribute[d]”
25 PMDI “in commerce.”
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1 114. Since at least 1988, within the meaning of TSCA Section 8(e), Huntsman, either
2 itself or through its predecessors-in-interest ICI plc and/or ICI Americas, has “distribute[d]” TDI
3 “in commerce.”

4 115. Because BASF is and has been since at least 1988 a “person who manufactures,
5 processes, or distributes in commerce [the] chemical substance[s] or mixture[s]” MDI, PMDI,
6 and/or TDI, BASF is and has been since at least 1988 obligated to “immediately inform the
7 Administrator [of the EPA]” of information it obtains “which reasonably supports the conclusion
8 that such substance or mixture [MDI, PMDI, and/or TDI] presents a substantial risk of injury to
9 health or the environment,” unless BASF “has actual knowledge that the Administrator has been
10 adequately informed of such information.” 15 U.S.C. § 2607(e).

11 116. Because Bayer either itself or through its predecessors is and has been since at
12 least 1979 a “person who manufactures, processes, or distributes in commerce [the] chemical
13 substance[s] or mixture[s]” MDI, PMDI, and/or TDI, Bayer is and has been since at least 1979
14 obligated to “immediately inform the Administrator [of the EPA]” of information it obtains
15 “which reasonably supports the conclusion that such substance or mixture [MDI, PMDI, and/or
16 TDI] presents a substantial risk of injury to health or the environment,” unless Bayer “has actual
17 knowledge that the Administrator has been adequately informed of such information.” 15 U.S.C.
18 § 2607(e).

19 117. Because Dow is and has been since at least 1986 a “person who manufactures,
20 processes, or distributes in commerce [the] chemical substance[s] or mixture[s]” MDI and
21 PMDI, Dow is and has been since at least 1986 obligated to “immediately inform the
22 Administrator [of the EPA]” of information it obtains “which reasonably supports the conclusion
23 that such substance or mixture [MDI and/or PMDI] presents a substantial risk of injury to health
24 or the environment,” unless Dow “has actual knowledge that the Administrator has been
25 adequately informed of such information.” 15 U.S.C. § 2607(e).

26 118. Because Dow is and has been since at least 1982 a “person who manufactures,
27 processes, or distributes in commerce [the] chemical substance or mixture” TDI, Dow is and has
28

1 been since at least 1982 obligated to “immediately inform the Administrator [of the EPA]” of
 2 information it obtains “which reasonably supports the conclusion that such substance or mixture
 3 [TDI] presents a substantial risk of injury to health or the environment,” unless Dow “has actual
 4 knowledge that the Administrator has been adequately informed of such information.” 15 U.S.C.
 5 § 2607(e).

6 119. Because Huntsman is and has been since at least 1988 a “person who
 7 manufactures, processes, or distributes in commerce a chemical substance or mixture,”
 8 Huntsman is and has been since at least 1988 obligated to “immediately inform the
 9 Administrator [of the EPA]” of information it obtains “which reasonably supports the conclusion
 10 that such substance or mixture presents a substantial risk of injury to health or the environment,”
 11 unless Huntsman “has actual knowledge that the Administrator has been adequately informed of
 12 such information.” 15 U.S.C. § 2607(e).

13 **3. The characteristics of reportable substantial risk information.**

14 120. TSCA Section 8(e) requires regulated companies immediately to report to the
 15 EPA non-exempt substantial risk information. The statute defines substantial risk information as
 16 information “which reasonably supports the conclusion that such [chemical] substance or
 17 mixture presents a substantial risk of injury to health or the environment,” and exempts the
 18 regulated company from reporting the information only if the company “has actual knowledge
 19 that the Administrator [of the EPA] has been adequately informed of such information.” 15
 20 U.S.C. § 2607(e).

21 121. TSCA defines substantial risk information as “information which reasonably
 22 supports the conclusion that such substance or mixture presents a substantial risk of injury to
 23 health or the environment.” 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that
 24 “‘reasonably supports the conclusion’ of substantial risk is not identical to a conclusive
 25 demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11110,
 26 Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a] person
 27 is not to delay reporting until he obtains conclusive information that a substantial risk exists, but
 28

1 is to immediately report any evidence which ‘reasonably supports’ that conclusion. Such
 2 evidence will generally not be conclusive as to the substantiality of the risk; it should, however,
 3 reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI. The EPA
 4 left this guidance unchanged by the 2003 TSCA Guidance Revisions. 2003 TSCA Guidance
 5 Revisions at 33139, Unit VI.

6 122. The EPA’s 1991 Reporting Guide reaffirmed the 1978 policy, providing that
 7 “such information need not and most typically does not establish conclusively that a substantial
 8 risk exists.” 1991 Reporting Guide at 2. The 1991 Reporting Guide provides that the “decision-
 9 making process for Section 8(e)-reportability should focus primarily on whether the toxicity or
 10 exposure information offers reasonable support for a conclusion of substantial risk under the
 11 criteria described above, but should not focus at all on whether the information is conclusive
 12 regarding the risk.” 1991 Reporting Guide at 2. Further, the 1991 Reporting Guide directs that
 13 “[t]he evidence that offers reasonable support for a conclusion of substantial risk need not be
 14 complete or definitive but should provide a plausible link between 1) an observed serious effect
 15 and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific product/activity
 16 and a previously unrecognized exposure to a chemical that is known or reasonably anticipated to
 17 cause serious adverse health or environmental effects.” 1991 Reporting Guide at 7.

18 123. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
 19 determination: “the seriousness of the effect” and “the fact or probability of its occurrence.”
 20 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
 21 factors are weighed differently for different effects. If the effects are among the human health
 22 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so
 23 serious that relatively little weight is given to exposure; the mere fact that the implicated
 24 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
 25 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
 26 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
 27 risk information.

124. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1). The EPA left that provision unchanged by the 2003 TSCA Guidance Revisions. See 2003 TSCA Guidance Revisions, 68 Fed. Reg. at 33138, Unit V(a)(1). Chemically-induced respiratory sensitization, which can lead to occupational asthma and permanent lung damage, is such a “serious” human health effect.

125. Accordingly, information about “[a]ny instance” of chemically-induced respiratory sensitization “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1). Indeed, the EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an effect is reportable: “It is anticipated here that reportable effects will generally occur in a pattern, where a significant common feature is exposure to the chemical. However, a single instance of . . . serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2). The EPA left that provision unchanged by the 2003 TSCA Guidance Revisions. 2003 TSCA Guidance Revisions 68 Fed. Reg. at 33138, Unit VI(2).

126. The “serious” human health effects identified in unit V(a)(2) of the 1978 Policy also include “[a]ny pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce . . . serious or prolonged incapacitation.” 1978 Policy Statement at 11112, Unit V(a)(2). The EPA left that provision unchanged by the 2003 TSCA Guidance Revisions. See 2003 TSCA Guidance Revisions, 68 Fed. Reg. at 33138, Unit V(a)(2). Chemically-induced respiratory sensitization, which can lead to occupational asthma and permanent lung damage, is such a human health effect.

127. Accordingly, “[a]ny pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce” chemically-induced respiratory

1 sensitization “must be reported” under TSCA Section 8(e), unless otherwise exempted. 1978
2 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1).

3 **4. Sources of substantial risk information.**

4 128. Congress intended a broad scope for the term “information” as used in TSCA
5 Section 8. Congress entitled Section 8 “Reporting and retention of *information*” and authorized
6 the EPA in Section 8(a)(2) to require regulated companies to maintain and report seven diverse
7 categories of information. 15 U.S.C. § 2607(a)(2). Those categories include various types of
8 information about the chemical substances or mixtures the regulated companies manufacture or
9 process (15 U.S.C. § 2607(a)(1)(A)-(D)), “all existing data concerning the environmental and
10 health effects of such substance or mixture” (*id.* at § 2607(a)(1)(E)), and various items of human
11 exposure information, including estimates of anticipated exposures, to those substances or
12 mixtures (*id.* at § 2607(a)(1)(F)).

13 129. Accordingly, the EPA’s 1978 Policy Statement provides that information that is
14 reportable under Section 8(e) may be obtained from sources other than designed, controlled
15 studies. Indeed, in its 1978 Policy Statement, the EPA identifies the sources of information that
16 “will often ‘reasonably support’ a conclusion of substantial risk.” 1978 Policy Statement, 43
17 Fed. Reg. at 11112, Unit VI. These sources include “reports concerning and studies of
18 undesigned, uncontrolled circumstances.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
19 VI(2). Examples of “[r]eports and studies of undesigned circumstances include: (i) medical and
20 health surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of effects in*
21 *consumers, workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
22 VI(2) (emphasis added). The EPA left these provisions unchanged by the 2003 TSCA Guidance
23 Revisions. 2003 TSCA Guidance Revisions, 68 Fed. Reg. at 33139, Units VI and VI(2).

24 130. As alleged more fully below, defendants obtained much of the reportable
25 substantial risk information that is the subject of this complaint from either written or verbal
26 reports at meetings of the International Isocyanate Institute (III). Those written or verbal reports
27 were “reports concerning . . . effects in consumers, workers, or the environment.”
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131. Additionally, as alleged more fully below, defendants obtained or developed medical and scientific data that constituted “evidence of effects in consumers, workers, or the environment.”

132. Further, the 1978 Policy Statement provides that a report from such “undesigned, uncontrolled circumstances” of “a single instance of . . . serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2). The EPA left this provision unchanged by the 2003 TSCA Guidance Revisions. 2003 TSCA Guidance Revisions, 68 Fed. Reg. at 33139, Unit VI(2). Chemically-induced respiratory sensitization, which can lead to occupational asthma and permanent lung damage, is a human health effect that can involve serious incapacitation.

133. The 1991 Reporting Guide reaffirms the 1978 Policy, providing that “TSCA Section 8(e)-reportable information can come from a variety of sources including, but not limited to draft, interim or final written reports (including study reports, letters, telegrams, telex reports) or verbal reports (received at meetings or by phone) that involve observations (including preliminary observations) from, for example, controlled or uncontrolled: (1) human or animal studies/events (including but not limited to studies/events that involve high dose levels *or non-routine routes of exposure*). . . .” 1991 Reporting Guide at 7 (emphasis added).

134. As alleged more fully below, defendants obtained much of the reportable substantial risk information that is the subject of this complaint from either written or verbal reports at meetings of the III. Those written or verbal reports involved observations from human events that involved a “non-routine route of exposure” (either skin contact or low-level inhalation exposure).

5. **The Section 8(e) reporting exemption does not exempt defendants’ reporting obligation.**

a. **Statutory reporting exemption.**

135. TSCA Section 8(e) provides a very limited exemption to its reporting obligation. The regulated company must report any substantial risk information it obtains unless the

1 company “has actual knowledge that the Administrator [of the EPA] has been adequately
2 informed of such information.” 15 U.S.C. § 2607(e).

3 136. As alleged more full with respect to each specific piece of substantial risk
4 information, none of the defendants had actual knowledge that the EPA had been adequately
5 informed of any of the substantial risk information, and each defendant was therefore required
6 immediately to report the information to the EPA.

7 137. Indeed, each defendant has publicly denied the existence of the very substantial
8 risk information that they are concealing, and have made such denials directly to the EPA as
9 recently as February 2013. None of the defendants can contend that they had actual knowledge
10 that the EPA was adequately informed of information the existence of which each defendant
11 publicly denies.

12 138. In a May 2002 III paper entitled “Respiratory sensitization: the role of dermal
13 contact with MDI and TDI,” defendants and other III member companies discussed the animal
14 and human data relevant to the potential link between skin contact with isocyanates and
15 respiratory sensitization. “Respiratory sensitization: the role of dermal contact with MDI and
16 TDI,” GIL Report, May 2002, CHARM 012422–012446, Exh. 2. The defendants neither
17 published nor otherwise discussed in that paper any of the substantial risk information at issue
18 here, even though all of that substantial risk information is relevant to the link between
19 isocyanate skin contact and human respiratory sensitization. Moreover, the defendants
20 concluded the paper by contending that the “available” human data was insufficient to establish
21 the link: “The available data do not provide sufficient evidence for a clear correlation between
22 skin exposure and occupational asthma.” *Id.* at CHARM 12442, Exh. 2. As shown on the title
23 page of that paper, each defendant or its predecessor-in-interest co-authored the paper. *Id.* at
24 CHARM 12425, Exh. 2. Further, Gilbert International Limited, the paper’s publisher, was the III
25 Scientific Office. *Id.* at CHARM 12422-12423.

26 139. Through the Diisocyanates Panel of the ACC, the defendants recently disputed the
27 potential for dermal induction of respiratory sensitization directly to the EPA. In April 2011, the
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1 EPA expressed its heightened interest in MDI and related chemicals by issuing an “MDI Action
 2 Plan.” *Methylene Diphenyl Diisocyanate (MDI) and Related Compounds Action Plan [RIN*
 3 *2070-ZA15]*, U.S. Environmental Protection Agency, April 2011 (“MDI Action Plan”). On
 4 February 26, 2013, defendants submitted comments to the EPA’s proposed MDI Action Plan
 5 through the ACC. Feb. 26, 2013 ACC Comments to MDI Action Plan, Exh. 3. Disputing the
 6 EPA’s statement in the MDI Action Plan that “[b]oth inhalation and dermal exposures to
 7 diisocyanates are thought to contribute to the development of isocyanate asthma” (*id.* at 9, Exh.
 8 3), the defendants contended “the role that dermal contact with diisocyanates plays in the
 9 development of occupational asthma remains unresolved for humans.” *Id.* at 10, Exh. 3.

10 140. Since defendants each denied as recently as February 2013 that dermal exposures
 11 are even “thought to contribute to the development of isocyanate asthma,” they cannot contend
 12 that they have now or have ever had actual knowledge that the EPA is adequately informed of
 13 the substantial risk information that shows and/or strongly suggests that dermal exposures
 14 contribute to the development of isocyanate asthma.

15 141. Defendants have also publicly disputed the possibility that low-level inhalation
 16 could cause respiratory sensitization. For example, in October 1993 the defendants, through the
 17 Diisocyanates Panel of the CMA (now the ACC), submitted comments to the EPA regarding its
 18 risk management process for diisocyanates. The defendants told the EPA that the proposition
 19 that “pulmonary function decrement and sensitization can occur at very low concentrations” was
 20 “not supported by available data.” *Comments of the Chemical Manufacturers Association*
 21 *Diisocyanate Panel on the RM1 Briefing Document for Diisocyanates*, October 12, 1993,
 22 BAY010036-010066 at BAY010037, Exh. 4. Each defendant or its predecessor-in-interest was
 23 a member of the CMA’s Diisocyanates Panel, which submitted these comments. *Id.* at
 24 BAY010041, n.1, Exh. 4.

25 142. More recently, through the Diisocyanates Panel of the ACC, the defendants again
 26 disputed the potential for low-level inhalation exposures to cause respiratory sensitization. In
 27 their February 26, 2013 comments to the EPA’s proposed MDI Action Plan, the defendants
 28

1 disputed the EPA's statement in the MDI Action Plan that "[b]oth inhalation and dermal
2 exposures to diisocyanates are thought to contribute to the development of isocyanate asthma"
3 (Feb. 26, 2013 ACC Comments to MDI Action Plan at 9, Exh. 3), the defendants contended:
4 "The ability of diisocyanates to induce respiratory sensitization in some individuals, and asthma
5 in some cases, is a known potential adverse health effect in humans *after exposure to*
6 *concentrations above workplace exposure limits.*" *Id.* at 10 (emphasis added), Exh. 3.

7 143. Since defendants each denied as recently as February 2013 that low-level
8 inhalation exposures are even "thought to contribute to the development of isocyanate asthma,"
9 they cannot contend that they have now or have ever had actual knowledge that the EPA is
10 adequately informed of the substantial risk information that shows and/or strongly suggests that
11 low-level inhalation exposures contribute to the development of isocyanate asthma.

12 **b. Exemptions under EPA's guidance documents.**

13 **i. Published-information and public-scientific-conference**
14 **exemptions.**

15 144. Although the EPA's guidance documents could be read to broaden this limited
16 exemption, the EPA's guidance documents cannot alter the scope of the statutory exemption, and
17 each defendant's reporting obligation is exempted only if each had "actual knowledge that the
18 Administrator [of the EPA] has been adequately informed of such information." 15 U.S.C. §
19 2607(e).

20 145. Regardless, however, none of the defendants' reporting obligations are exempted
21 even under a broad reading of the exemptions suggested in the EPA's guidance documents.

22 146. The EPA's 1978 Policy Statement provides that substantial risk information is
23 exempted from reporting if the information: "(a) Has been published by EPA in reports; (b) Has
24 been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or
25 any other authority administered by EPA . . . ; (c) Has been published in the scientific literature
26 and referenced [by one of several listed abstract services]; (d) Is corroborative of well-
27 established adverse effects already documented in the scientific literature and referenced [by one
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1 of the abstract services listed in (c) above]; or (e) [Is contained in an environmental notification
2 of spills].” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VII(a) through (e).

3 147. In its 1991 Reporting Guide, EPA added two new exemptions and both clarified
4 and expanded the published-information exemption. The two new exemptions covered
5 information that (1) is contained in a formal report, publication, or public statement of another
6 Federal agency or (2) constitutes national security information based upon a determination by the
7 President of the United States. 1991 Reporting Guide at 8. The EPA expanded the exemption
8 for published information to include “information that is obtained from major U.S. news
9 publications (e.g., newspapers or news magazines with national circulation) or nationally
10 broadcast U.S. radio and/or television news reports.” The EPA clarified, however, that the
11 published-information exemption exempted the reporting requirement only if the regulated
12 company “obtained” the information from the published literature:

13 With regard to item (2) on the preceding page [that is, “published in the open
14 scientific literature”], EPA believes that for the purposes of Section 8(e)
15 reporting, a subject person need not report information that is *obtained from* well-
16 established/well-recognized scientific journals, such as those typically abstracted
17 in a) major computerized abstract data bases, or 2) [sic] publications such as
18 Current Contents, published by the Institute for Scientific Information (ISI), Inc.
19 (Philadelphia, Pennsylvania. Similarly, information that is *obtained from major*
20 U.S. news publications (e.g., newspapers or news magazines with national
21 circulation) or nationally broadcast U.S. radio and/or television news reports
22 typically need not be submitted to EPA under Section 8(e) of TSCA. However,
23 with regard to information *obtained from* lesser known scientific journals, or from
24 other magazines, newspapers, radio, or television reports, a subject person must
25 have actual knowledge that EPA has been adequately informed about such
26 information [to be exempt from the reporting obligation].

21 1991 Reporting Guide at 9 (italicized emphases added, other emphases in original).

22 148. In its 1991 Reporting Guide, the EPA also provided that information obtained at
23 public scientific conferences or meetings is exempt from reporting if there is a written record of
24 the meeting that adequately describes the information and is released to the public in a
25 reasonable time frame. The EPA indicated, however, that information obtained at a private
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1 conference or meeting is not exempt and should be considered for reporting. 1991 Reporting
2 Guide at 7.

3 149. In its 1993 Proposed Policy Clarification, the EPA confirmed that the prior-
4 publication exemption applied to information that the regulated company “obtained solely from”
5 one of several sources. 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37739. Those
6 sources include official federal reports, certain scientific publications, certain databases to which
7 EPA has access, major written news publications, nationally-broadcast radio and television
8 reports, or certain national public scientific conferences. 1993 Proposed Policy Clarification, 58
9 Fed. Reg. at 37739 and 37741, Unit VII(a)(1)-(6). Because none of the defendants obtained the
10 substantial risk information at issue here from official federal reports, scientific publications,
11 databases to which EPA has access, or news reports, the prior-publication exemption does not
12 apply. Further, because none of the meetings at which defendants obtained the information at
13 issue here were public scientific conferences, and because none of the minutes of those meetings
14 were published or abstracted as contemplated by the 1993 Proposed Policy Clarification, the
15 public-scientific-meeting exemption does not apply.

16 150. In its 1993 Proposed Policy Clarification, the EPA also provided additional
17 explanation of the corroborative-of-a-well-established-adverse-effect exemption, as alleged more
18 fully below. 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37739-37740.

19 151. In its 2003 TSCA Guidance Revisions, the EPA confirmed its 1993 Proposed
20 Policy Clarification that the prior-publication exemption applied to information that the regulated
21 company “obtained in its entirety from” one of several sources. 2003 TSCA Guidance
22 Revisions, 68 Fed. Reg. at 33139, Unit VII(a)(1)-(8). The EPA expanded and clarified some of
23 the sources that it had listed in its 1993 Proposed Policy Clarification., expanding the TV, radio,
24 and news reports exemptions it had proposed in 1993; adding an exemption for information
25 developed by another federal agency in collaboration with EPA (as opposed to reports published
26 by other federal agencies); and adding an exemption for public scientific conferences sponsored
27 or co-sponsored by EPA. 2003 TSCA Guidance Revisions, 68 Fed. Reg. at 33139-33140, Unit
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1 VII(a)(1)-(8). Because none of the defendants obtained any of the information at issue here from
2 TV, radio, or news reports, the 2003 revisions to those exemptions do not apply. Further,
3 because none of the defendants obtained any of the information at issue here from information
4 developed by EPA or by another Federal agency in collaboration with the EPA, the new 2003
5 exemption for such information do not apply.

6 152. The 2003 revisions to the public-scientific-conference exemption provide that
7 reportable information obtained at a public scientific conference is exempt from reporting if
8 there is a written record of the meeting that adequately describes the information and is
9 published or abstracted within 90 days in a scientific publication, bibliographic database, or
10 scientific database of the type referenced in the guidance. 2003 TSCA Guidance Revisions, 68
11 Fed. Reg. at 33139, Unit VII(a)(7). Because none of the meetings at which defendants obtained
12 the information at issue here were public scientific conferences, and because none of the minutes
13 of those meetings were published or abstracted as contemplated by the 2003 TSCA Guidance
14 Revisions, this exemption does not apply.

15 153. As alleged more fully below, the EPA's 2003 TSCA Guidance Revisions
16 specified the corroborative-of-a-well-established-adverse-effect exemption in terms virtually
17 identical to those contained in its 1993 Proposed Policy Clarification.

18 154. Thus, the EPA's guidance documents provide for three main categories of
19 exempted information: (1) information obtained from the open scientific literature, the public
20 media, or a public scientific conference; (2) information obtained from an EPA or other federal
21 agency report; or (3) information that is corroborative of a well-established adverse effect.

22 155. None of the substantial risk information obtained by defendants here is exempt
23 from reporting under the EPA's guidance documents. Defendants obtained the reportable
24 substantial risk information that is the subject of this complaint from either written or verbal
25 reports at non-public meetings of the III, or from non-public medical and scientific data obtained
26 or developed by III member companies and then shared privately with other III member
27 companies. Accordingly, defendants did not obtain this information from the open scientific
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1 literature, through the public media, at a public scientific conference, or from an EPA or other
 2 federal agency report, and neither the first category of exempt information (information obtained
 3 from the open scientific literature, through the public media, or at a public scientific conference),
 4 nor the second category of exempt information (information obtained from an EPA or other
 5 federal agency report), apply.

6 156. Moreover, neither of these two exemptions apply even if the exemptions are read,
 7 prior to the EPA's issuance of the 1991 Reporting Guide, to apply to published information
 8 regardless of whether defendant obtained the information from the published source, or, prior to
 9 the EPA's issuance of the 1993 Proposed Policy Clarification, to apply to published information
 10 regardless of whether defendant obtained the information "solely" or "in its entirety" from the
 11 published information. KBT&F or its agents have analyzed the scientific literature and relevant
 12 reports issues by EPA or other federal agencies, and allege on information and belief that none of
 13 the substantial risk information obtained by defendants here was published in the open scientific
 14 literature, published or broadcast by the national public media, or published in an EPA or other
 15 federal agency report prior to the EPA's 1991 Reporting Guide (issued in June 1991).

16 ii. **Corroborative-of-a-well-established-adverse-effect exemption.**

17 157. The third category of exempt information under the EPA's guidance documents is
 18 information that is corroborative of a well-established adverse effect. The 1978 Policy Statement
 19 provides "Information need not be reported if it . . . [i]s corroborative of well-established adverse
 20 effect already documented in the scientific literature and referenced [in one of the listed abstract
 21 services]." 1978 Policy Statement, Unit VII(d).

22 158. The 1991 Reporting Guide reaffirms the 1978 policy by providing that to be
 23 exempt from the reporting requirement the new information must be "corroborative (in terms of,
 24 for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a
 25 well-established adverse effect." 1991 Reporting Guide at 8 (emphasis in original). The EPA
 26 stated further: "It is important to note, however, that information that newly identifies a serious
 27 toxic effect at a lower dose level for example, or confirms a serious effect that was previously
 28

only suspected, is not considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.” 1991 Reporting Guide at 8.

159. Thus, consistent with the statutory requirement to report information reasonably supporting a conclusion that the chemical presents a substantial *risk* of injury, the EPA defined “adverse effect” in the context of “risk”—not only whether a chemical causes an adverse effect but how (route of exposure) or under what circumstances (dose levels or time to onset). As one company commented in response to the EPA’s proposals that preceded its 1978 Policy Statement, “[a] determination that information ‘reasonably supports the conclusion’ of substantial risk cannot be made independently of consideration of use, since the method and manner of using a chemical may influence the occurrence of an effect.” 1978 Policy Statement, 43 Fed. Reg. at 11115, Comment 19. Although the company apparently offered the comment in the context of normal versus abnormal use (*id.*), the EPA agreed that “[t]he method and manner of using a chemical is one of several factors determining its exposure potential,” and further observed that “a definition of ‘normal’ use for a particular chemical will often depend upon a *knowledge of the risks* associated with the chemical.” *Id.* at 11115, Response to Comment 19. The EPA’s 1991 Reporting Guide confirmed that “the method and manner of use”—route of exposure and dose—was an integral part of the “adverse effect” being considered.

160. EPA further confirmed this policy in its 1993 Proposed Policy Clarification: EPA maintains its position under Part VII(c) of the 1978 Policy Statement that information need not be reported under section 8(e) of TSCA if the information corroborates well established, serious adverse effects that are already documented. The term “corroborates,” in the context of this particular reporting exclusion, means that the information *essentially duplicates and/or confirms an existing and well-documented understanding of a serious adverse effect* of a particular chemical substance or mixture. EPA has correctly received, and expects to continue to receive, substantial risk reports that show adverse effects of a more serious degree or of a different kind than are already established. In other words, the Agency expects subject persons to immediately consider reporting information on serious toxic effects (including but not limited to cancer, developmental, reproductive toxicity, or neurotoxicity) if, for example: such effects are substantially more serious in terms of the severity of the effects or the number of animals affected; occur within a significantly shorter time frame following exposure; *occur via a different route of exposure; occur at a*

1 *significantly lower dose or concentration*; or occur in a different species, strain, or
2 sex.

3 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37739 (emphasis added).

4 161. In 2003, EPA further reaffirmed the 1978 policy by explaining that corroborative
5 information is information that “substantially duplicates or confirms” a “well-recognized/well-
6 established serious adverse effect for the chemical(s) under consideration.” 2003 TSCA
7 Guidance Revisions at 33139, Unit VII(b).

8 162. The potential for inhalation of isocyanates, at levels above established
9 “permissible exposure limits” (PELs), “threshold limit values” (TLVs), or “short-term exposure
10 limits (STELs) to cause respiratory sensitization has been well-established in the scientific
11 literature for decades. However, the potential for dermal exposure to isocyanates to cause human
12 respiratory sensitization was not “well-established” in the open scientific literature at the time
13 defendants obtained the substantial risk information at issue in this case, and indeed is still today
14 presented in the open scientific literature as merely a possibility. There was not and is not today
15 “an existing and well-documented understanding” in the open scientific literature that the dermal
16 induction of isocyanates can cause human respiratory sensitization. 1993 Proposed Policy
17 Clarification, 58 Fed. Reg. at 37739. Accordingly, the substantial risk information that
18 defendants obtained was not then (and is not today) “corroborative of well-established adverse
19 effects already documented in the scientific literature and referenced [in one of the listed abstract
20 services].” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VII(d).

21 163. Similarly, while the potential for inhalation of isocyanates, at levels above
22 established PELs, TLVs, or STELs to cause respiratory sensitization has been well-established in
23 the scientific literature for decades, the potential for inhalation of isocyanates at levels below the
24 PELs, TLVs, or STELs to cause human respiratory sensitization (low-level inhalation) was not
25 “well-established” in the open scientific literature at the time defendants obtained the substantial
26 risk information at issue in this case, and indeed is still today presented in the open scientific
27 literature as merely a possibility. There was not and is not today “an existing and well-
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1 documented understanding” in the open scientific literature that low-level inhalation of
2 isocyanates can cause human respiratory sensitization. 1993 Proposed Policy Clarification, 58
3 Fed. Reg. at 37739. Accordingly, the substantial risk information that defendants obtained was
4 not then (and is not today) “corroborative of well-established adverse effects already documented
5 in the scientific literature and referenced [in one of the listed abstract services].” 1978 Policy
6 Statement, 43 Fed. Reg. at 11112, Unit VII(d).

7 164. Moreover, since obtaining the substantial risk information, the defendants,
8 individually and in conspiracy through and with the III, the CMA, the ACC, and other industry
9 organizations, have publicly disputed the potential for both dermal induction of respiratory
10 sensitization and low-level-inhalation-induction of respiratory sensitization.

11 165. As alleged more thoroughly below, each defendant either omitted from their
12 isocyanate products’ hazard warnings the possibility of dermal induction of respiratory
13 sensitization or downplayed the possibility in those “warnings.”

14 166. Further, defendants have publicly contended that the scant publicly-available
15 information that suggests such a possibility is anecdotal, inconclusive, and unreliable. For
16 example, in their May 2002 III paper entitled “Respiratory sensitization: the role of dermal
17 contact with MDI and TDI,” defendants and other III member companies discussed the animal
18 and human data relevant to the potential link between skin contact with MDI and respiratory
19 sensitization. Exh. 2 at CHARM 012422–012446. The defendants neither published nor
20 otherwise discussed in that paper any of the substantial risk information at issue here, even
21 though all of that substantial risk information is relevant to the link between human isocyanate
22 skin contact and respiratory sensitization. Moreover, the defendants concluded the paper by
23 contending that the link between respiratory sensitization and isocyanate skin contact was not
24 well-established and that the “available” human data was insufficient to establish the link: “The
25 available data do not provide sufficient evidence for a clear correlation between skin exposure
26 and occupational asthma.” *Id.* at CHARM 12442, Exh. 2.

1 167. Furthermore, through the Diisocyanates Panel of the ACC, the defendants have
2 recently represented disputed the potential for dermal induction of respiratory sensitization
3 directly to the EPA. In April 2011, the EPA expressed its heightened interest in MDI and related
4 chemicals by issuing an “MDI Action Plan.” *Methylene Diphenyl Diisocyanate (MDI) and*
5 *Related Compounds Action Plan [RIN 2070-ZA15]*, U.S. Environmental Protection Agency,
6 April 2011 (“MDI Action Plan”). On February 26, 2013, defendants submitted comments to the
7 EPA’s proposed MDI Action Plan through the ACC. Feb. 26, 2013 ACC Comments to MDI
8 Action Plan, Exh. 3. Disputing the EPA’s statement in the MDI Action Plan that “[b]oth
9 inhalation and dermal exposures to diisocyanates are thought to contribute to the development of
10 isocyanate asthma” (*id.* at 9, Exh. 3), the defendants contended “the role that dermal contact with
11 diisocyanates plays in the development of occupational asthma remains unresolved for humans.”
12 *Id.* at 10, Exh. 3.

13 168. Since defendants each contended as recently as February 2013 that there is no
14 established link, much less a well-established link, between isocyanate skin contact and
15 respiratory sensitization, the reporting exemption for information that corroborates a well-
16 established adverse effect can not apply to the substantial risk information they obtained.

17 169. Similarly, since obtaining the substantial risk information, the defendants,
18 individually and in conspiracy through and with the III, the CMA, the ACC, and other industry
19 organizations, have publicly disputed the potential for low-level inhalation to cause respiratory
20 sensitization.

21 170. As alleged more thoroughly below, each defendant omitted this possibility from,
22 or downplayed the possibility in, their isocyanate products’ hazard “warnings.”

23 171. Further, defendants have publicly disputed the possibility that low-level inhalation
24 could cause respiratory sensitization. For example, in October 1993 the defendants, through the
25 Diisocyanates Panel of the CMA (now the ACC), submitted comments to the EPA regarding its
26 risk management process for diisocyanates. The defendants told the EPA that the proposition
27 that “pulmonary function decrement and sensitization can occur at very low concentrations” was
28

1 “not supported by available data.” *Comments of the Chemical Manufacturers Association*
 2 *Diisocyanate Panel on the RMI Briefing Document for Diisocyanates*, October 12, 1993, at
 3 BAY010037, Exh. 4. Each defendant or its predecessor-in-interest was a member of the CMA’s
 4 Diisocyanates Panel, which submitted these comments. *Id.* at BAY010041, n.1, Exh. 4.

5 172. Furthermore, through the Diisocyanates Panel of the ACC, the defendants have
 6 recently disputed the potential for low-level inhalation exposures to cause respiratory
 7 sensitization. In their February 26, 2013 comments to the EPA’s proposed MDI Action Plan, the
 8 defendants disputed the EPA’s statement in the MDI Action Plan that “[b]oth inhalation and
 9 dermal exposures to diisocyanates are thought to contribute to the development of isocyanate
 10 asthma” (Feb. 26, 2013 ACC Comments to MDI Action Plan at 9, Exh. 3), the defendants
 11 contended: “The ability of diisocyanates to induce respiratory sensitization in some individuals,
 12 and asthma in some cases, is a known potential adverse health effect in humans *after exposure to*
 13 *concentrations above workplace exposure limits.*” *Id.* at 10 (emphasis added), Exh. 3.

14 173. Since defendants each contended as late as February 2013 that there is no
 15 established link, much less a well-established link, between respiratory sensitization and low-
 16 level inhalation exposures, the reporting exemption for information that corroborates a well-
 17 established adverse effect can not apply to the substantial risk information they obtained.

18 **C. Defendants Obtained but Failed to Report Substantial Risk Information.**

19 **1. Historical understanding of isocyanate hazards.**

20 174. There are several exposure standards applicable to MDI and PMDI inhalation
 21 exposure.

- 22 a. The first, promulgated by the U.S. Occupational Safety and Health
 23 Administration (OSHA), is a ceiling limit, or maximum allowable
 24 concentration, of 20 parts per billion (ppb), sometimes expressed as 0.02
 25 parts per million (ppm) or 0.20 mg/m³. The ceiling limit is commonly
 26 referred to as the Permissible Exposure Limit (PEL).
- 27 b. The second standard is recommended by the National Institute for
 28 Occupational Safety and Health (NIOSH). This recommendation, called
 the Recommended Exposure Limit (REL), is expressed as a time-weighted
 average (TWA) of 0.05 mg/m³ (0.005 ppm or 5 ppb), and as a 10-minute
 ceiling of 0.2 mg/m³ (0.02 ppm or 20 ppb). The NIOSH TWA

recommendation “indicates a time-weighted average concentration for up to a 10-hour workday over a 40-hour workweek.”

<http://www.cdc.gov/niosh/npg/pgintrod.html> (last visited April 21, 2015).

- c. The third standard is a recommendation set by the American Conference of Governmental Industrial Hygienists (“ACGIH”). This recommendation, called the Threshold Limit Value (TLV), is expressed as a TWA of 5 ppb over an eight-hour period, and as a Short-Term Exposure Limit (STEL) of 20 ppb measured over a 15 minute period.

175. There are several exposure standards applicable to TDI inhalation exposure.

- a. The first, promulgated by OSHA, is a ceiling limit, or maximum allowable concentration, of 20 ppb, sometimes expressed as 0.02 ppm or 0.14 mg/m³. This ceiling limit is the PEL. Previously, OSHA had expressed its TDI PEL as a TWA of 0.005 ppm (5 ppb or 0.04 mg/m³) and a STEL of 0.02 ppm (0.15 mg/m³ or 20 ppb).
- b. The second standard is the ACGIH’s TLV recommendation of a TWA of 0.005 ppm (0.036 mg/m³ or 5 ppb) over an eight-hour period, and a STEL of 0.02 ppm (0.14 mg/m³ or 20 ppb).
- c. NIOSH has not established an REL for TDI.

176. The defendants have long known, and the scientific literature has documented for decades, that inhalation of isocyanates, including TDI, MDI, and PMDI, at levels that exceed these regulatory and recommended exposure limits, can cause respiratory sensitization and/or other respiratory injury, including occupational asthma.

177. In the early 1970s, some researchers, particularly Dr. John Peters of the Harvard School of Public Health, began suggesting that isocyanates, TDI in particular, could cause respiratory sensitization and/or other respiratory injury from inhalation exposures at levels below the regulatory and recommended exposure limits (low-level inhalation). Both NIOSH and the ACGIH thereafter initiated proceedings to consider lowering the regulatory and recommended exposure limits for isocyanates. The isocyanate industry, including each defendant, criticized and attacked the studies that suggested the low-level inhalation risk, while they simultaneously undertook significant and ultimately successful efforts to oppose a lowering of the regulatory and recommended exposure limits for isocyanates. Those efforts included each defendant’s concealment of information that it obtained and/or developed that reasonably supported a conclusion that low-level inhalation of isocyanates, including particularly TDI, MDI, and/or PMDI, could cause respiratory sensitization and/or other respiratory injury.

1 178. For example, in their March 14, 1984 submission to the EPA's ITC regarding
2 MDI and PMDI, each defendant, through the III, represented to the EPA:

3 In man, chemically-induced bronchitis and bronchopneumonia and conjunctivitis
4 may occur after exposure to high concentrations. *Repeated exposure to low*
5 *concentrations can cause only subjective symptoms such as burning eyes, dry*
6 *throat and coughing.* Besides the effects due to the specific irritant action of the
isocyanate, sensitization leading to bronchial asthma has been observed in some
workers. Recognition of this action serves as the basis of the present TLV of 0.2
mg/m³ (ceiling).

7 Exh. 1 at EPA00621 (emphasis added). Thus, each defendant represented to the EPA in March
8 1984 that inhalation exposures to MDI and/or PMDI at "low" concentrations—below the
9 recommended ceiling of 0.2 mg/m³—would not cause sensitization and permanent injury, but
10 rather only minor, transient irritation.

11 179. In the mid-to-late 1970s, some researchers, including particularly Dr. Meryl
12 Karol, a leading researcher at the University of Pittsburgh, began to suspect that isocyanate skin
13 contact, rather than inhalation exposure, might be causing human respiratory injury in the
14 industrial setting. In 1981, Dr. Karol published a seminal study in which she demonstrated that a
15 minimal amount (as small as a single drop) of TDI on the skin of guinea pigs resulted in
16 respiratory hypersensitivity in the animal model she developed. Karol, M.H., et al., "Dermal
17 Contact with Toluene Diisocyanate (TDI) Produces Respiratory Tract Hypersensitivity in Guinea
18 Pigs," 58 Toxicology and Applied Pharmacology, 221-230 (1981). Dr. Karol commented in her
19 article that she commenced the study in part to investigate suspicions that skin contact in the
20 industrial setting, rather than inhalation exposure, was causing human respiratory injury. *Id.* at
21 222 and 228.

22 180. Prior to publishing her study, and during a December 8-9, 1980 III symposium,
23 Dr. Karol presented her findings to III member companies, including representatives from
24 defendants BASF, Bayer, and Dow. May 6, 2008 Deposition of Dow through its Rule 30(b)(6)
25 witness Michael Woolhiser at 120-121 (May 6, 2008 Dow-Woolhiser Depo), Exh. 5. KBT&F
26 alleges on information and belief that one of Huntsman's predecessors-in-interest also had
27 representatives at this meeting.

181. After presenting the results of her animal study to the III member representatives, Dr. Karol responded to a question in which one of the attendees suggested that Dr. Karol's TDI animal results should prompt efforts to protect against human workers having skin exposure not only for TDI, but also for MDI. Dr. Karol responded that the study's findings indicated that users should avoid skin contact with any of these isocyanates. May 6, 2008 Dow-Woolhiser Depo at 131, Exh. 5.

182. Thus, each defendant was aware by December 1980 that Dr. Karol's TDI animal findings were relevant to human exposures to MDI and/or PMDI.

183. At least one of the defendants, however, already possessed information reasonably supporting the conclusion that skin contact with MDI and/or PMDI could cause respiratory injury to humans, and the others would soon obtain such information.

2. By the end of 1979, Bayer had obtained "Bayer's 1979 Skin Contact SRI," which comprised substantial risk information about MDI skin contact.

a. Bayer obtained the information by 1979.

184. By "sometime in 1979" Bayer had obtained information that reasonably supported a conclusion that skin contact with MDI or PMDI could cause respiratory sensitization and other respiratory injury. Mr. Dave Hussey, who was employed by Bayer's predecessor-in-interest Mobay during the late 1970s and early 1980s, testified that he received isocyanate hazard training at Mobay in 1979. He testified that Mobay's industrial hygienists told him during that training, which occurred "sometime in 1979," that skin contact with MDI could cause respiratory sensitization ("becoming allergic to the chemical") and "reduced lung function." April 21, 2005 Deposition of David Hussey at 56-62, 66, Exh. 6.

185. Mr. Hussey testified that the Mobay industrial hygienists instructed him that safe handling of isocyanates required "having protective clothing, keeping it off of your skin, and particularly high protection equipment and practicing good hygiene in general using the chemical, keeping splashes off of you, primarily personal hygiene around the use of the chemical." April 21, 2005 Deposition of David Hussey at 57:20-58:3, Exh. 6. Mobay's

1 industrial hygienists told him that if he failed to employ these safeguards, “skin rashes, eye
2 irritation, if it got in your eyes, could occur, and possibly becoming allergic to the chemical.” *Id.*
3 at 58:7-10, Exh. 6.

4 186. Those industrial hygienists explained the consequences of “becoming allergic to
5 the chemical”: “That you would no longer be able to work around the chemical, that you would
6 develop antibodies that would activate the immune system. And in turn, you would have severe
7 – mild to severe reaction to the chemical.” *Id.* at 58:22-59:4, Exh. 6. The industrial hygienists
8 described the “mild reaction” as “[r]ashes, skin rashes, irritation. Even in amounts below the
9 TLVs that you could have shortness of breath.” *Id.* at 59:7-9, Exh. 6. The person having such a
10 reaction “would be someone who became sensitized . . . [s]ome people after contact with – mild
11 contact with – through skin absorption can get – start to develop antibodies.” *Id.* at 61:12-13, 18-
12 21, Exh. 6. Such a person could also sustain “reduced lung function” from such exposure. *Id.* at
13 66:3-14, Exh. 6.

14 **b. Bayer’s 1979 Skin Contact SRI was “substantial risk information.”**

15 187. This information that Bayer had obtained by 1979 (“Bayer’s 1979 Skin Contact
16 SRI”) reasonably supported a conclusion of substantial risk or injury. The EPA’s 1978 Policy
17 Statement provides that “‘reasonably supports the conclusion’ of substantial risk is not identical
18 to a conclusive demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at
19 11110, Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a]
20 person is not to delay reporting until he obtains conclusive information that a substantial risk
21 exists, but is to immediately report any evidence which ‘reasonably supports’ that conclusion.
22 Such evidence will generally not be conclusive as to the substantiality of the risk; it should,
23 however, reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI.
24 Bayer’s 1979 Skin Contact SRI may not have been “conclusive,” but it “reliably ascribe[d] the
25 effect to the chemical” to such a degree that Bayer’s industrial hygiene department instructed its
26 employees that skin contact with isocyanates could cause respiratory sensitization and/or reduced
27 lung function.
28

c. **Bayer obtained Bayer's Skin Contact SRI by December 31, 1979**

188. Mr. Hussey testified that Mobay's industrial hygienists provided Bayer's 1979 Skin Contact SRI to him "sometime in 1979." April 21, 2005 Deposition of David Hussey at 62:14-16. Thus, defendant Bayer had obtained Bayer's 1979 Skin Contact SRI by December 31, 1979 at the very latest.

d. **TSCA required Bayer to report Bayer's Skin Contact SRI by January 22, 1980.**

189. The EPA's 1978 Policy Statement provides that "a person has 'immediately informed' the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit IV. Thus, TSCA required that Bayer report Bayer's 1979 Skin Contact SRI to the EPA by January 22, 1980, the fifteenth working day after the date that Bayer obtained the information.

e. **Bayer was subject to TSCA's reporting requirement when it obtained Bayer's Skin Contact SRI.**

190. At the time that it obtained Bayer's 1979 Skin Contact SRI, Bayer was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

f. **Bayer failed to report Bayer's Skin Contact SRI, even though TSCA did not exempt its reporting obligation.**

191. Bayer did not report Bayer's 1979 Skin Contact SRI to the EPA "immediately" after obtaining it.

192. Bayer has never reported Bayer's 1979 Skin Contact SRI to the EPA.

193. Bayer did not have knowledge as of January 22, 1980 that some entity other than Bayer had submitted Bayer's 1979 Skin Contact SRI to the EPA.

1 194. Bayer has not acquired knowledge since January 22, 1980 that some entity other
2 than Bayer has submitted Bayer's 1979 Skin Contact SRI to the EPA.

3 195. Bayer did not have actual knowledge as of January 22, 1980 that the EPA was
4 adequately informed of Bayer's 1979 Skin Contact SRI.

5 196. Bayer has not acquired actual knowledge since January 22, 1980 that the EPA has
6 become adequately informed of Bayer's 1979 Skin Contact SRI.

7 197. Therefore, TSCA did not exempt Bayer from its obligation to report Bayer's 1979
8 Skin Contact SRI.

9 g. **The EPA's guidance documents did not exempt Bayer's obligation to**
10 **report Bayer's 1979 Skin Contact SRI.**

11 198. Although the EPA's guidance documents could be read to broaden TSCA's
12 limited exemption, the EPA's guidance documents cannot alter the scope of the statutory
13 exemption, and each defendant's separate reporting obligation is exempted only if it had "actual
14 knowledge that the Administrator [of the EPA] has been adequately informed of such
15 information." 15 U.S.C. § 2607(e).

16 199. Regardless, however, the EPA's guidance documents did not exempt Bayer from
17 the obligation to report Bayer's 1979 Skin Contact SRI.

18 200. As of January 22, 1980, the latest date by which TSCA required Bayer to report
19 Bayer's 1979 Skin Contact SRI, the EPA's 1978 Policy Statement provided that substantial risk
20 information was exempted from reporting if the information: "(a) Has been published by EPA in
21 reports; (b) Has been submitted in writing to EPA pursuant to mandatory reporting requirements
22 under TSCA or any other authority administered by EPA . . .; (c) Has been published in the
23 scientific literature and referenced [by one of several listed abstract services]; (d) Is
24 corroborative of well-established adverse effects already documented in the scientific literature
25 and referenced [by one of the abstract services listed in (c) above]; or (e) [Is contained in an
26 environmental notification of spills]." 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
27 VII(a) through (e).
28

201. As of January 22, 1980, Bayer's 1979 Skin Contact SRI had not been "published by EPA in reports."

202. As of January 22, 1980, Bayer's 1979 Skin Contact SRI had not been "submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA."

203. As of January 22, 1980, Bayer's 1979 Skin Contact SRI had not been "published in the scientific literature and referenced [by one of several listed abstract services]."

204. As of January 22, 1980, Bayer's 1979 Skin Contact SRI was not "corroborative of well-established adverse effects already documented in the scientific literature and referenced [by one of the abstract services listed in (c) above]." To the contrary, a little more than four years after obtaining Bayer's 1979 Skin Contact SRI, Bayer joined with the III in omitting any reference to this health effect from the III's submission to the EPA about MDI and PMDI. The III first discussed the serious pulmonary health effects associated with inhalation exposures: The main risk to health of man is via inhalation. . . . In man, chemically-induced bronchitis and bronchopneumonia and conjunctivitis may occur after exposure to high concentrations. . . . Besides the effects due to the specific irritant action of the isocyanate, sensitization leading to bronchial asthma has been observed in some workers. . . .

Initial Submission: Letter from International Isocyanate Institute to U.S. EPA submitting information on Monomeric and Polymeric MDI, Submitted March 14, 1984, EPA Document ID: FYI-OTS-0794-1027, EPA00609-00626 at 00621, Exh. 1. After documenting these serious pulmonary health effects associated with inhalation exposures, the III limited the health effects associated with dermal contact to "irritancy": "Dermal and eye contact is of concern with regard to irritancy." Id.

205. Bayer was a member of the III on March 14, 1984 and had a representative on the III's Board of Directors. Bayer, through the III, represented to the EPA on March 14, 1984 that the "concern" about MDI or PMDI skin contact was "irritancy," but Bayer's 1979 Skin Contact SRI indicated that skin contact with MDI could cause respiratory sensitization and reduced lung

1 function, and Bayer's industrial hygienists communicated that information to Bayer's employees
 2 as part of their isocyanate hazard training. Bayer cannot contend that Bayer's 1979 Skin Contact
 3 SRI was "corroborative of well-established adverse effects already documented in the scientific
 4 literature," because it represented to the EPA on March 14, 1984 that the only health "concern"
 5 related to MDI or PMDI skin contact was "irritancy."

6 **3. By April 1982, Bayer and Dow had each obtained the "1982 Japanese Skin**
 7 **Contact SRI," which comprised substantial risk information about TDI and**
 8 **MDI skin contact.**

9 **a. Bayer and Dow obtained the information by April 1982.**

10 206. In April 1982, Bayer and Dow obtained substantial risk information about
 11 "whether skin absorption [of MDI or TDI] can lead to pulmonary sensitisation [European
 12 spelling of sensitization]." The minutes of the III Safety Committee Meeting of April 19 and 20,
 13 1982, indicate that, during their discussion of the topic "Dermal toxicity of TDI and MDI," the
 14 attendees acknowledged that "[o]nce [sic, read "one"] concern is whether skin absorption can
 15 lead to pulmonary sensitisation. *Some relevant Japanese work is available.*" Minutes of the
 16 meeting of the III Safety Committee, April 19-20, 1982, III(Bice)003123-003134 at 003127
 17 (emphasis added), Exh. 7. These minutes indicate that the "Japanese work" (the "1982 Japanese
 18 Skin Contact SRI") was relevant to the "concern" of pulmonary sensitization induced by MDI or
 19 TDI skin contact.

20 **b. The 1982 Japanese Skin Contact SRI was "substantial risk**
 21 **information."**

22 207. The 1982 Japanese Skin Contact SRI reasonably supported a conclusion of
 23 substantial risk or injury. Because neither Bayer nor Dow (nor any other entity) reported the
 24 1982 Japanese Skin Contact SRI to the EPA, and because neither Bayer nor Dow produced the
 25 1982 Japanese Skin Contact SRI during the *Bice* litigation, despite the *Bice* plaintiffs requests for
 26 such information, Bayer and Dow have prevented KBT&F and the U.S. government, including
 27 the EPA, from examining the information. Nonetheless, the minutes indicate that the 1982
 28 Japanese Skin Contact SRI comprised "work," which indicates some degree of analysis of

1 underlying data. And the minutes further indicate that the underlying data being analyzed
 2 concerned—indeed was “relevant” to—“whether skin absorption can lead to pulmonary
 3 sensitization.” Minutes of the meeting of the III Safety Committee, April 19-20, 1982,
 4 III(Bice)003123-003134 at 003127, Exh. 7.

5 208. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
 6 determination: “the seriousness of the effect” and “the fact or probability of its occurrence.”
 7 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
 8 factors are weighed differently for different effects. If the effects are among the human health
 9 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so
 10 serious that relatively little weight is given to exposure; the mere fact that the implicated
 11 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
 12 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
 13 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
 14 risk information.

15 209. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy
 16 include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
 17 inability to use a normal bodily function with a consequent relatively serious impairment of
 18 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
 19 43 Fed. Reg. at 11112, Unit V(a)(1). “Pulmonary sensitization,” which can lead to occupational
 20 asthma and permanent lung damage, is such a “serious” human health effect.

21 210. Accordingly, information about “[a]ny instance” of “pulmonary sensitization”
 22 “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few)
 23 chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1).
 24 Indeed, the EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an
 25 effect is reportable: “It is anticipated here that reportable effects will generally occur in a
 26 pattern, where a significant common feature is exposure to the chemical. However, a single
 27 instance of . . . serious incapacitation in a human would be reportable if one (or a few)
 28

1 chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
2 VI(2).

3 211. The “serious” human health effects identified in unit V(a)(2) of the 1978 Policy
4 also include “[a]ny pattern of effects or evidence which reasonably supports the conclusion that
5 the chemical substance or mixture can produce . . . serious or prolonged incapacitation.” 1978
6 Policy Statement at 11112, Unit V(a)(2). “Pulmonary sensitization,” which can lead to
7 occupational asthma and permanent lung damage, is such a human health effect.

8 212. Accordingly, “[a]ny pattern of effects or evidence which reasonably supports the
9 conclusion that the chemical substance or mixture can produce” pulmonary sensitization “must
10 be reported” under TSCA Section 8(e), unless otherwise exempted. 1978 Policy Statement, 43
11 Fed. Reg. at 11112, Unit V(a)(1).

12 213. Thus, the 1982 Japanese Skin Contact SRI constituted reportable substantial risk
13 information. As the minutes from the April 1982 meeting confirm, the “Japanese work” or data
14 analysis was “relevant” to whether skin exposure to TDI or MDI could produce a serious health
15 effect, pulmonary sensitization.

16 c. **Bayer and Dow separately obtained the 1982 Japanese Skin Contact**
17 **SRI.**

18 214. Both Bayer and Dow had representatives present at this April 19-20, 1982
19 meeting of the III Safety Committee. *Id.* at III(Bice)003124. By sending these representatives
20 on their behalf to attend and participate in the meeting of the III’s Safety Committee, both Bayer
21 and Dow indicated their confidence in these employees’ respective capabilities to appreciate the
22 significance of isocyanate safety information that they would obtain at the meeting. Under
23 TSCA, a “business organization is considered to have obtained any information which any
24 officer or employee capable of appreciating the significance of that information has obtained.”
25 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II. Thus, both Bayer and Dow obtained the
26 1982 Japanese Skin Contact SRI by April 20, 1982, the final day of the III Safety Committee
27 meeting.
28

d. **TSCA required that Bayer and Dow each report the 1982 Japanese Skin Contact SRI by May 11, 1982.**

215. The EPA's 1978 Policy Statement provides that "a person has 'immediately informed' the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit IV. Thus, TSCA required that both Bayer and Dow report the 1982 Japanese Skin Contact SRI to the EPA by May 11, 1982, the fifteenth working day after the date that Bayer and Dow each obtained the information.

e. **Bayer and Dow were subject to TSCA's reporting requirement when they separately obtained the 1982 Japanese Skin Contact SRI.**

216. At the time that it obtained the 1982 Japanese Skin Contact SRI, Bayer was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned each MDI, PMDI, and TDI.

217. At the time that it obtained the 1982 Japanese Skin Contact SRI, Dow was a "person who manufactures, processes, or distributes in commerce [the] chemical substance or mixture" TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned TDI.

f. **Bayer and Dow each failed to report the 1982 Japanese Skin Contact SRI, even though TSCA did not exempt their reporting obligations.**

218. Bayer did not report the 1982 Japanese Skin Contact SRI to the EPA "immediately" after obtaining it.

219. Bayer has never reported the 1982 Japanese Skin Contact SRI to the EPA.

220. Bayer did not have knowledge as of May 11, 1982 that some entity other than Bayer had submitted the 1982 Japanese Skin Contact SRI to the EPA.

221. Bayer has not acquired knowledge since May 11, 1982 that some entity other than Bayer has submitted the 1982 Japanese Skin Contact SRI to the EPA.

222. Bayer did not have actual knowledge as of May 11, 1982 that the EPA was adequately informed of the 1982 Japanese Skin Contact SRI.

223. Bayer has not acquired actual knowledge since May 11, 1982 that the EPA has become adequately informed of the 1982 Japanese Skin Contact SRI.

224. Therefore, TSCA did not exempt Bayer from its obligation to report the 1982 Japanese Skin Contact SRI.

225. Dow did not report the 1982 Japanese Skin Contact SRI to the EPA “immediately” after obtaining it.

226. Dow has never reported the 1982 Japanese Skin Contact SRI to the EPA.

227. Dow did not have knowledge as of May 11, 1982 that some entity other than Dow had submitted the 1982 Japanese Skin Contact SRI to the EPA.

228. Dow has not acquired knowledge since May 11, 1982 that some entity other than Dow has submitted the 1982 Japanese Skin Contact SRI to the EPA.

229. Dow did not have actual knowledge as of May 11, 1982 that the EPA was adequately informed of the 1982 Japanese Skin Contact SRI.

230. Dow has not acquired actual knowledge since May 11, 1982 that the EPA has become adequately informed of the 1982 Japanese Skin Contact SRI.

231. Therefore, TSCA did not exempt Dow from its obligation to report the 1982 Japanese Skin Contact SRI.

g. **The EPA’s guidance documents did not exempt Bayer or Dow’s obligation to report the 1982 Japanese Skin Contact SRI.**

232. Although the EPA’s guidance documents could be read to broaden TSCA’s limited exemption, the EPA’s guidance documents cannot alter the scope of the statutory exemption, and each defendant’s separate reporting obligation is exempted only if it had “actual knowledge that the Administrator [of the EPA] has been adequately informed of such information.” 15 U.S.C. § 2607(e).

233. Regardless, however, the EPA's guidance documents did not exempt either Bayer or Dow from the obligation to report the 1982 Japanese Skin Contact SRI.

234. As of May 11, 1982, the latest date by which TSCA required Bayer and Dow to report the 1982 Japanese Skin Contact SRI, the EPA's 1978 Policy Statement provided that substantial risk information was exempted from reporting if the information: "(a) Has been published by EPA in reports; (b) Has been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA . . .; (c) Has been published in the scientific literature and referenced [by one of several listed abstract services]; (d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced [by one of the abstract services listed in (c) above]; or (e) [Is contained in an environmental notification of spills]." 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VII(a) through (e).

235. As of May 11, 1982, the 1982 Japanese Skin Contact SRI had not been "published by EPA in reports."

236. As of May 11, 1982, the 1982 Japanese Skin Contact SRI had not been "submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA."

237. As of May 11, 1982, the 1982 Japanese Skin Contact SRI had not been "published in the scientific literature and referenced [by one of several listed abstract services]."

238. As of May 11, 1982, the Japanese Skin Contact SRI was not "corroborative of well-established adverse effects already documented in the scientific literature and referenced [by one of the abstract services listed in (c) above]." To the contrary, less than two years after obtaining the Japanese Skin Contact SRI, the III omitted any reference to this health effect from its submission to the EPA about MDI and PMDI. The III first discussed the serious pulmonary health effects associated with inhalation exposures:

The main risk to health of man is via inhalation. . . . In man, chemically-induced bronchitis and bronchopneumonia and conjunctivitis may occur after exposure to high concentrations. . . . Besides the effects due to the specific irritant action of

1 the isocyanate, sensitization leading to bronchial asthma has been observed in
2 some workers. . . .

3 *Initial Submission: Letter from International Isocyanate Institute to U.S. EPA submitting*
4 *information on Monomeric and Polymeric MDI*, Submitted March 14, 1984, EPA Document ID:
5 FYI-OTS-0794-1027, EPA00609-00626 at 00621, Exh. 1. After documenting these serious
6 pulmonary health effects associated with inhalation exposures, the III limited the health effects
7 associated with dermal contact to “irritancy”: “*Dermal and eye contact is of concern with*
8 *regard to irritancy.*” *Id.*

9 239. Bayer was a member of the III on March 14, 1984 and had a representative on the
10 III’s Board of Directors. Bayer, through the III, represented to the EPA on March 14, 1984 that
11 the “concern” about MDI or PMDI skin contact was “irritancy,” but Bayer’s 1979 Skin Contact
12 SRI indicated that skin contact with MDI could cause respiratory sensitization and reduced lung
13 function, and Bayer’s industrial hygienists communicated that information to Bayer’s employees
14 as part of their isocyanate hazard training. Bayer cannot contend that Bayer’s 1979 Skin Contact
15 SRI was “corroborative of well-established adverse effects already documented in the scientific
16 literature,” because it represented to the EPA on March 14, 1984 that the only health “concern”
17 related to MDI or PMDI skin contact was “irritancy.”

18 240. Both Bayer and Dow were members of the III on March 14, 1984, and each had a
19 representative on the III’s Board of Directors. Both Bayer and Dow, through the III, represented
20 to the EPA on March 14, 1984 that the “concern” about MDI or PMDI skin contact was
21 “irritancy,” but the 1982 Japanese Skin Contact SRI, dealt with the “concern” of “whether skin
22 absorption can lead to pulmonary sensitisation.” Bayer and Dow cannot contend that the 1982
23 Japanese Skin Contact SRI was “corroborative of well-established adverse effects already
24 documented in the scientific literature,” because they each represented to the EPA on March 14,
25 1984 that the only health “concern” related to MDI or PMDI skin contact was “irritancy.”
26
27
28

4. **In or shortly after September 1988, each defendant had separately obtained “the 1988 Mineworkers SRI,” which comprised substantial risk information about PMDI skin contact and low-level inhalation exposure.**

a. **Each defendant separately obtained the information in or shortly after September 1988.**

241. In or shortly after September 1988, each defendant separately obtained substantial risk information about respiratory sensitization in humans caused either by skin contact with or low-level inhalation of PMDI. The minutes of the III Safety Committee’s September 6-8, 1988 meeting memorialize the attendees’ discussion of “Respiratory Studies.” Minutes of the September 6-8, 1988 meeting of the III Safety Committee, III(Bice)007155-007186 at 007178, Item 10.6, Exh. 8. In the context of discussing a potential “project on the possible respiratory effects resulting from dermal (only) exposure to MDI,” the minutes indicate:

Mann [Safety Committee Chairman, from Bayer AG] referred to cases of sensitization found in miners who had no access to other isocyanates. *Sensitization had thus resulted from either dermal exposure or exposure to very low levels of airborne polymeric MDI.*

Id. (emphasis added). Dr. Mann made his comments in the context of a discussion of “Respiratory Studies,” and specifically a study to investigate the potential for MDI skin contact to produce “respiratory effects.” This context indicates that the “sensitization” that Dr. Mann indicated had resulted from skin contact or low-level inhalation was *respiratory* sensitization.

242. The multiple “cases,” plural, to which Dr. Mann referred involved human, not animal, respiratory sensitization.

243. And Dr. Mann characterized as conclusive the causal link between PMDI skin contact or low-level inhalation exposure and respiratory sensitization: “Sensitization *had thus resulted from either* dermal exposure or exposure to very low levels of airborne polymeric MDI.” *Id.*, Exh. 8.

b. **The 1988 Mineworkers SRI was “substantial risk information.”**

244. This information, the “1988 Mineworkers SRI,” was reportable substantial risk information.

245. TSCA defines substantial risk information as “information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment.” 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that “‘reasonably supports the conclusion’ of substantial risk is not identical to a conclusive demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11110, Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a] person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which ‘reasonably supports’ that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI.

246. The minutes indicate that the 1988 Mineworkers SRI conclusively ascribed the health effect to the chemical, either through skin contact or low-level inhalation. At a minimum, however, the 1988 Mineworkers SRI “reliably ascribe[s] the effect to the chemical.” Accordingly, the 1988 Mineworkers SRI was reportable substantial risk information.

c. **Each defendant separately obtained the 1988 Mineworkers SRI.**

247. Dow and Huntsman (through its predecessor-in-interest ICI Americas) each had representatives present at this September 6-8, 1988 meeting of the III Safety Committee. Larry Rampy represented Dow and R.F. Hoffman represented ICI Americas. Minutes of the September 6-8, 1988 III Safety Committee, Exh. 8 at III(Bice)007156. By sending these representatives on their behalf to attend and participate in the meeting of the III’s Safety Committee, Dow and Huntsman each indicated their respective confidence in their employee’s capability to appreciate the significance of isocyanate safety information that they would obtain at the meeting. Under TSCA, a “business organization is considered to have obtained any information which any officer or employee capable of appreciating the significance of that information has obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II. Thus, Dow and Huntsman each obtained the 1988 Mineworkers SRI as of September 8, 1988, the last day of the meeting.

1 248. The minutes indicate that the III distributed copies to the “III Members Present”
2 (which included defendants Dow and Huntsman), to the “Members of the Executive,” and to
3 “Sub Committee Chairmen.” Exh. 8 at III(Bice)007156.

4 249. As of June 1988, the III’s Executive Committee included a representative from
5 defendant BASF (M. Buller) and from Huntsman’s predecessor-in-interest, ICI Americas (R.
6 Gadsby). Attendance List from May 11, 1988 III Executive Committee Meeting,
7 III(Bice)006990, Exh. 9. Both M. Buller from BASF and R. Gadsby from ICI Americas were
8 still on the Executive Committee as of January 1989. III Organization Chart, January 1989,
9 III(Bice)007025-007026 at 007026, Exh. 10. Thus, on the dates of the September 6-8, 1988 III
10 Safety Committee meeting and in the four-month period following the meeting, both BASF and
11 Huntsman had representatives on the Executive Committee to whom the minutes of this meeting
12 were distributed. By appointing these individuals as their representatives on the III’s Executive
13 Committee, both BASF and Huntsman indicated their confidence in these employees’ respective
14 capabilities to appreciate the significance of isocyanate safety information that they would obtain
15 as members of the Executive Committee. Through these representatives, both BASF and
16 Huntsman obtained the 1988 Mineworkers SRI when those representatives received copies of
17 these minutes. Although the minutes do not indicate when they were distributed, a conservative
18 estimate of 60 days after the meeting would place BASF and Huntsman as obtaining the 1988
19 Mineworkers SRI as of November 7, 1988. (Huntsman first obtained the information at the
20 meeting through the attendance of its representative.)

21 250. As of June 15, 1988, Bayer’s predecessor-in-interest, Mobay, chaired the III’s
22 Americas Region Transportation and Handling Subcommittee through its employee, William
23 Niggel. Minutes of the June 15, 1988 III Americas Region Transportation and Handling
24 Subcommittee, III(Bice)007108-007113 at 007113, Exh. 11. As of January 1989, Mr. Niggel
25 was still Chairman of that subcommittee. III Organization Chart, January 1989, Exh. 10 at
26 III(Bice)007025. Thus, on the dates of the September 6-8, 1988 III Safety Committee meeting
27 and in the four-month period following the meeting, Bayer’s predecessor-in-interest Mobay
28

1 chaired a III Sub-Committee through its employee William Niggel, to whom the minutes of this
 2 meeting were distributed. By appointing Mr. Niggel as its representative to chair the III's
 3 Americas Region Transportation and Handling Committee, Bayer's predecessor-in-interest
 4 Mobay indicated its confidence in Mr. Niggel's capability to appreciate the significance of
 5 isocyanate safety information that he would obtain as chairman of that sub-committee. Through
 6 Mr. Niggel, Bayer obtained the 1988 Mineworkers SRI when Mr. Niggel received a copy of
 7 these minutes. Although the minutes do not indicate when they were distributed, a conservative
 8 estimate of 60 days after the meeting would place Bayer as obtaining the 1988 Mineworkers SRI
 9 as of November 7, 1988.

10 d. **TSCA required that Dow and Huntsman report the 1988**
 11 **Mineworkers SRI by September 29, 1988, and that BASF and Bayer**
 12 **report the information by November 30, 1988.**

13 251. The EPA's 1978 Policy Statement provides that "a person has 'immediately
 14 informed' the Administrator if information is received by EPA not later than the 15th working
 15 day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at
 16 11111, Unit IV. Both Dow and Huntsman obtained the 1988 Mineworkers SRI on September 8,
 17 1988 and TSCA required that both Dow and Huntsman report the 1988 Mineworkers SRI to the
 18 EPA by September 29, 1988, the fifteenth working day after the date that Dow and Huntsman
 19 obtained the information.

20 252. Both BASF and Bayer obtained the 1988 Mineworkers SRI through distribution
 21 of the minutes of the meeting, and based on a conservative estimate that the minutes were
 22 distributed within sixty-days after the meeting, they obtained the 1988 Mineworkers SRI by
 23 November 7, 1988. TSCA required that both BASF and Bayer report the 1988 Mineworkers SRI
 24 to the EPA by November 30, 1988, the fifteenth working day after the date that BASF and Bayer
 25 obtained the information.

e. **Each defendant was subject to TSCA's reporting requirement when it obtained the 1988 Mineworkers SRI.**

253. At the time that it obtained the 1988 Mineworkers SRI, Bayer was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

254. At the time that it obtained the 1988 Mineworkers SRI, BASF was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

255. At the time that it obtained the 1988 Mineworkers SRI, Dow was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

256. At the time that it obtained the 1988 Mineworkers SRI, Huntsman was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

f. **Each defendant failed to report the 1988 Mineworkers SRI, even though TSCA did not exempt its reporting obligation.**

257. BASF did not report the 1988 Mineworkers SRI to the EPA "immediately" after obtaining it.

258. BASF has never reported the 1988 Mineworkers SRI to the EPA.

1 259. BASF did not have knowledge as of November 30, 1988 that some entity other
2 than BASF had submitted the 1988 Mineworkers SRI to the EPA.

3 260. BASF has not acquired knowledge since November 30, 1988 that some entity
4 other than BASF has submitted the 1988 Mineworkers SRI to the EPA.

5 261. BASF did not have actual knowledge as of November 30, 1988 that the EPA was
6 adequately informed of the 1988 Mineworkers SRI.

7 262. BASF has not acquired actual knowledge since November 30, 1988 that the EPA
8 has become adequately informed of the 1988 Mineworkers SRI.

9 263. Therefore, TSCA did not exempt BASF from its obligation to report the 1988
10 Mineworkers SRI.

11 264. Bayer did not report the 1988 Mineworkers SRI to the EPA “immediately” after
12 obtaining it.

13 265. Bayer has never reported the 1988 Mineworkers SRI to the EPA.

14 266. Bayer did not have knowledge as of November 30, 1988 that some entity other
15 than Bayer had submitted the 1988 Mineworkers SRI to the EPA.

16 267. Bayer has not acquired knowledge since November 30, 1988 that some entity
17 other than Bayer has submitted the 1988 Mineworkers SRI to the EPA.

18 268. Bayer did not have actual knowledge as of November 30, 1988 that the EPA was
19 adequately informed of the 1988 Mineworkers SRI.

20 269. Bayer has not acquired actual knowledge since November 30, 1988 that the EPA
21 has become adequately informed of the 1988 Mineworkers SRI.

22 270. Therefore, TSCA did not exempt Bayer from its obligation to report the 1988
23 Mineworkers SRI.

24 271. Dow did not report the 1988 Mineworkers SRI to the EPA “immediately” after
25 obtaining it.

26 272. Dow has never reported the 1988 Mineworkers SRI to the EPA.

273. Dow did not have knowledge as of September 29, 1988 that some entity other than Dow had submitted the 1988 Mineworkers SRI to the EPA.

274. Dow has not acquired knowledge since September 29, 1988 that some entity other than Dow has submitted the 1988 Mineworkers SRI to the EPA.

275. Dow did not have actual knowledge as of September 29, 1988 that the EPA was adequately informed of the 1988 Mineworkers SRI.

276. Dow has not acquired actual knowledge since September 29, 1988 that the EPA has become adequately informed of the 1988 Mineworkers SRI.

277. Therefore, TSCA did not exempt Dow from its obligation to report the 1988 Mineworkers SRI.

278. Huntsman did not report the 1988 Mineworkers SRI to the EPA “immediately” after obtaining it.

279. Huntsman has never reported the 1988 Mineworkers SRI to the EPA.

280. Huntsman did not have knowledge as of September 29, 1988 that some entity other than Huntsman had submitted the 1988 Mineworkers SRI to the EPA.

281. Huntsman has not acquired knowledge since September 29, 1988 that some entity other than Huntsman has submitted the 1988 Mineworkers SRI to the EPA.

282. Huntsman did not have actual knowledge as of September 29, 1988 that the EPA was adequately informed of the 1988 Mineworkers SRI.

283. Huntsman has not acquired actual knowledge since September 29, 1988 that the EPA has become adequately informed of the 1988 Mineworkers SRI.

284. Therefore, TSCA did not exempt Huntsman from its obligation to report the 1988 Mineworkers SRI.

g. The EPA’s guidance documents did not exempt any defendant’s obligation to report the 1988 Mineworkers SRI.

285. Although the EPA’s guidance documents could be read to broaden TSCA’s limited exemption, the EPA’s guidance documents cannot alter the scope of the statutory

1 exemption, and each defendant's separate reporting obligation is exempted only if it had "actual
2 knowledge that the Administrator [of the EPA] has been adequately informed of such
3 information." 15 U.S.C. § 2607(e).

4 286. Regardless, however, the EPA's guidance documents did not exempt BASF,
5 Bayer, Dow, or Huntsman from the obligation to report the 1988 Mineworkers SRI.

6 287. As of both September 29, 1988, the latest date by which TSCA required Dow and
7 Huntsman to report the 1988 Mineworkers SRI, and November 30, 1988, the latest date by which
8 TSCA required BASF and Bayer to report the information, the EPA's 1978 Policy Statement
9 provided that substantial risk information was exempted from reporting if the information: "(a)
10 Has been published by EPA in reports; (b) Has been submitted in writing to EPA pursuant to
11 mandatory reporting requirements under TSCA or any other authority administered by EPA . . . ;
12 (c) Has been published in the scientific literature and referenced [by one of several listed abstract
13 services]; (d) Is corroborative of well-established adverse effects already documented in the
14 scientific literature and referenced [by one of the abstract services listed in (c) above]; or (e) [Is
15 contained in an environmental notification of spills]." 1978 Policy Statement, 43 Fed. Reg. at
16 11112, Unit VII(a) through (e).

17 288. As of November 30, 1988, the 1988 Mineworkers SRI had not been "published by
18 EPA in reports."

19 289. As of November 30, 1988, the 1988 Mineworkers SRI had not been "submitted in
20 writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority
21 administered by EPA."

22 290. As of November 30, 1988, the 1988 Mineworkers SRI had not been "published in
23 the scientific literature and referenced [by one of several listed abstract services]."

24 291. As of November 30, 1988, the 1988 Mineworkers SRI was not "corroborative of
25 well-established adverse effects already documented in the scientific literature and referenced
26 [by one of the abstract services listed in (c) above]." To the contrary, each defendant has
27 publicly contended that the scant publicly-available information that suggests that the possibility
28

1 for isocyanate skin contact to cause respiratory sensitization is anecdotal, inconclusive, and
 2 unreliable. For example, in a May 2002 III paper entitled “Respiratory sensitization: the role of
 3 dermal contact with MDI and TDI,” defendants and other III member companies discussed the
 4 animal and human data relevant to the potential link between skin contact with MDI and
 5 respiratory sensitization. Exh. 2, at CHARM 012422–012446. The defendants neither published
 6 nor otherwise discussed in that paper the 1988 Mineworkers SRI, even though that substantial
 7 risk information is relevant to the link between human isocyanate skin contact and respiratory
 8 sensitization. Moreover, the defendants concluded their May 2002 paper by contending that the
 9 link between respiratory sensitization and MDI skin contact was not well-established and that the
 10 “available” human data was insufficient to establish the link: “The available data do not provide
 11 sufficient evidence for a clear correlation between skin exposure and occupational asthma.” *Id.*
 12 at CHARM 12442, Exh. 2. Each defendant was a co-author of that 2002 III paper. *Id.* at
 13 CHARM 12425, Exh. 2.

14 292. None of the defendants can contend that the 1988 Mineworkers SRI was
 15 “corroborative of well-established adverse effects already documented in the scientific
 16 literature,” because they contended afterwards, in May 2002, that “[t]he available data do not
 17 provide sufficient evidence for a clear correlation between skin exposure and occupational
 18 asthma.” *Id.* at CHARM 12442, Exh. 2.

19 293. Defendants have also publicly disputed the possibility that low-level inhalation
 20 could cause respiratory sensitization. For example, in October 1993 the defendants, through the
 21 Diisocyanates Panel of the CMA (now the ACC), submitted comments to the EPA regarding its
 22 risk management process for diisocyanates. The defendants told the EPA that the proposition
 23 that “pulmonary function decrement and sensitization can occur at very low concentrations” was
 24 “not supported by available data.” *Comments of the Chemical Manufacturers Association*
 25 *Diisocyanate Panel on the RM1 Briefing Document for Diisocyanates*, October 12, 1993, at
 26 BAY010037, Exh. 4. Each defendant or its predecessor-in-interest was a member of the CMA’s
 27 Diisocyanates Panel, which submitted these comments. *Id.* at BAY010041, n.1, Exh. 4.

294. None of the defendants can contend that the 1988 Mineworkers SRI was “corroborative of well-established adverse effects already documented in the scientific literature,” because they contended afterwards, in October 1993, that the proposition that “pulmonary function decrement and sensitization can occur at very low concentrations” was “not supported by available data.” *Id.* at BAY010037, Exh. 4.

5. **In or shortly after March 1989, each defendant had separately obtained the “1989 Human Cases SRI,” which comprised substantial risk information about MDI and PMDI skin contact and low-level inhalation exposure.**

a. **Each defendant separately obtained the information in or shortly after March 1989.**

295. In or shortly after March 1989, each defendant obtained substantial risk information about respiratory sensitization in humans caused either by skin contact with or low-level inhalation of PMDI. The minutes of the III Scientific Committee’s March 6-9, 1989 meeting establish that the meeting’s attendees discussed the anticipated efforts of the III’s newly-formed Medical Advisory Group (MAG). III(Bice)007421-007468 at III(Bice)007425, Exh. 12. The attendees reviewed a “list of areas to be addressed,” prepared by the MAG during its inaugural meeting. The first item concerned “Sensitization”:

There was still a pressing need to investigate respiratory effects resulting from percutaneous administration of MDI in animals, *with a view to explaining certain human cases of MDI sensitization in which inhalation exposure appeared to have been negligible*. From current evidence sensitization remains the major issue to be addressed.

Exh. 12 at III(Bice)007425, Item 7.0(A) (emphasis added).

296. This information, the “1989 Human Cases SRI,” comprised “evidence” relating to multiple “cases,” plural, of MDI respiratory sensitization in humans, caused by MDI exposure in what appeared to be a low-level (“negligible”) inhalation exposure environment. The minutes indicate that this “evidence” caused the III’s Medical Advisory Group to associate the human respiratory sensitization with skin exposure, as the MAG observed the “pressing need” to investigate the dermal induction route in animals. *Id.*, Exh. 12 at III(Bice)007425, Item 7.0(A).

b. **The 1989 Human Cases SRI was “substantial risk information.”**

297. TSCA defines substantial risk information as “information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment.” 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that “‘reasonably supports the conclusion’ of substantial risk is not identical to a conclusive demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11110, Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a] person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which ‘reasonably supports’ that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI.

298. The 1989 Human Cases SRI “reliably ascribe[d] the effect to the chemical,” and was therefore reportable substantial risk information. The minutes establish that the III’s Medical Advisory Group viewed the 1989 Human Cases SRI “evidence” as conclusive that these humans had “MDI sensitization”—in other words, respiratory sensitization caused by MDI exposure. Moreover, the minutes establish that the MAG associated the human respiratory sensitization with either MDI skin contact or low-level (“negligible”) MDI inhalation exposure. Thus, the 1989 Human Cases SRI not only “reliably ascribe[d] the effect to the chemical [MDI],” but it also characterized the effect in terms of two alternative MDI exposure routes, neither of which was known by the EPA to cause respiratory sensitization. The 1989 Human Cases SRI was therefore reportable substantial risk information.

299. The 1978 Policy Statement identifies two factors to weigh in the substantial risk determination: “the seriousness of the effect” and “the fact or probability of its occurrence.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these factors are weighed differently for different effects. If the effects are among the human health effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so serious that relatively little weight is given to exposure; the mere fact that the implicated

1 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
 2 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
 3 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
 4 risk information.

5 300. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy
 6 include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
 7 inability to use a normal bodily function with a consequent relatively serious impairment of
 8 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
 9 43 Fed. Reg. at 11112, Unit V(a)(1). Respiratory sensitization, which can lead to occupational
 10 asthma and permanent lung damage, is such a “serious” human health effect.

11 301. Accordingly, information about “[a]ny instance” of respiratory sensitization
 12 “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few)
 13 chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1).
 14 Indeed, the EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an
 15 effect is reportable: “It is anticipated here that reportable effects will generally occur in a
 16 pattern, where a significant common feature is exposure to the chemical. However, a single
 17 instance of . . . serious incapacitation in a human would be reportable if one (or a few)
 18 chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
 19 VI(2).

20 302. The 1989 Human Cases SRI, which concerned the human health effect of
 21 respiratory sensitization caused either by MDI skin contact or low-level MDI inhalation
 22 exposure, was therefore reportable substantial risk information. The 1989 Human Cases SRI
 23 involved effects that “occur[red] in a pattern, where a significant common feature [was] exposure
 24 to the chemical,” here, exposure in an environment of “negligible” inhalation exposure to MDI.
 25 And, as the III’s MAG Group viewed the 1989 Human Cases SRI “evidence” as conclusive that
 26 these humans had “MDI sensitization”—in other words, respiratory sensitization caused by MDI
 27
 28

1 exposure, “one . . . chemical[] is strongly implicated.” The 1989 Human Cases SRI was
2 reportable substantial risk information.

3 303. The EPA’s 1978 Policy Statement provides that information that is reportable
4 under Section 8(e) may be obtained from sources other than designed, controlled studies.
5 Indeed, in its 1978 Policy Statement, the EPA identifies the sources of information that “will
6 often ‘reasonably support’ a conclusion of substantial risk.” 1978 Policy Statement, 43 Fed.
7 Reg. at 11112, Unit VI. These sources include “reports concerning and studies of undesigned,
8 uncontrolled circumstances.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2).
9 Examples of “[r]eports and studies of undesigned circumstances include: (i) medical and health
10 surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of effects in consumers,*
11 *workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2)
12 (emphasis added).

13 304. The defendants obtained the 1989 Human Cases SRI from “reports concerning . . .
14 undesigned, uncontrolled circumstances,” including “reports concerning and evidence of effects
15 in consumers, workers, or the environment.” The 1989 Human Cases SRI therefore comprises
16 information that is reportable under TSCA Section 8(e).

17 c. **Each defendant separately obtained the 1989 Human Cases SRI.**

18 305. BASF, Dow, and Huntsman (through its predecessor-in-interest ICI Americas)
19 had representatives present at this March 6-9, 1989 meeting of the III Scientific Committee.
20 K.S. Brenner represented BASF, Larry Rampy and C. Bastian represented Dow, and R.F.
21 Hoffman represented ICI Americas. Minutes of the March 6-9, 1989 III Scientific Committee
22 meeting, Exh. 12 at III(Bice)007421. By sending these representatives on their behalf to attend
23 and participate in the meeting of the III’s Scientific Committee, BASF, Dow, and Huntsman
24 each indicated their confidence in their respective employees’ capabilities to appreciate the
25 significance of isocyanate safety and/or scientific information that they would obtain at the
26 meeting. Under TSCA, a “business organization is considered to have obtained any information
27 which any officer or employee capable of appreciating the significance of that information has
28

1 obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II. Thus, BASF, Dow, and
2 Huntsman each obtained the 1989 Human Cases SRI as of March 9, 1989, the last day of the
3 meeting.

4 306. The minutes indicate that the III distributed copies to the “III Members Present”
5 (which included defendants BASF, Dow, and Huntsman), to the “Members of the Executive,”
6 and to “Sub Committee Chairmen.” Exh. 12 at III(Bice)007421.

7 307. As of January 1989, Bayer’s predecessor-in-interest, Mobay, chaired the III’s
8 Americas Region Transportation and Handling Sub-Committee through its employee, William
9 Niggel. III Organization Chart, January 1989, Exh. 10 at III(Bice)007025. As of June 1989, Mr.
10 Niggel was still chairman of the sub-committee. Minutes of the June 6, 1989 meeting of the
11 Americas Region Transportation and Handling Sub-Committee, III(Bice)007672-007679 at
12 007679, Exh. 13. Indeed, Mr. Niggel had been elected to a two-year term as chairman of the
13 subcommittee in June 1988, so his chairmanship of the sub-committee ran through June 1990.
14 Minutes of the June 7, 1988 meeting of the Americas Region Transportation and Handling Sub-
15 Committee, III(Bice)007108-007113 at 7110, Exh. 14.

16 308. Thus, on the dates of the March 6-9, 1989 III Scientific Committee meeting and in
17 the four-month period following the meeting, Bayer’s predecessor-in-interest Mobay chaired a
18 III Sub-Committee through its employee William Niggel, to whom the minutes of this meeting
19 were distributed. By appointing Mr. Niggel as its representative to chair the III’s Americas
20 Region Transportation and Handling Committee, Bayer’s predecessor-in-interest Mobay
21 indicated its confidence in Mr. Niggel’s capability to appreciate the significance of isocyanate
22 safety information that he would obtain as chairman of that sub-committee. Through Mr. Niggel,
23 Bayer obtained the 1989 Human Cases SRI when Mr. Niggel received a copy of these minutes.
24 Although the minutes do not indicate when they were distributed, a conservative estimate of 60
25 days after the meeting would place Bayer as obtaining the 1989 Human Cases SRI as of May 8,
26 1989.

d. **TSCA required that BASF, Dow, and Huntsman each report the 1989 Human Cases SRI by March 30, 1989, and that Bayer report the information by May 30, 1989.**

309. The EPA's 1978 Policy Statement provides that "a person has 'immediately informed' the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit IV.

310. As alleged more thoroughly above, BASF, Dow, and Huntsman each obtained the 1989 Human Cases SRI on March 9, 1989, and TSCA required that BASF, Dow, and Huntsman each report the 1989 Human Cases SRI to the EPA by March 30, 1989, the fifteenth working day after the date that BASF, Dow, and Huntsman each obtained the information.

311. As alleged more thoroughly above, Bayer obtained the 1989 Human Cases SRI by May 8, 1989, and TSCA required that Bayer report the 1989 Human Cases SRI to the EPA by May 30, 1989, the fifteenth working day after the date that Bayer obtained the information.

e. **Each defendant was subject to TSCA's reporting requirement when it separately obtained the 1989 Human Cases SRI.**

312. At the time that it obtained the 1989 Human Cases SRI, Bayer was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

313. At the time that it obtained the 1989 Human Cases SRI, BASF was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

314. At the time that it obtained the 1989 Human Cases SRI, Dow was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]"

1 MDI, PMDI, and TDI, and thus was obligated to “immediately inform the Administrator [of the
2 EPA]” of the substantial risk information, which directly concerned MDI and PMDI, and which
3 concerned TDI either directly or as a closely related chemical.

4 315. At the time that it obtained the 1989 Human Cases SRI, Huntsman was a “person
5 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
6 mixture[s]” MDI, PMDI, and TDI, and thus was obligated to “immediately inform the
7 Administrator [of the EPA]” of the substantial risk information, which directly concerned MDI
8 and PMDI, and which concerned TDI either directly or as a closely related chemical.

9 f. **Each defendant failed to report the 1989 Human Cases SRI, even**
10 **though TSCA did not exempt its reporting obligation.**

11 316. BASF did not report the 1989 Human Cases SRI to the EPA “immediately” after
12 obtaining it.

13 317. BASF has never reported the 1989 Human Cases SRI to the EPA.

14 318. BASF did not have knowledge as of March 30, 1989 that some entity other than
15 BASF had submitted the 1989 Human Cases SRI to the EPA.

16 319. BASF has not acquired knowledge since March 30, 1989 that some entity other
17 than BASF has submitted the 1989 Human Cases SRI to the EPA.

18 320. BASF did not have actual knowledge as of March 30, 1989 that the EPA was
19 adequately informed of the 1989 Human Cases SRI.

20 321. BASF has not acquired actual knowledge since March 30, 1989 that the EPA has
21 become adequately informed of the 1989 Human Cases SRI.

22 322. Therefore, TSCA did not exempt BASF from its obligation to report the 1989
23 Human Cases SRI.

24 323. Bayer did not report the 1989 Human Cases SRI to the EPA “immediately” after
25 obtaining it.

26 324. Bayer has never reported the 1989 Human Cases SRI to the EPA.

1 325. Bayer did not have knowledge as of May 30, 1989 that some entity other than
2 Bayer had submitted the 1989 Human Cases SRI to the EPA.

3 326. Bayer has not acquired knowledge since May 30, 1989 that some entity other than
4 Bayer has submitted the 1989 Human Cases SRI to the EPA.

5 327. Bayer did not have actual knowledge as of May 30, 1989 that the EPA was
6 adequately informed of the 1989 Human Cases SRI.

7 328. Bayer has not acquired actual knowledge since May 30, 1989 that the EPA has
8 become adequately informed of the 1989 Human Cases SRI.

9 329. Therefore, TSCA did not exempt Bayer from its obligation to report the 1989
10 Human Cases SRI.

11 330. Dow did not report the 1989 Human Cases SRI to the EPA “immediately” after
12 obtaining it.

13 331. Dow has never reported the 1989 Human Cases SRI to the EPA.

14 332. Dow did not have knowledge as of March 30, 1989 that some entity other than
15 Dow had submitted the 1989 Human Cases SRI to the EPA.

16 333. Dow has not acquired knowledge since March 30, 1989 that some entity other
17 than Dow has submitted the 1989 Human Cases SRI to the EPA.

18 334. Dow did not have actual knowledge as of March 30, 1989 that the EPA was
19 adequately informed of the 1989 Human Cases SRI.

20 335. Dow has not acquired actual knowledge since March 30, 1989 that the EPA has
21 become adequately informed of the 1989 Human Cases SRI.

22 336. Therefore, TSCA did not exempt Dow from its obligation to report the 1989
23 Human Cases SRI.

24 337. Huntsman did not report the 1989 Human Cases SRI to the EPA “immediately”
25 after obtaining it.

26 338. Huntsman has never reported the 1989 Human Cases SRI to the EPA.
27
28

1 339. Huntsman did not have knowledge as of March 30, 1989 that some entity other
2 than Huntsman had submitted the 1989 Human Cases SRI to the EPA.

3 340. Huntsman has not acquired knowledge since March 30, 1989 that some entity
4 other than Huntsman has submitted the 1989 Human Cases SRI to the EPA.

5 341. Huntsman did not have actual knowledge as of March 30, 1989 that the EPA was
6 adequately informed of the 1989 Human Cases SRI.

7 342. Huntsman has not acquired actual knowledge since March 30, 1989 that the EPA
8 has become adequately informed of the 1989 Human Cases SRI.

9 343. Therefore, TSCA did not exempt Huntsman from its obligation to report the 1989
10 Human Cases SRI.

11 g. **The EPA's guidance documents did not exempt any defendant's**
12 **obligation to report the 1989 Human Cases SRI.**

13 344. Although the EPA's guidance documents could be read to broaden TSCA's
14 limited exemption, the EPA's guidance documents cannot alter the scope of the statutory
15 exemption, and each defendant's separate reporting obligation is exempted only if it had "actual
16 knowledge that the Administrator [of the EPA] has been adequately informed of such
17 information." 15 U.S.C. § 2607(e).

18 345. Regardless, however, the EPA's guidance documents did not exempt BASF,
19 Bayer, Dow, or Huntsman from the obligation to report the 1989 Human Cases SRI.

20 346. As of both March 30, 1989, the latest date by which TSCA required BASF, Dow,
21 and Huntsman to report the 1989 Human Cases SRI, and May 30, 1989, the latest date by which
22 TSCA required Bayer to report the information, the EPA's 1978 Policy Statement provided that
23 substantial risk information was exempted from reporting if the information: "(a) Has been
24 published by EPA in reports; (b) Has been submitted in writing to EPA pursuant to mandatory
25 reporting requirements under TSCA or any other authority administered by EPA . . .; (c) Has
26 been published in the scientific literature and referenced [by one of several listed abstract
27 services]; (d) Is corroborative of well-established adverse effects already documented in the
28

1 scientific literature and referenced [by one of the abstract services listed in (c) above]; or (e) [Is
2 contained in an environmental notification of spills].” 1978 Policy Statement, 43 Fed. Reg. at
3 11112, Unit VII(a) through (e).

4 347. As of May 30, 1989, the 1989 Human Cases SRI had not been “published by EPA
5 in reports.”

6 348. As of May 30, 1989, the 1989 Human Cases SRI had not been “submitted in
7 writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority
8 administered by EPA.”

9 349. As of May 30, 1989, the 1989 Human Cases SRI had not been “published in the
10 scientific literature and referenced [by one of several listed abstract services].”

11 350. As of May 30, 1989, the 1989 Human Cases SRI was not “corroborative of well-
12 established adverse effects already documented in the scientific literature and referenced [by one
13 of the abstract services listed in (c) above].” To the contrary, each defendant has publicly
14 contended that the scant publicly-available information that suggests that the possibility for
15 isocyanate skin contact to cause respiratory sensitization is anecdotal, inconclusive, and
16 unreliable. For example, in a May 2002 III paper entitled “Respiratory sensitization: the role of
17 dermal contact with MDI and TDI,” defendants and other III member companies discussed the
18 animal and human data relevant to the potential link between skin contact with MDI and
19 respiratory sensitization. Exh. 2, at CHARM 012422–012446. The defendants neither published
20 nor otherwise discussed in that paper the 1989 Human Cases SRI, even though that substantial
21 risk information is relevant to the link between human isocyanate skin contact and respiratory
22 sensitization. Moreover, the defendants concluded their May 2002 paper by contending that the
23 link between respiratory sensitization and MDI skin contact was not well-established and that the
24 “available” human data was insufficient to establish the link: “The available data do not provide
25 sufficient evidence for a clear correlation between skin exposure and occupational asthma.” *Id.*
26 at CHARM 12442, Exh. 2. Each defendant was a co-author of that 2002 III paper. *Id.* at
27 CHARM 12425, Exh. 2.

351. None of the defendants can contend that the 1989 Human Cases SRI was “corroborative of well-established adverse effects already documented in the scientific literature,” because they contended afterwards, in May 2002, that “[t]he available data do not provide sufficient evidence for a clear correlation between skin exposure and occupational asthma.” *Id.* at CHARM 12442, Exh. 2.

352. Defendants have also publicly disputed the possibility that low-level inhalation could cause respiratory sensitization. For example, in October 1993 the defendants, through the Diisocyanates Panel of the CMA (now the ACC), submitted comments to the EPA regarding its risk management process for diisocyanates. The defendants told the EPA that the proposition that “pulmonary function decrement and sensitization can occur at very low concentrations” was “not supported by available data.” *Comments of the Chemical Manufacturers Association Diisocyanate Panel on the RMI Briefing Document for Diisocyanates*, October 12, 1993, at BAY010037, Exh. 4. Each defendant or its predecessor-in-interest was a member of the CMA’s Diisocyanates Panel, which submitted these comments. *Id.* at BAY010041, n.1, Exh. 4.

353. None of the defendants can contend that the 1989 Human Cases SRI was “corroborative of well-established adverse effects already documented in the scientific literature,” because they contended afterwards, in October 1993, that the proposition that “pulmonary function decrement and sensitization can occur at very low concentrations” was “not supported by available data.” *Id.* at BAY010037, Exh. 4.

6. **In or shortly after March 1989, each defendant had separately obtained the “1989 German Mine SRI,” which comprised substantial risk information about MDI skin contact and low-level inhalation exposure.**

a. **Each defendant separately obtained the information in or shortly after March 1989.**

354. In or shortly after March 1989, each defendant obtained substantial risk information about respiratory sensitization in humans caused either by skin contact with or low-level inhalation of PMDI. The minutes of the III Scientific Committee’s March 6-9, 1989 meeting memorialize a discussion at the meeting under the heading “Respiratory Effects from

1 Dermal Contact with Polymeric MDI (Karol).” III(Bice)007421-007468 at III(Bice)007436

2 (emphasis in original), Exh. 12. In addition to discussing Dr. Meryl Karol’s proposal “to
3 investigate the effect of polymeric MDI in guinea pigs, by intradermal application,” the attendees
4 discussed human evidence of MDI and/or PMDI respiratory sensitization:

5 There are situations (notably is a well-monitored W. German mine) where MDI
6 respiratory sensitization appears to have resulted either from inordinately low
7 levels of airborne MDI or from skin contact.

8 Exh. 12 at III(Bice)007436.

9 355. This information, the “1989 German Mine SRI,” comprised information relating
10 to multiple “situations,” plural, of “MDI respiratory sensitization” in humans, caused either by
11 MDI skin contact or by low-level (“inordinately low”) MDI inhalation exposure. The minutes
12 indicate that air-monitoring data from “a well-monitored W. German mine” established the
13 “inordinately low levels of airborne MDI” associated with at least some of these “situations” that
14 involved “MDI respiratory sensitization.” *Id.*, Ex. 12 at III(Bice)007436.

15 **b. The 1989 German Mine SRI was “substantial risk information.”**

16 356. TSCA defines substantial risk information as “information which reasonably
17 supports the conclusion that such substance or mixture presents a substantial risk of injury to
18 health or the environment.” 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that
19 “‘reasonably supports the conclusion’ of substantial risk is not identical to a conclusive
20 demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11110,
21 Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a] person
22 is not to delay reporting until he obtains conclusive information that a substantial risk exists, but
23 is to immediately report any evidence which ‘reasonably supports’ that conclusion. Such
24 evidence will generally not be conclusive as to the substantiality of the risk; it should, however,
25 reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI.

26 357. The 1989 German Mine SRI “reliably ascribe[d] the effect to the chemical,” and
27 was therefore reportable substantial risk information. The minutes establish that the III’s
28 Scientific Committee viewed the 1989 German Mine SRI as conclusive that these humans had

1 “MDI respiratory sensitization”—in other words, respiratory sensitization caused by MDI
2 exposure.

3 358. Moreover, the minutes establish that the Scientific Committee closely associated
4 the human respiratory sensitization with either MDI skin contact or “inordinately low levels of
5 airborne MDI.” Specifically, the Scientific Committee used air-monitoring data from “a well-
6 monitored W. German mine” to establish that at least some of those sensitized (those who
7 worked in this particular mine) had experienced only “inordinately low levels of airborne MDI”
8 exposure. And based at least in part on the confidence that data provided about the workers’
9 exposures, the Scientific Committee indicated an apparent (“appears to have resulted”) causal
10 link between the MDI respiratory sensitization and either MDI skin contact or low-level
11 inhalation exposure.

12 359. Thus, the 1989 German Mine SRI not only “reliably ascribe[d] the effect to the
13 chemical [PMDI and MDI],” but it also characterized the effect in terms of two alternative MDI
14 exposure routes, neither of which was known by the EPA to cause respiratory sensitization. The
15 1989 German Mine SRI was therefore reportable substantial risk information.

16 360. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
17 determination: “the seriousness of the effect” and “the fact or probability of its occurrence.”
18 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
19 factors are weighed differently for different effects. If the effects are among the human health
20 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so
21 serious that relatively little weight is given to exposure; the mere fact that the implicated
22 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
23 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
24 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
25 risk information.

26 361. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy
27 include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
28

1 inability to use a normal bodily function with a consequent relatively serious impairment of
2 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
3 43 Fed. Reg. at 11112, Unit V(a)(1). Respiratory sensitization, which can lead to occupational
4 asthma and permanent lung damage, is such a “serious” human health effect.

5 362. Accordingly, information about “[a]ny instance” of respiratory sensitization
6 “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few)
7 chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1).
8 Indeed, the EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an
9 effect is reportable: “It is anticipated here that reportable effects will generally occur in a
10 pattern, where a significant common feature is exposure to the chemical. However, a single
11 instance of . . . serious incapacitation in a human would be reportable if one (or a few)
12 chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
13 VI(2).

14 363. The 1989 German Mine SRI, which concerned the human health effect of
15 respiratory sensitization caused either by MDI skin contact or inordinately low-level MDI
16 inhalation exposure, was therefore reportable substantial risk information. The 1989 German
17 Mine SRI involved effects that “occur[red] in a pattern, where a significant common feature
18 [was] exposure to the chemical,” here, exposure in an environment of “inordinately low”
19 inhalation exposure to MDI, as established at least in some of the “situations” with air-
20 monitoring data. And, as the III’s Scientific Committee viewed the 1989 German Mine SRI data
21 as conclusive that these humans had “MDI respiratory sensitization”—in other words, respiratory
22 sensitization caused by MDI exposure, “one . . . chemical[] is strongly implicated.” The 1989
23 German Mine SRI was reportable substantial risk information.

24 364. The EPA’s 1978 Policy Statement provides that information that is reportable
25 under Section 8(e) may be obtained from sources other than designed, controlled studies.
26 Indeed, in its 1978 Policy Statement, the EPA identifies the sources of information that “will
27 often ‘reasonably support’ a conclusion of substantial risk.” 1978 Policy Statement, 43 Fed.
28

1 Reg. at 11112, Unit VI. These sources include “reports concerning and studies of undesigned,
 2 uncontrolled circumstances.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2).
 3 Examples of “[r]eports and studies of undesigned circumstances include: (i) medical and health
 4 surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of effects in consumers,*
 5 *workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2)
 6 (emphasis added).

7 365. The defendants obtained the 1989 German Mine SRI from “reports concerning. . .
 8 undesigned, uncontrolled circumstances,” including “reports concerning and evidence of effects
 9 in consumers, workers, or the environment.” The 1989 German Mine SRI therefore comprises
 10 information that is reportable under TSCA Section 8(e).

11 c. **Each defendant separately obtained the 1989 German Mine SRI.**

12 366. BASF, Dow, and Huntsman (through its predecessor-in-interest ICI Americas)
 13 had representatives present at this March 6-9, 1989 meeting of the III Scientific Committee.
 14 K.S. Brenner represented BASF, Larry Rampy and C. Bastian represented Dow, and R.F.
 15 Hoffman represented ICI Americas. Minutes of the March 6-9, 1989 III Scientific Committee
 16 meeting, Exh. 12 at III(Bice)007421. By sending these representatives on their behalf to attend
 17 and participate in the meeting of the III’s Scientific Committee, BASF, Dow, and Huntsman
 18 each indicated their confidence in their respective employees’ capabilities to appreciate the
 19 significance of isocyanate safety and/or scientific information that they would obtain at the
 20 meeting. Under TSCA, a “business organization is considered to have obtained any information
 21 which any officer or employee capable of appreciating the significance of that information has
 22 obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II. Thus, BASF, Dow, and
 23 Huntsman each obtained the 1989 German Mine SRI as of March 9, 1989, the last day of the
 24 meeting.

25 367. The minutes indicate that the III distributed copies to the “III Members Present”
 26 (which included defendants BASF, Dow, and Huntsman), to the “Members of the Executive,”
 27 and to “Sub Committee Chairmen.” Exh. 12 at III(Bice)007421.

368. As of January 1989, Bayer's predecessor-in-interest, Mobay, chaired the III's Americas Region Transportation and Handling Subcommittee through its employee, William Niggel. III Organization Chart, January 1989, Exh. 10 at III(Bice)007025. As of June 1989, Mr. Niggel was still chairman of the sub-committee. Minutes of the June 6, 1989 meeting of the III's Americas Region Transportation and Handling Subcommittee, III(Bice)007672-007679 at 007679, Exh. 13. Indeed, Mr. Niggel had been elected to a two-year term as chairman of the subcommittee in June 1988, so his chairmanship of the sub-committee ran through June 1990. Minutes of the June 7, 1988 meeting of the III's Americas Region Transportation and Handling Subcommittee, III(Bice)007108-007113 at 7110, Exh. 14.

369. Thus, on the dates of the March 6-9, 1989 III Scientific Committee meeting and in the four-month period following the meeting, Bayer's predecessor-in-interest Mobay chaired a III Sub-Committee through its employee William Niggel, to whom the minutes of this meeting were distributed. By appointing Mr. Niggel as its representative to chair the III's Americas Region Transportation and Handling Committee, Bayer's predecessor-in-interest Mobay indicated its confidence in Mr. Niggel's capability to appreciate the significance of isocyanate safety information that he would obtain as chairman of that sub-committee. Through Mr. Niggel, Bayer obtained the 1989 German Mine SRI when Mr. Niggel received a copy of these minutes. Although the minutes do not indicate when they were distributed, a conservative estimate of 60 days after the meeting would place Bayer as obtaining the 1989 German Mine SRI as of May 8, 1989.

d. **TSCA required that BASF, Dow, and Huntsman each report the 1989 German Mine SRI by March 30, 1989, and that Bayer report the information by May 30, 1989.**

370. The EPA's 1978 Policy Statement provides that "a person has 'immediately informed' the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit IV.

371. As alleged more thoroughly above, BASF, Dow, and Huntsman each obtained the 1989 German Mine SRI on March 9, 1989, and TSCA required that BASF, Dow, and Huntsman each report the 1989 German Mine SRI to the EPA by March 30, 1989, the fifteenth working day after the date that BASF, Dow, and Huntsman each obtained the information.

372. As alleged more thoroughly above, Bayer obtained the 1989 German Mine SRI by May 8, 1989, and TSCA required that Bayer report the 1989 German Mine SRI to the EPA by May 30, 1989, the fifteenth working day after the date that Bayer obtained the information.

e. **Each defendant was subject to TSCA's reporting requirement when it separately obtained the 1989 German Mine SRI.**

373. At the time that it obtained the 1989 German Mine SRI, Bayer was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

374. At the time that it obtained the 1989 German Mine SRI, BASF was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

375. At the time that it obtained the 1989 German Mine SRI, Dow was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

376. At the time that it obtained the 1989 German Mine SRI, Huntsman was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the

1 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
2 and PMDI, and which concerned TDI either directly or as a closely related chemical.

3 f. **Each defendant failed to report the 1989 German Mine SRI, even**
4 **though TSCA did not exempt its reporting obligation.**

5 377. BASF did not report the 1989 German Mine SRI to the EPA "immediately" after
6 obtaining it.

7 378. BASF has never reported the 1989 German Mine SRI to the EPA.

8 379. BASF did not have knowledge as of March 30, 1989 that some entity other than
9 BASF had submitted the 1989 German Mine SRI to the EPA.

10 380. BASF has not acquired knowledge since March 30, 1989 that some entity other
11 than BASF has submitted the 1989 German Mine SRI to the EPA.

12 381. BASF did not have actual knowledge as of March 30, 1989 that the EPA was
13 adequately informed of the 1989 German Mine SRI.

14 382. BASF has not acquired actual knowledge since March 30, 1989 that the EPA has
15 become adequately informed of the 1989 German Mine SRI.

16 383. Therefore, TSCA did not exempt BASF from its obligation to report the 1989
17 German Mine SRI.

18 384. Bayer did not report the 1989 German Mine SRI to the EPA "immediately" after
19 obtaining it.

20 385. Bayer has never reported the 1989 German Mine SRI to the EPA.

21 386. Bayer did not have knowledge as of May 30, 1989 that some entity other than
22 Bayer had submitted the 1989 German Mine SRI to the EPA.

23 387. Bayer has not acquired knowledge since May 30, 1989 that some entity other than
24 Bayer has submitted the 1989 German Mine SRI to the EPA.

25 388. Bayer did not have actual knowledge as of May 30, 1989 that the EPA was
26 adequately informed of the 1989 German Mine SRI.

1 389. Bayer has not acquired actual knowledge since May 30, 1989 that the EPA has
2 become adequately informed of the 1989 German Mine SRI.

3 390. Therefore, TSCA did not exempt Bayer from its obligation to report the 1989
4 German Mine SRI.

5 391. Dow did not report the 1989 German Mine SRI to the EPA “immediately” after
6 obtaining it.

7 392. Dow has never reported the 1989 German Mine SRI to the EPA.

8 393. Dow did not have knowledge as of March 30, 1989 that some entity other than
9 Dow had submitted the 1989 German Mine SRI to the EPA.

10 394. Dow has not acquired knowledge since March 30, 1989 that some entity other
11 than Dow has submitted the 1989 German Mine SRI to the EPA.

12 395. Dow did not have actual knowledge as of March 30, 1989 that the EPA was
13 adequately informed of the 1989 German Mine SRI.

14 396. Dow has not acquired actual knowledge since March 30, 1989 that the EPA has
15 become adequately informed of the 1989 German Mine SRI.

16 397. Therefore, TSCA did not exempt Dow from its obligation to report the 1989
17 German Mine SRI.

18 398. Huntsman did not report the 1989 German Mine SRI to the EPA “immediately”
19 after obtaining it.

20 399. Huntsman has never reported the 1989 German Mine SRI to the EPA.

21 400. Huntsman did not have knowledge as of March 30, 1989 that some entity other
22 than Huntsman had submitted the 1989 German Mine SRI to the EPA.

23 401. Huntsman has not acquired knowledge since March 30, 1989 that some entity
24 other than Huntsman has submitted the 1989 German Mine SRI to the EPA.

25 402. Huntsman did not have actual knowledge as of March 30, 1989 that the EPA was
26 adequately informed of the 1989 German Mine SRI.

1 403. Huntsman has not acquired actual knowledge since March 30, 1989 that the EPA
2 has become adequately informed of the 1989 German Mine SRI.

3 404. Therefore, TSCA did not exempt Huntsman from its obligation to report the 1989
4 German Mine SRI.

5 g. **The EPA's guidance documents did not exempt any defendant's**
6 **obligation to report the 1989 German Mine SRI.**

7 405. Although the EPA's guidance documents could be read to broaden TSCA's
8 limited exemption, the EPA's guidance documents cannot alter the scope of the statutory
9 exemption, and each defendant's separate reporting obligation is exempted only if it had "actual
10 knowledge that the Administrator [of the EPA] has been adequately informed of such
11 information." 15 U.S.C. § 2607(e).

12 406. Regardless, however, the EPA's guidance documents did not exempt BASF,
13 Bayer, Dow, or Huntsman from the obligation to report the 1989 German Mine SRI.

14 407. As of both March 30, 1989, the latest date by which TSCA required BASF, Dow,
15 and Huntsman to report the 1989 German Mine SRI, and May 30, 1989, the latest date by which
16 TSCA required Bayer to report the information, the EPA's 1978 Policy Statement provided that
17 substantial risk information was exempted from reporting if the information: "(a) Has been
18 published by EPA in reports; (b) Has been submitted in writing to EPA pursuant to mandatory
19 reporting requirements under TSCA or any other authority administered by EPA . . .; (c) Has
20 been published in the scientific literature and referenced [by one of several listed abstract
21 services]; (d) Is corroborative of well-established adverse effects already documented in the
22 scientific literature and referenced [by one of the abstract services listed in (c) above]; or (e) [Is
23 contained in an environmental notification of spills]." 1978 Policy Statement, 43 Fed. Reg. at
24 11112, Unit VII(a) through (e).

25 408. As of May 30, 1989, the 1989 German Mine SRI had not been "published by EPA
26 in reports."

1 409. As of May 30, 1989, the 1989 German Mine SRI had not been “submitted in
2 writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority
3 administered by EPA.”

4 410. As of May 30, 1989, the 1989 German Mine SRI had not been “published in the
5 scientific literature and referenced [by one of several listed abstract services].”

6 411. As of May 30, 1989, the 1989 German Mine SRI was not “corroborative of well-
7 established adverse effects already documented in the scientific literature and referenced [by one
8 of the abstract services listed in (c) above].” To the contrary, each defendant has publicly
9 contended that the scant publicly-available information that suggests that the possibility for
10 isocyanate skin contact to cause respiratory sensitization is anecdotal, inconclusive, and
11 unreliable. For example, in a May 2002 III paper entitled “Respiratory sensitization: the role of
12 dermal contact with MDI and TDI,” defendants and other III member companies discussed the
13 animal and human data relevant to the potential link between skin contact with MDI and
14 respiratory sensitization. Exh. 2, at CHARM 012422–012446. The defendants neither published
15 nor otherwise discussed in that paper the 1989 German Mine SRI, even though that substantial
16 risk information is relevant to the link between human isocyanate skin contact and respiratory
17 sensitization. Moreover, the defendants concluded their May 2002 paper by contending that the
18 link between respiratory sensitization and MDI skin contact was not well-established and that the
19 “available” human data was insufficient to establish the link: “The available data do not provide
20 sufficient evidence for a clear correlation between skin exposure and occupational asthma.” *Id.*
21 at CHARM 12442, Exh. 2. Each defendant was a co-author of that 2002 III paper. *Id.* at
22 CHARM 12425, Exh. 2.

23 412. None of the defendants can contend that the 1989 German Mine SRI was
24 “corroborative of well-established adverse effects already documented in the scientific
25 literature,” because they contended afterwards, in May 2002, that “[t]he available data do not
26 provide sufficient evidence for a clear correlation between skin exposure and occupational
27 asthma.” *Id.* at CHARM 12442, Exh. 2.

413. Defendants have also publicly disputed the possibility that low-level inhalation could cause respiratory sensitization. For example, in October 1993 the defendants, through the Diisocyanates Panel of the CMA (now the ACC), submitted comments to the EPA regarding its risk management process for diisocyanates. The defendants told the EPA that the proposition that “pulmonary function decrement and sensitization can occur at very low concentrations” was “not supported by available data.” *Comments of the Chemical Manufacturers Association Diisocyanate Panel on the RM1 Briefing Document for Diisocyanates*, October 12, 1993, at BAY010037, Exh. 4. Each defendant or its predecessor-in-interest was a member of the CMA’s Diisocyanates Panel, which submitted these comments. *Id.* at BAY010041, n.1, Exh. 4.

414. None of the defendants can contend that the 1989 German Mine SRI was “corroborative of well-established adverse effects already documented in the scientific literature,” because they contended afterwards, in October 1993, that the proposition that “pulmonary function decrement and sensitization can occur at very low concentrations” was “not supported by available data.” *Id.* at BAY010037, Exh. 4.

7. **In or shortly after March 1989, each defendant had separately obtained the “1989 Nakata Papers SRI,” which comprised substantial risk information about MDI skin contact or low-level inhalation exposure.**

a. **Each defendant separately obtained the information in or shortly after March 1989.**

415. In or shortly after March 1989, each defendant obtained substantial risk information about respiratory sensitization in humans caused by skin contact with MDI. The minutes of the III Scientific Committee’s March 6-9, 1989 meeting memorialize a discussion at the meeting under the heading “Respiratory Effects from Dermal Contact with Polymeric MDI (Karol).” III(Bice)007421-007468 at III(Bice)007436 (emphasis in original), Exh. 12. In the context of the attendees’ discussion of the German Mine SRI, which comprised information about multiple “situations” of “MDI respiratory sensitization” caused by MDI skin contact or low-level inhalation exposure, and Dr. Meryl Karol’s proposal “to investigate the effect of

1 polymeric MDI in guinea pigs, by intradermal application,” the attendees noted the III’s receipt
2 of several related studies:

3 Nakata submitted to the Scientific Office several papers relating to sensitization
4 following MDI contact. He saw pressure moving from TDI exposure situations to
5 those involving MDI. Both Karol and Newman Taylor indicated that the
6 incidence of MDI sensitization is now much higher than that of TDI.

7 Exh. 12 at III(Bice)007436.

8 416. Mr. Nakata, who submitted the papers to the III’s Scientific Office, is M. Nakata
9 of SBU (Sumitomo Bayer Urethane). *Id.*, Exh. 12 at III(Bice)007421. Sumitomo Bayer
10 Urethane was a III member company and held a seat on the III’s Board of Directors in 1989.
11 1989 III Organizational Chart, Exh. 10 at III(Bice)007026.

12 **b. The 1989 Nakata Papers SRI was “substantial risk information.”**

13 417. This information, the “1989 Nakata Papers SRI,” comprised “several” papers
14 about “sensitization following MDI contact.” None of the defendants (nor any other entity)
15 reported the 1989 Nakata Papers SRI to the EPA, and BASF, Bayer, and Dow each failed to
16 produce the 1989 Nakata Papers SRI during the *Bice* litigation, despite the *Bice* plaintiffs’
17 requests for such information. Thus, the defendants have prevented KBT&F and the U.S.
18 government, including the EPA, from examining the information. Nonetheless, the minutes
19 establish several important facts about the information.

20 418. First, the context of the discussion indicates that the “several” papers that
21 comprise the 1989 Nakata Papers SRI addressed *respiratory* sensitization. The minutes’ topical
22 header for this portion of the meeting, “Respiratory Effects from Dermal Contact with Polymeric
23 MDI (Karol),” establish that Mr. Nakata’s discussion of these papers occurred in the context of
24 the attendees’ discussion “respiratory effects.” Exh. 12, at III(Bice)007436 (emphasis in
25 original). Mr. Nakata discussed the papers after the attendees had discussed the 1989 German
26 Mine SRI, which involved respiratory sensitization, and Dr. Karol’s proposal for animal studies
27 to further investigate respiratory sensitization. This context strongly urges the conclusion that
28

1 the 1989 Nakata Papers SRI also addressed respiratory sensitization, the topic under discussion
2 when Mr. Nakata submitted, or discussed his submission of, the papers.

3 419. Second, the context of the discussion indicates that the 1989 Nakata Papers SRI
4 addressed *human* respiratory sensitization. When he submitted the papers, Mr. Nakata indicated
5 that he “saw pressure moving from TDI exposure situations to those involving MDI,” a clear
6 reference to human exposure situations. Human work environments, not animal studies, involve
7 “exposure situations,” such as the human work “situations” that were the subject of the 1989
8 German Mine SRI the attendees had just discussed. Exh. 12, at III(Bice)007436.

9 420. Further, the attendees noted information from isocyanate researchers Dr. Meryl
10 Karol and Anthony J. Newman-Taylor that “the incidence of MDI sensitization is now much
11 higher than that of TDI,” another clear reference to human respiratory sensitization. Reading the
12 paragraph cohesively, this noted increase in the human MDI respiratory sensitization rate
13 logically serves as the impetus for the “pressure” that is moving from TDI to MDI exposure
14 situations.

15 421. Third, the context also indicates that the 1989 Nakata Papers SRI addressed
16 human respiratory sensitization associated with MDI *skin* contact. The minutes’ topical header
17 for this portion of the meeting, “Respiratory Effects from Dermal Contact with Polymeric MDI
18 (Karol),” establish that Mr. Nakata’s discussion of these papers occurred in the context of the
19 attendees’ discussion of the “dermal contact” exposure route as a cause of respiratory effects.
20 Exh. 12, at III(Bice)007436 (emphasis in original). Further, when describing the MDI
21 respiratory sensitization “situations” involved in the 1989 German Mines SRI, the minutes
22 distinguish between the exposure routes: “from inordinately low levels of airborne MDI or from
23 skin contact.” *Id.*, Exh. 12. In both instances, “contact” exposure meant skin exposure.
24 Logically, then, the minutes’ indication that the papers related to “sensitization following MDI
25 *contact*” meant sensitization following MDI *skin* contact.

26 422. Fourth, the 1989 Nakata Papers SRI comprised “several papers,” with “papers”
27 indicating a written analysis of underlying data. This underlying data involved both medical data
28

1 (a determination of human MDI respiratory sensitization) and industrial hygiene data
2 (information that the subjects were exposed by skin contact).

3 423. Finally, the papers analyzed causation—“sensitization *following* MDI contact.”
4 Exh. 12 at III(Bice)007436. The syntax strongly suggests a positive causation finding, and
5 excludes a negative causation finding. Indeed, in the context of the surrounding discussion, the
6 absence of a negative causation statement in the minutes constitutes strong evidence that the
7 findings were positive. The III’s Scientific Committee had just discussed multiple cases,
8 including in a well-monitored work environment, where “MDI respiratory sensitization appears
9 to have resulted either from inordinately low levels of airborne MDI or from skin contact.” *Id.*,
10 Exh. 12 at III(Bice)007436. Logic indicates that Mr. Nakata would have emphasized any
11 contrary negative findings in the papers he submitted, especially as the committee discussed
12 whether to fund animal studies to investigate the dermal induction route. *Id.* Yet the minutes
13 establish that the attendees characterized causation as likely (“appears to have resulted from”) in
14 the multiple cases that comprised the 1989 German Mineworkers SRI, and contain no suggestion
15 that the attendees viewed the 1989 Nakata Papers SRI to contain contrary information. *Id.*

16 424. The minutes therefore establish that the 1989 Nakata Papers SRI comprised
17 several papers that analyzed medical and industrial hygiene data and determined, based on that
18 analysis, an apparent causal relationship between documented MDI skin contact and confirmed
19 human cases of MDI respiratory sensitization.

20 425. TSCA defines substantial risk information as “information which reasonably
21 supports the conclusion that such substance or mixture presents a substantial risk of injury to
22 health or the environment.” 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that
23 “‘reasonably supports the conclusion’ of substantial risk is not identical to a conclusive
24 demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11110,
25 Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a] person
26 is not to delay reporting until he obtains conclusive information that a substantial risk exists, but
27 is to immediately report any evidence which ‘reasonably supports’ that conclusion. Such
28

1 evidence will generally not be conclusive as to the substantiality of the risk; it should, however,
2 reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI.

3 426. As established above, the 1989 Nakata Papers SRI “reliably ascribe[d] the effect
4 to the chemical,” and was therefore reportable substantial risk information. The minutes
5 establish that the 1989 Nakata Papers were several papers that analyzed medical and industrial
6 hygiene data and determined, based on that analysis, an apparent causal relationship between
7 documented MDI skin contact and confirmed human cases of MDI respiratory sensitization.

8 427. The 1989 Nakata Papers SRI not only “reliably ascribe[d] the effect to the
9 chemical [PMDI and MDI],” but it also characterized the effect in terms of MDI skin contact,
10 which was not known by the EPA to cause respiratory sensitization. The 1989 Nakata Papers
11 SRI was therefore reportable substantial risk information.

12 428. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
13 determination: “the seriousness of the effect” and “the fact or probability of its occurrence.”
14 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
15 factors are weighed differently for different effects. If the effects are among the human health
16 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so
17 serious that relatively little weight is given to exposure; the mere fact that the implicated
18 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
19 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
20 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
21 risk information.

22 429. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy
23 include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
24 inability to use a normal bodily function with a consequent relatively serious impairment of
25 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
26 43 Fed. Reg. at 11112, Unit V(a)(1). Respiratory sensitization, which can lead to occupational
27 asthma and permanent lung damage, is such a “serious” human health effect.

430. Accordingly, information about “[a]ny instance” of respiratory sensitization “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1). Indeed, the EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an effect is reportable: “It is anticipated here that reportable effects will generally occur in a pattern, where a significant common feature is exposure to the chemical. However, a single instance of . . . serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2).

431. The 1989 Nakata Papers SRI, which concerned the human health effect of respiratory sensitization caused by MDI skin contact was therefore reportable substantial risk information. The 1989 Nakata Papers SRI involved effects that “occur[red] in a pattern, where a significant common feature [was] exposure to the chemical,” here, exposure through skin contact. And, as the III’s Scientific Committee viewed the 1989 Nakata Papers SRI data as conclusive that these humans had “MDI respiratory sensitization”—in other words, respiratory sensitization caused by MDI exposure, “one . . . chemical[] is strongly implicated.” The 1989 Nakata Papers SRI was reportable substantial risk information.

432. The EPA’s 1978 Policy Statement provides that information that is reportable under Section 8(e) may be obtained from sources other than designed, controlled studies, although designed, controlled studies must be reported. 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(1). Indeed, in its 1978 Policy Statement, the EPA identifies the sources of information that “will often ‘reasonably support’ a conclusion of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI. These sources include “reports concerning and studies of undesigned, uncontrolled circumstances.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2). Examples of “[r]eports and studies of undesigned circumstances include: (i) medical and health surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of*

1 *effects in consumers, workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at
2 11112, Unit VI(2) (emphasis added).

3 433. The 1989 Nakata Papers SRI may constitute reports of designed, controlled
4 studies. At a minimum, however, the defendants obtained the 1989 Nakata Papers SRI from
5 “reports concerning. . . undesigned, uncontrolled circumstances,” including “reports concerning
6 and evidence of effects in consumers, workers, or the environment.” The 1989 Nakata Papers
7 SRI therefore comprises information that is reportable under TSCA Section 8(e).

8 c. **Each defendant separately obtained the 1989 Nakata Papers SRI.**

9 434. BASF, Dow, and Huntsman (through its predecessor-in-interest ICI Americas)
10 had representatives present at this March 6-9, 1989 meeting of the III Scientific Committee.
11 K.S. Brenner represented BASF, Larry Rampy and C. Bastian represented Dow, and R.F.
12 Hoffman represented ICI Americas. Minutes of the March 6-9, 1989 III Scientific Committee
13 meeting, Exh. 12 at III(Bice)007421. By sending these representatives on their behalf to attend
14 and participate in the meeting of the III’s Scientific Committee, BASF, Dow, and Huntsman
15 each indicated their confidence in their respective employees’ capabilities to appreciate the
16 significance of isocyanate safety and/or scientific information that they would obtain at the
17 meeting. Under TSCA, a “business organization is considered to have obtained any information
18 which any officer or employee capable of appreciating the significance of that information has
19 obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II. Thus, BASF, Dow, and
20 Huntsman each obtained the 1989 Nakata Papers SRI as of March 9, 1989, the last day of the
21 meeting.

22 435. The minutes indicate that the III distributed copies to the “III Members Present”
23 (which included defendants BASF, Dow, and Huntsman), to the “Members of the Executive,”
24 and to “Sub Committee Chairmen.” Exh. 12 at III(Bice)007421.

25 436. As of January 1989, Bayer’s predecessor-in-interest, Mobay, chaired the III’s
26 Americas Region Transportation and Handling Subcommittee through its employee, William
27 Niggel. III Organization Chart, January 1989, Exh. 10 at III(Bice)007025. As of June 1989, Mr.
28

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1 Niggel was still chairman of the sub-committee. Minutes of the June 6, 1989 meeting of the III's
2 Americas Region Transportation and Handling Subcommittee, III(Bice)007672-007679 at
3 007679, Exh. 13. Indeed, Mr. Niggel had been elected to a two-year term as chairman of the
4 subcommittee in June 1988, so his chairmanship of the sub-committee ran through June 1990.
5 Minutes of the June 7, 1988 meeting of the III's Americas Region Transportation and Handling
6 Subcommittee, III(Bice)007108-007113 at 7110, Exh. 14. Thus, on the dates of the March 6-9,
7 1989 III Scientific Committee meeting and in the four-month period following the meeting,
8 Bayer's predecessor-in-interest Mobay chaired a III Sub-Committee through its employee
9 William Niggel, to whom the minutes of this meeting were distributed. By appointing Mr.
10 Niggel as its representative to chair the III's Americas Region Transportation and Handling
11 Committee, Bayer's predecessor-in-interest Mobay indicated its confidence in Mr. Niggel's
12 capability to appreciate the significance of isocyanate safety information that he would obtain as
13 chairman of that sub-committee. Through Mr. Niggel, Bayer obtained the 1989 Nakata Papers
14 SRI when Mr. Niggel received a copy of these minutes. Although the minutes do not indicate
15 when they were distributed, a conservative estimate of 60 days after the meeting would place
16 Bayer as obtaining the 1989 Nakata Papers SRI as of May 8, 1989.

17 d. **TSCA required that BASF, Dow, and Huntsman each report the 1989**
18 **Nakata Papers SRI by March 30, 1989, and that Bayer report the**
19 **information by May 30, 1989.**

20 437. The EPA's 1978 Policy Statement provides that "a person has 'immediately
21 informed' the Administrator if information is received by EPA not later than the 15th working
22 day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at
23 11111, Unit IV.

24 438. As alleged more thoroughly above, BASF, Dow, and Huntsman each obtained the
25 1989 Nakata Papers SRI on March 9, 1989, and TSCA required that BASF, Dow, and Huntsman
26 each report the 1989 Nakata Papers SRI to the EPA by March 30, 1989, the fifteenth working
27 day after the date that BASF, Dow, and Huntsman each obtained the information.
28

1 439. As alleged more thoroughly above, Bayer obtained the 1989 Nakata Papers SRI
2 by May 8, 1989, and TSCA required that Bayer report the 1989 Nakata Papers SRI to the EPA
3 by May 30, 1989, the fifteenth working day after the date that Bayer obtained the information.

4 e. **Each defendant was subject to TSCA's reporting requirement when it**
5 **separately obtained the 1989 Nakata Papers SRI.**

6 440. At the time that it obtained the 1989 Nakata Papers SRI, Bayer was a "person who
7 manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]"
8 MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the
9 EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which
10 concerned TDI either directly or as a closely related chemical.

11 441. At the time that it obtained the 1989 Nakata Papers SRI, BASF was a "person
12 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
13 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
14 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
15 and PMDI, and which concerned TDI either directly or as a closely related chemical.

16 442. At the time that it obtained the 1989 Nakata Papers SRI, Dow was a "person who
17 manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]"
18 MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the
19 EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which
20 concerned TDI either directly or as a closely related chemical.

21 443. At the time that it obtained the 1989 Nakata Papers SRI, Huntsman was a "person
22 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
23 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
24 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
25 and PMDI, and which concerned TDI either directly or as a closely related chemical.

f. **Each defendant failed to report the 1989 Nakata Papers SRI, even though TSCA did not exempt its reporting obligation.**

444. BASF did not report the 1989 Nakata Papers SRI to the EPA “immediately” after obtaining it.

445. BASF has never reported the 1989 Nakata Papers SRI to the EPA.

446. BASF did not have knowledge as of March 30, 1989 that some entity other than BASF had submitted the 1989 Nakata Papers SRI to the EPA.

447. BASF has not acquired knowledge since March 30, 1989 that some entity other than BASF has submitted the 1989 Nakata Papers SRI to the EPA.

448. BASF did not have actual knowledge as of March 30, 1989 that the EPA was adequately informed of the 1989 Nakata Papers SRI.

449. BASF has not acquired actual knowledge since March 30, 1989 that the EPA has become adequately informed of the 1989 Nakata Papers SRI.

450. Therefore, TSCA did not exempt BASF from its obligation to report the 1989 Nakata Papers SRI.

451. Bayer did not report the 1989 Nakata Papers SRI to the EPA “immediately” after obtaining it.

452. Bayer has never reported the 1989 Nakata Papers SRI to the EPA.

453. Bayer did not have knowledge as of May 30, 1989 that some entity other than Bayer had submitted the 1989 Nakata Papers SRI to the EPA.

454. Bayer has not acquired knowledge since May 30, 1989 that some entity other than Bayer has submitted the 1989 Nakata Papers SRI to the EPA.

455. Bayer did not have actual knowledge as of May 30, 1989 that the EPA was adequately informed of the 1989 Nakata Papers SRI.

456. Bayer has not acquired actual knowledge since May 30, 1989 that the EPA has become adequately informed of the 1989 Nakata Papers SRI.

1 457. Therefore, TSCA did not exempt Bayer from its obligation to report the 1989
2 Nakata Papers SRI.

3 458. Dow did not report the 1989 Nakata Papers SRI to the EPA “immediately” after
4 obtaining it.

5 459. Dow has never reported the 1989 Nakata Papers SRI to the EPA.

6 460. Dow did not have knowledge as of March 30, 1989 that some entity other than
7 Dow had submitted the 1989 Nakata Papers SRI to the EPA.

8 461. Dow has not acquired knowledge since March 30, 1989 that some entity other
9 than Dow has submitted the 1989 Nakata Papers SRI to the EPA.

10 462. Dow did not have actual knowledge as of March 30, 1989 that the EPA was
11 adequately informed of the 1989 Nakata Papers SRI.

12 463. Dow has not acquired actual knowledge since March 30, 1989 that the EPA has
13 become adequately informed of the 1989 Nakata Papers SRI.

14 464. Therefore, TSCA did not exempt Dow from its obligation to report the 1989
15 Nakata Papers SRI.

16 465. Huntsman did not report the 1989 Nakata Papers SRI to the EPA “immediately”
17 after obtaining it.

18 466. Huntsman has never reported the 1989 Nakata Papers SRI to the EPA.

19 467. Huntsman did not have knowledge as of March 30, 1989 that some entity other
20 than Huntsman had submitted the 1989 Nakata Papers SRI to the EPA.

21 468. Huntsman has not acquired knowledge since March 30, 1989 that some entity
22 other than Huntsman has submitted the 1989 Nakata Papers SRI to the EPA.

23 469. Huntsman did not have actual knowledge as of March 30, 1989 that the EPA was
24 adequately informed of the 1989 Nakata Papers SRI.

25 470. Huntsman has not acquired actual knowledge since March 30, 1989 that the EPA
26 has become adequately informed of the 1989 Nakata Papers SRI.

1 471. Therefore, TSCA did not exempt Huntsman from its obligation to report the 1989
2 Nakata Papers SRI.

3 g. **The EPA's guidance documents did not exempt any defendant's**
4 **obligation to report the 1989 Nakata Papers SRI.**

5 472. Although the EPA's guidance documents could be read to broaden TSCA's
6 limited exemption, the EPA's guidance documents cannot alter the scope of the statutory
7 exemption, and each defendant's separate reporting obligation is exempted only if it had "actual
8 knowledge that the Administrator [of the EPA] has been adequately informed of such
9 information." 15 U.S.C. § 2607(e).

10 473. Regardless, however, the EPA's guidance documents did not exempt BASF,
11 Bayer, Dow, or Huntsman from the obligation to report the 1989 Nakata Papers SRI.

12 474. As of both March 30, 1989, the latest date by which TSCA required BASF, Dow,
13 and Huntsman to report the 1989 Nakata Papers SRI, and May 30, 1989, the latest date by which
14 TSCA required Bayer to report the information, the EPA's 1978 Policy Statement provided that
15 substantial risk information was exempted from reporting if the information: "(a) Has been
16 published by EPA in reports; (b) Has been submitted in writing to EPA pursuant to mandatory
17 reporting requirements under TSCA or any other authority administered by EPA . . .; (c) Has
18 been published in the scientific literature and referenced [by one of several listed abstract
19 services]; (d) Is corroborative of well-established adverse effects already documented in the
20 scientific literature and referenced [by one of the abstract services listed in (c) above]; or (e) [Is
21 contained in an environmental notification of spills]." 1978 Policy Statement, 43 Fed. Reg. at
22 11112, Unit VII(a) through (e).

23 475. As of May 30, 1989, the 1989 Nakata Papers SRI had not been "published by
24 EPA in reports."

25 476. As of May 30, 1989, the 1989 Nakata Papers SRI had not been "submitted in
26 writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority
27 administered by EPA."
28

1 477. As of May 30, 1989, the 1989 Nakata Papers SRI had not been “published in the
2 scientific literature and referenced [by one of several listed abstract services].”

3 478. As of May 30, 1989, the 1989 Nakata Papers SRI was not “corroborative of well-
4 established adverse effects already documented in the scientific literature and referenced [by one
5 of the abstract services listed in (c) above].” To the contrary, each defendant has publicly
6 contended that the scant publicly-available information that suggests that the possibility for
7 isocyanate skin contact to cause respiratory sensitization is anecdotal, inconclusive, and
8 unreliable. For example, in a May 2002 III paper entitled “Respiratory sensitization: the role of
9 dermal contact with MDI and TDI,” defendants and other III member companies discussed the
10 animal and human data relevant to the potential link between skin contact with MDI and
11 respiratory sensitization. Exh. 2, at CHARM 012422–012446. The defendants neither published
12 nor otherwise discussed in that paper the 1989 Nakata Papers SRI, even though that substantial
13 risk information is relevant to the link between human isocyanate skin contact and respiratory
14 sensitization. Moreover, the defendants concluded their May 2002 paper by contending that the
15 link between respiratory sensitization and MDI skin contact was not well-established and that the
16 “available” human data was insufficient to establish the link: “The available data do not provide
17 sufficient evidence for a clear correlation between skin exposure and occupational asthma.” *Id.*
18 at CHARM 12442, Exh. 2. Each defendant was a co-author of that 2002 III paper. *Id.* at
19 CHARM 12425, Exh. 2.

20 479. None of the defendants can contend that the 1989 Nakata Papers SRI was
21 “corroborative of well-established adverse effects already documented in the scientific
22 literature,” because they contended afterwards, in May 2002, that “[t]he available data do not
23 provide sufficient evidence for a clear correlation between skin exposure and occupational
24 asthma.” *Id.* at CHARM 12442, Exh. 2.

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8. **In or shortly after January 1992, each defendant obtained the “1992 Human Cases SRI,” which comprised substantial risk information about MDI skin contact.**

a. **Each defendant separately obtained the information in or shortly after January 1992.**

480. In or shortly after January 1992, BASF, Bayer, Dow, and Huntsman each obtained substantial risk information about respiratory sensitization in humans caused by skin contact with MDI. The minutes of the III European Med-Tox (EU-MTX) Sub-Committee’s January 16, 1992 meeting memorialize a discussion at the meeting under the general heading “SENSITISATION AND ASTHMA.” III(Bice)009470-009485 at 009472, Item 5.0 (emphasis in original), Exh. 15. Under the sub-heading “5.1 Project E-AB-82 – Animal Model for MDI (Kimber).” the minutes indicate that “Members cited cases where dermal contact was *the likely source* of human sensitisation to MDI, supporting the conclusion of the animal model.” *Id.*, Exh. 15 at III(Bice)009472, Item 5.1 (emphasis added).

481. This information, the “1992 Human Cases SRI,” comprised human cases of respiratory sensitization to MDI, where the member companies analyzed the data and concluded that skin contact with MDI was “the likely source” of the sensitization.

b. **The 1992 Human Cases SRI was “substantial risk information.”**

482. The context establishes that the 1992 Human Cases SRI involved the dermal induction of human *respiratory* sensitization. The attendees discussed these human cases in the context of III Project E-AB-82. *Id.*, Exh. 15 at III(Bice)009472, Item 5.1. That project, led by Dr. Ian Kimber of ICI Central Toxicology Laboratory in the United Kingdom, investigated the potential for dermal MDI exposure to induce respiratory hypersensitivity in guinea pigs. June 11, 1992 letter from III Managing Director R.K. Rigger to TSCA Section 8(e) Coordinator at United States EPA, Bice/Dow12306, Exh. 16. As the III reported to the EPA in June 1992, that study indicated “that respiratory hypersensitivity in guinea pigs may result from dermal exposure to MDI.” *Id.*, Exh. 16. The minutes of the January 16, 1992 minutes indicate that the human cases that the members cited, in which “dermal conduct was the likely source of human

1 sensitisation to MDI,” “support[ed] the conclusion of the animal model.” January 16, 1992
 2 Minutes of EU-MTX Sub-Committee Meeting, Exh.15 at III(Bice)009472. Since the
 3 “conclusion of the animal model” was that dermal contact could cause respiratory
 4 hypersensitivity, the human sensitization which dermal contact had induced was necessarily
 5 *respiratory* sensitization.

6 483. The 1992 Human Cases SRI comprised multiple “cases,” plural, in which “dermal
 7 contact [with MDI] was the likely source” of human respiratory sensitization. Moreover, the
 8 minutes indicate that “Members,” plural, cited these multiple cases. That multiple members
 9 cited to multiple cases suggests that these various cases arose in multiple situations.

10 484. Importantly, the III members at the meeting expressed a high degree of
 11 confidence that MDI skin contact had caused the respiratory sensitization sustained by the
 12 multiple subjects: “dermal contact *was the likely source* of human sensitisation to MDI.” *Id.*,
 13 Exh. 15 at III(Bice)009472 (emphasis added). This confidence indicates that the III members
 14 had analyzed the underlying data concerning these cases, or had reviewed (and agreed with)
 15 analysis conducted by someone else. This underlying data involved both medical data (a
 16 determination of human MDI respiratory sensitization) and industrial hygiene data (information
 17 that the subjects were exposed by skin contact).

18 485. The minutes therefore establish that the 1992 Human Cases SRI comprised
 19 underlying medical and industrial hygiene data from which various III member companies had
 20 concluded a “likely” causal relationship between documented MDI skin contact and confirmed
 21 human cases of MDI respiratory sensitization.

22 486. TSCA defines substantial risk information as “information which reasonably
 23 supports the conclusion that such substance or mixture presents a substantial risk of injury to
 24 health or the environment.” 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that
 25 “‘reasonably supports the conclusion’ of substantial risk is not identical to a conclusive
 26 demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11110,
 27 Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a] person
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1 is not to delay reporting until he obtains conclusive information that a substantial risk exists, but
 2 is to immediately report any evidence which ‘reasonably supports’ that conclusion. Such
 3 evidence will generally not be conclusive as to the substantiality of the risk; it should, however,
 4 reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI.

5 487. In its June 1991 Reporting Guide, the EPA reaffirmed the 1978 policy, providing
 6 that “such information need not and most typically does not establish conclusively that a
 7 substantial risk exists.” 1991 Reporting Guide at 2. The 1991 Reporting Guide provides that the
 8 “decision-making process for Section 8(e)-reportability should focus primarily on whether the
 9 toxicity or exposure information offers reasonable support for a conclusion of substantial risk
 10 under the criteria described above, but should not focus at all on whether the information is
 11 conclusive regarding the risk.” 1991 Reporting Guide at 2. Further, the 1991 Reporting Guide
 12 directs that “[t]he evidence that offers reasonable support for a conclusion of substantial risk
 13 need not be complete or definitive but should provide a plausible link between 1) an observed
 14 serious effect and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific
 15 product/activity and a previously unrecognized exposure to a chemical that is known or
 16 reasonably anticipated to cause serious adverse health or environmental effects.” 1991
 17 Reporting Guide at 7.

18 488. As established above, the 1992 Human Cases SRI “reliably ascribe[d] the effect
 19 to the chemical,” and was therefore reportable substantial risk information. 1978 Policy
 20 Statement at 11112, Unit VI. The minutes establish that the 1992 Human Cases SRI comprised
 21 underlying medical and industrial hygiene data from which various III member companies had
 22 concluded a “likely” causal relationship between documented MDI skin contact and confirmed
 23 human cases of MDI respiratory sensitization.

24 489. The 1992 Human Cases SRI not only “reliably ascribe[d] the effect to the
 25 chemical [PMDI and MDI],” but it also characterized the effect in terms of MDI skin contact,
 26 which was not known by the EPA to cause respiratory sensitization in humans. Thus, the
 27 information “provide[d] a plausible link between . . . 2) a specific product/activity [here, MDI
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1 and/or MDI skin contact] and a previously *unrecognized exposure* to a chemical [here, human
2 skin contact] that is known or reasonably anticipated to cause serious adverse health or
3 environmental effects.” 1991 Reporting Guide at 7 (emphasis added). The 1992 Human Cases
4 SRI was therefore reportable substantial risk information under the 1991 Reporting Guide.

5 490. Indeed, each defendant expressly demonstrated its recognition that such
6 information constitutes reportable substantial risk information. As referenced briefly above, on
7 June 11, 1992, each defendant, through the III, reported to the EPA’s TSCA Section 8(e)
8 Coordinator the then-unpublished results of Dr. Ian Kimber’s study of the dermal induction of
9 respiratory hypersensitivity in guinea pigs. Exh. 16, Bice/Dow12306. According to the III’s
10 June 11, 1992 TSCA Section 8(e) submission, the animal data “indicate that respiratory
11 hypersensitivity in guinea pigs *may result* from dermal exposure to MDI.” *Id.* (emphasis added).
12 Yet during the six months prior to this submission, these defendants failed to report information
13 about *human* cases in which certain III member companies had determined that “dermal contact
14 *was the likely source* of human sensitisation to MDI.” January 16, 1992 EU-MTX meeting
15 minutes, Exh. 15 at III(Bice)009472 (emphasis added). Since the defendants correctly
16 recognized the reportability of information that they claimed indicated the *possible* dermal
17 induction of respiratory hypersensitivity in *animals*, they necessarily recognized the reportability
18 of information that indicated the “*likely*” dermal induction of respiratory sensitization in *humans*.

19 491. Further, the III member companies that had analyzed the 1992 Human Cases SRI
20 had concluded that it “support[ed] the conclusion of the animal model.” *Id.*, Exh. 15 at
21 III(Bice)009472. Remarkably, the defendants reported to the EPA “the conclusion of the animal
22 model,” but then failed (or rather refused) to report the more certain human data that certain III
23 member companies had determined “support[ed]” the very animal model they reported.

24 492. In other words, the defendants knowingly concealed the existence of the 1992
25 Human Cases SRI from the EPA.

26 493. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
27 determination: “the seriousness of the effect” and “the fact or probability of its occurrence.”
28

1 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
 2 factors are weighed differently for different effects. If the effects are among the human health
 3 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so
 4 serious that relatively little weight is given to exposure; the mere fact that the implicated
 5 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
 6 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
 7 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
 8 risk information.

9 494. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy
 10 include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
 11 inability to use a normal bodily function with a consequent relatively serious impairment of
 12 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
 13 43 Fed. Reg. at 11112, Unit V(a)(1). Respiratory sensitization, which can lead to occupational
 14 asthma and permanent lung damage, is such a “serious” human health effect.

15 495. Accordingly, information about “[a]ny instance” of respiratory sensitization
 16 “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few)
 17 chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1).
 18 Indeed, the EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an
 19 effect is reportable: “It is anticipated here that reportable effects will generally occur in a
 20 pattern, where a significant common feature is exposure to the chemical. However, a single
 21 instance of . . . serious incapacitation in a human would be reportable if one (or a few)
 22 chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
 23 VI(2).

24 496. The 1992 Human Cases SRI, which concerned the human health effect of
 25 respiratory sensitization caused by MDI skin contact was therefore reportable substantial risk
 26 information. The 1992 Human Cases SRI involved effects that “occur[ed] in a pattern, where a
 27 significant common feature [was] exposure to the chemical,” here, exposure through skin
 28

1 contact. And, as the III's European Med-Tox Sub-Committee viewed the 1992 Human Cases
 2 SRI data as conclusive that these humans had MDI respiratory sensitization—in other words,
 3 respiratory sensitization caused by MDI exposure, “one . . . chemical[] is strongly implicated.”
 4 The 1992 Human Cases SRI was reportable substantial risk information.

5 497. The EPA's 1978 Policy Statement provides that information that is reportable
 6 under Section 8(e) may be obtained from sources other than designed, controlled studies,
 7 although designed, controlled studies must be reported. 1978 Policy Statement, 43 Fed. Reg. at
 8 11112, Unit VI(1). Indeed, in its 1978 Policy Statement, the EPA identifies the sources of
 9 information that “will often ‘reasonably support’ a conclusion of substantial risk.” 1978 Policy
 10 Statement, 43 Fed. Reg. at 11112, Unit VI. These sources include “reports concerning and
 11 studies of undesigned, uncontrolled circumstances.” 1978 Policy Statement, 43 Fed. Reg. at
 12 11112, Unit VI(2). Examples of “[r]eports and studies of undesigned circumstances include: (i)
 13 medical and health surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of*
 14 *effects in consumers, workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at
 15 11112, Unit VI(2) (emphasis added).

16 498. The 1992 Human Cases SRI may constitute reports of designed, controlled
 17 studies. At a minimum, however, the defendants obtained the 1992 Human Cases SRI from
 18 “reports concerning. . . undesigned, uncontrolled circumstances,” including “reports concerning
 19 and evidence of effects in consumers, workers, or the environment.” The 1992 Human Cases
 20 SRI therefore comprises information that is reportable under TSCA Section 8(e).

21 **c. Each defendant separately obtained the 1992 Human Cases SRI.**

22 499. Under TSCA, a “business organization is considered to have obtained any
 23 information which any officer or employee capable of appreciating the significance of that
 24 information has obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II.

25 500. Although none of the defendants had representatives present at this January 16,
 26 1992 meeting of the III European Medical Toxicology Sub-Committee, the minutes indicate that
 27 the III distributed copies of the minutes to the “Scientific Committee,” the “AM-MTX Chairman
 28

1 [American Medical Toxicology Sub-Committee Chairman],” and through an “Alerting Note to
2 AM-MTX Sub-Committee.” Exh. 15, at III(Bice)009470.

3 501. As of January 2, 1992, defendant Huntsman’s predecessor-in-interest, ICI
4 Americas, chaired the III’s AM-MTX Sub-Committee through its employee, J.P. Lyon. January
5 2, 1992 III Organizational Chart, BASF-038606-038607, at 038606, Exh. 17. As of June 9,
6 1992, Mr. Lyon was still chairman of the sub-committee. June 9, 1992 III Organizational Chart,
7 BASF-038667-038668 at 038667, Exh. 18. Thus, on the date of the January 16, 1992 EU-MTX
8 sub-committee meeting, and in the nearly five-month period following the meeting, Huntsman’s
9 predecessor-in-interest ICI Americas chaired the AM-MTX sub-committee through its employee
10 J.P. Lyon, to whom the minutes of this meeting were distributed. By appointing Mr. Lyon as its
11 representative to chair the III’s AM-MTX Sub-Committee, Huntsman’s predecessor-in-interest
12 ICI Americas indicated its confidence in Mr. Lyon’s capability to appreciate the significance of
13 isocyanate safety information that he would obtain as chairman of that sub-committee. Through
14 Mr. Lyon, Huntsman obtained the 1992 Human Cases SRI when Mr. Niggel received a copy of
15 these minutes. Although the minutes do not indicate when they were distributed, a conservative
16 estimate of 60 days after the meeting would place Mr. Lyon as receiving the minutes as of March
17 16, 1992. Under TSCA, a “business organization is considered to have obtained any information
18 which any officer or employee capable of appreciating the significance of that information has
19 obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II. Thus, Huntsman obtained
20 1992 Human Cases SRI as of March 16, 1992.

21 502. The January 16, 1992 EU-MTX Sub-Committee meeting minutes also indicate
22 that the III distributed copies of the minutes through an “Alerting Note to AM-MTX Sub-
23 Committee.” Exh. 15, at III(Bice)009470.

24 503. As of January 2, 1992, the AM-MTX Sub-Committee, to which the minutes were
25 distributed, included representatives of BASF (W. Hartz and D.C. Steinmetz), Bayer’s
26 predecessor-in-interest Mobay (J.H. Chapman and G.K. Sangha), Dow (M.K. Lee and C.
27 Timchalk), and, as alleged above, Huntsman’s predecessor-in-interest, ICI Americas (Chairman
28

1 J.P. Lyon). January 2, 1992 III Organizational Chart, Exh. 17 at BASF-038606. As of June 9,
2 1992, the AM-MTX Sub-Committee still included representatives of all four defendants: BASF
3 (W. Hartz and D.C. Steinmetz), Bayer's predecessor-in-interest Miles (J.H. Chapman and G.K.
4 Sangha), Dow (M.K. Lee and C. Timchalk), and, as alleged above, Huntsman's predecessor-in-
5 interest, ICI Americas (Chairman J.P. Lyon). June 9, 1992 III Organizational Chart, Exh. 18 at
6 BASF-038667.

7 504. Thus, on the date of the January 16, 1992 EU-MTX sub-committee meeting, and
8 in the nearly five-month period following the meeting, each defendant had representatives on the
9 AM-MTX sub-committee to whom the minutes of this meeting were distributed. By appointing
10 these individuals as their representatives on the AM-MTX Sub-Committee each defendant
11 indicated its confidence in their respective employees' capability to appreciate the significance of
12 isocyanate safety information that they would obtain as members of the AM-MTX Sub-
13 Committee. Through these representatives, each defendant separately obtained the 1992 Human
14 Cases SRI when those representatives received copies of these minutes. Although the minutes
15 do not indicate when they were distributed, a conservative estimate of 60 days after the meeting
16 would place each defendant as obtaining the 1992 Human Cases SRI as of March 16, 1992.

17 505. The January 16, 1992 EU-MTX Sub-Committee meeting minutes also indicate
18 that the III distributed copies of the minutes to the "Scientific Committee." Exh. 15, at
19 III(Bice)009470.

20 506. As of January 2, 1992, the III Scientific Committee, to which the minutes were
21 distributed, included a representative of Dow (L.W. Rampy) and Huntsman's predecessor-in-
22 interest ICI Americas (R.F. Hoffman). January 2, 1992 III Organizational Chart, Exh. 17 at
23 BASF-038607. As of June 9, 1992, the III Scientific Committee still included a representative of
24 Dow (L.W. Rampy) and Huntsman's predecessor-in-interest ICI Americas (R.F. Hoffman). June
25 9, 1992 III Organizational Chart, Exh. 18 at BASF-038668.

26 507. Thus, on the date of the January 16, 1992 EU-MTX sub-committee meeting, and
27 in the nearly five-month period following the meeting, Dow and Huntsman each had
28

representatives on the III Scientific Committee to whom the minutes of this meeting were distributed. By appointing these individuals as their representatives on the Scientific Committee, Dow and Huntsman each indicated its confidence in their respective employees' capability to appreciate the significance of isocyanate safety information that they would obtain as members of the Scientific Committee. Through these representatives, Dow and Huntsman separately obtained the 1992 Human Cases SRI when those representatives received copies of these minutes. Although the minutes do not indicate when they were distributed, a conservative estimate of 60 days after the meeting would place Dow and Huntsman as obtaining the 1992 Human Cases SRI as of March 16, 1992.

d. **TSCA required that each defendant report the 1992 Human Cases SRI by April 6, 1992.**

508. The EPA's 1978 Policy Statement provides that "a person has 'immediately informed' the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit IV.

509. As alleged more thoroughly above, each defendant obtained the 1992 Human Cases SRI by March 16, 1992, and TSCA required that each defendant report the 1992 Human Cases SRI to the EPA by April 6, 1992, the fifteenth working day after the date that each defendant separately obtained the information.

e. **Each defendant was subject to TSCA's reporting requirement when it separately obtained the 1992 Human Cases SRI.**

510. At the time that it obtained the 1992 Human Cases SRI, Bayer was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

511. At the time that it obtained the 1992 Human Cases SRI, BASF was a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]"

MDI, PMDI, and TDI, and thus was obligated to “immediately inform the Administrator [of the EPA]” of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

512. At the time that it obtained the 1992 Human Cases SRI, Dow was a “person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]” MDI, PMDI, and TDI, and thus was obligated to “immediately inform the Administrator [of the EPA]” of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

513. At the time that it obtained the 1992 Human Cases SRI, Huntsman was a “person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or mixture[s]” MDI, PMDI, and TDI, and thus was obligated to “immediately inform the Administrator [of the EPA]” of the substantial risk information, which directly concerned MDI and PMDI, and which concerned TDI either directly or as a closely related chemical.

f. Each defendant failed to report the 1992 Human Cases SRI, even though TSCA did not exempt its reporting obligation.

514. BASF did not report the 1992 Human Cases SRI to the EPA “immediately” after obtaining it.

515. BASF has never reported the 1992 Human Cases SRI to the EPA.

516. BASF did not have knowledge as of April 6, 1992 that some entity other than BASF had submitted the 1992 Human Cases SRI to the EPA.

517. BASF has not acquired knowledge since April 6, 1992 that some entity other than BASF has submitted the 1992 Human Cases SRI to the EPA.

518. BASF did not have actual knowledge as of April 6, 1992 that the EPA was adequately informed of the 1992 Human Cases SRI.

519. BASF has not acquired actual knowledge since April 6, 1992 that the EPA has become adequately informed of the 1992 Human Cases SRI.

1 520. Therefore, TSCA did not exempt BASF from its obligation to report the 1992
2 Human Cases SRI.

3 521. Bayer did not report the 1992 Human Cases SRI to the EPA “immediately” after
4 obtaining it.

5 522. Bayer has never reported the 1992 Human Cases SRI to the EPA.

6 523. Bayer did not have knowledge as of April 6, 1992 that some entity other than
7 Bayer had submitted the 1992 Human Cases SRI to the EPA.

8 524. Bayer has not acquired knowledge since April 6, 1992 that some entity other than
9 Bayer has submitted the 1992 Human Cases SRI to the EPA.

10 525. Bayer did not have actual knowledge as of April 6, 1992 that the EPA was
11 adequately informed of the 1992 Human Cases SRI.

12 526. Bayer has not acquired actual knowledge since April 6, 1992 that the EPA has
13 become adequately informed of the 1992 Human Cases SRI.

14 527. Therefore, TSCA did not exempt Bayer from its obligation to report the 1992
15 Human Cases SRI.

16 528. Dow did not report the 1992 Human Cases SRI to the EPA “immediately” after
17 obtaining it.

18 529. Dow has never reported the 1992 Human Cases SRI to the EPA.

19 530. Dow did not have knowledge as of April 6, 1992 that some entity other than Dow
20 had submitted the 1992 Human Cases SRI to the EPA.

21 531. Dow has not acquired knowledge since April 6, 1992 that some entity other than
22 Dow has submitted the 1992 Human Cases SRI to the EPA.

23 532. Dow did not have actual knowledge as of April 6, 1992 that the EPA was
24 adequately informed of the 1992 Human Cases SRI.

25 533. Dow has not acquired actual knowledge since April 6, 1992 that the EPA has
26 become adequately informed of the 1992 Human Cases SRI.

1 534. Therefore, TSCA did not exempt Dow from its obligation to report the 1992
2 Human Cases SRI.

3 535. Huntsman did not report the 1992 Human Cases SRI to the EPA “immediately”
4 after obtaining it.

5 536. Huntsman has never reported the 1992 Human Cases SRI to the EPA.

6 537. Huntsman did not have knowledge as of April 6, 1992 that some entity other than
7 Huntsman had submitted the 1992 Human Cases SRI to the EPA.

8 538. Huntsman has not acquired knowledge since April 6, 1992 that some entity other
9 than Huntsman has submitted the 1992 Human Cases SRI to the EPA.

10 539. Huntsman did not have actual knowledge as of April 6, 1992 that the EPA was
11 adequately informed of the 1992 Human Cases SRI.

12 540. Huntsman has not acquired actual knowledge since April 6, 1992 that the EPA
13 has become adequately informed of the 1992 Human Cases SRI.

14 541. Therefore, TSCA did not exempt Huntsman from its obligation to report the 1992
15 Human Cases SRI.

16 g. **The EPA’s guidance documents did not exempt any defendant’s**
obligation to report the 1992 Human Cases SRI.

17
18 542. Although the EPA’s guidance documents could be read to broaden TSCA’s
19 limited exemption, the EPA’s guidance documents cannot alter the scope of the statutory
20 exemption, and each defendant’s separate reporting obligation is exempted only if it had “actual
21 knowledge that the Administrator [of the EPA] has been adequately informed of such
22 information.” 15 U.S.C. § 2607(e).

23 543. Regardless, however, the EPA’s guidance documents did not exempt BASF,
24 Bayer, Dow, or Huntsman from the obligation to report the 1992 Human Cases SRI.

25 544. The EPA’s 1978 Policy Statement provided that substantial risk information was
26 exempted from reporting if the information: “(a) Has been published by EPA in reports; (b) Has
27 been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or
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any other authority administered by EPA . . . ; (c) Has been published in the scientific literature and referenced [by one of several listed abstract services]; (d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced [by one of the abstract services listed in (c) above]; or (e) [Is contained in an environmental notification of spills].” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VII(a) through (e).

545. In its June 1991 Reporting Guide, EPA added two new exemptions, covering information that (1) is contained in a formal report, publication, or public statement of another Federal agency or (2) constitutes national security information based upon a determination by the President of the United States. 1991 Reporting Guide at 8.

546. As of April 6, 1992, the latest date by which TSCA required BASF, Bayer, Dow, and Huntsman to report the 1992 Human Cases SRI, the EPA’s 1991 Reporting Guide provided that substantial risk information was exempted from reporting if the information:

- (1) is contained in an EPA study or report.
 - (2) is published in the open scientific literature.
 - (3) has been submitted already to EPA under another mandatory reporting provision of 1) TSCA, or 2) some other authority that is administered by EPA.
 - (4) is contained in a formal publication/report or a formal statement made available to the general public by another Federal agency.
 - (5) is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a **well-established** adverse effect.
- It is important to note, however, that information that newly identifies a serious toxic effect **at a lower dose level for example, or confirms a serious effect that was previously only suspected,** is **not** considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.
- (6) [constitutes national security information based upon a determination of the President of the United States.]

1991 Reporting Guide at 8 (emphasis in original). The EPA noted in a separate section of the 1991 Reporting Guide that information obtained at public scientific conferences or meetings is exempt from reporting if there is a written record of the meeting that adequately describes the information and is released to the public in a reasonable time frame. The EPA indicated,

1 however, that information obtained at a private conference or meeting is not exempt and should
2 be considered for reporting. 1991 Reporting Guide at 7.

3 547. The EPA's 1991 Reporting Guide expanded the exemption for published
4 information to include "information that is obtained from major U.S. news publications (e.g.,
5 newspapers or news magazines with national circulation) or nationally broadcast U.S. radio
6 and/or television news reports." 1991 Reporting Guide at 9. The EPA clarified, however, that
7 the published-information exemption exempted the reporting requirement only if the regulated
8 company "obtained" the information from the published literature:

9 With regard to item (2) on the preceding page [that is, "published in the open
10 scientific literature"], EPA believes that for the purposes of Section 8(e)
11 reporting, a subject person need not report information that is *obtained from* well-
12 established/well-recognized scientific journals, such as those typically abstracted
13 in a) major computerized abstract data bases, or 2) [sic] publications such as
14 Current Contents, published by the Institute for Scientific Information (ISI), Inc.
15 (Philadelphia, Pennsylvania. Similarly, information that is *obtained from major*
16 U.S. news publications (e.g., newspapers or news magazines with national
17 circulation) or nationally broadcast U.S. radio and/or television news reports
18 typically need not be submitted to EPA under Section 8(e) of TSCA. However,
19 with regard to information *obtained from* lesser known scientific journals, or from
20 other magazines, newspapers, radio, or television reports, a subject person must
21 have actual knowledge that EPA has been adequately informed about such
22 information [to be exempt from the reporting obligation].

23 1991 Reporting Guide at 9 (italicized emphases added, other emphases in original).

24 548. The EPA's 1991 Reporting Guide did not exempt any defendant from its
25 obligation to report the 1992 Human Cases SRI.

26 549. As of April 6, 1992, the 1992 Human Cases SRI was not "contained in an EPA
27 study or report." 1991 Reporting Guide at 8, Item 1.

28 550. As of April 6, 1992, none of the defendants had "obtained" the 1992 Human
Cases SRI from "well-established/well-recognized scientific journals," or "major U.S. news
publications (e.g., newspapers or news magazines with national circulation) or nationally
broadcast U.S. radio and/or television news reports." 1991 Reporting Guide at 9, clarifying Item
2 on page 8.

1 551. As of April 6, 1992, the 1992 Human Cases SRI had not been “submitted already
2 to EPA under another mandatory reporting provision of 1) TSCA, or 2) some other authority that
3 is administered by EPA.” 1991 Reporting Guide at 8, Item 3.

4 552. As of April 6, 1992, the 1992 Human Cases SRI was not “contained in a formal
5 publication/report or a formal statement made available to the general public by another Federal
6 agency.” 1991 Reporting Guide at 8, Item 4.

7 553. As of April 6, 1992, the President of the United States had not determined that the
8 1992 Human Cases SRI was national security information. 1991 Reporting Guide at 8, Item 6.

9 554. As of April 6, 1992, the 1992 Human Cases SRI was not obtained from a *public*
10 scientific conference or meeting, and the 1992 Human Cases SRI was not “captured
11 accurately/adequately in a meeting transcript, abstract or other such written record or document
12 *that is to be formally released to the public within a reasonable time frame.*” 1991 Reporting
13 Guide at 7 (emphasis added).

14 555. The remaining exemption provided in the EPA’s 1991 Reporting Guide is for
15 information that “is corroborative (in terms of, for example, route of exposure, dose, species,
16 time to onset, severity, species, strain, etc.) of a well-established adverse effect.” 1991
17 Reporting Guide at 8, Item 5 (emphasis in original). The EPA explained: “It is important to
18 note, however, that information that newly identifies a serious toxic effect at a lower dose level
19 for example, or confirms a serious effect that was previously only suspected, is not considered by
20 EPA to be corroborative and should be reported under Section 8(e) of TSCA.” 1991 Reporting
21 Guide at 8.

22 556. Thus, consistent with the statutory requirement to report information reasonably
23 supporting a conclusion that the chemical presents a substantial *risk* of injury, the EPA defined
24 “adverse effect” in the context of “risk”—not only whether a chemical causes a particular
25 adverse effect, but how (route of exposure) or under what circumstances (dose levels or time to
26 onset). As one company commented in response to the EPA’s proposals that preceded its 1978
27 Policy Statement, “[a] determination that information ‘reasonably supports the conclusion’ of
28

1 substantial risk cannot be made independently of consideration of use, since the method and
 2 manner of using a chemical may influence the occurrence of an effect.” 1978 Policy Statement,
 3 43 Fed. Reg. at 11115, Comment 19. Although the company apparently offered the comment in
 4 the context of normal versus abnormal use (*id.*), the EPA agreed that “[t]he method and manner
 5 of using a chemical is one of several factors determining its exposure potential,” and further
 6 observed that “a definition of ‘normal’ use for a particular chemical will often depend upon a
 7 *knowledge of the risks* associated with the chemical.” *Id.* at 11115, Response to Comment 19.
 8 The EPA’s 1991 Reporting Guide confirmed that “the method and manner of use”—route of
 9 exposure and dose—was an integral part of the “adverse effect” being considered.

10 557. As of April 6, 1992, the 1992 Human Cases SRI was not corroborative (in terms
 11 of, for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a
 12 **well-established** adverse effect.” 1991 Reporting Guide at 8, Item 5. Indeed, a little more than
 13 two months after April 6, 1992, the latest date by which TSCA required BASF, Bayer, Dow, and
 14 Huntsman to report the 1992 Human Cases SRI, those defendants, through the III, reported
 15 animal data that they claimed indicated the possibility that MDI dermal exposure could cause
 16 respiratory hypersensitivity in guinea pigs. June 11, 1992 TSCA Section 8(e) Submission, Exh.
 17 16 at Bice/Dow12306. By reporting the supposedly uncertain animal data, the defendants
 18 indicated that the effect they were reporting was *not* “corroborative . . . of a well-established
 19 adverse effect.” None of the defendants can contend that the 1992 Human Cases SRI
 20 corroborated a well-established adverse effect as of April 6, 1992, because they conceded on
 21 June 11, 1992 that that same adverse effect was not well-established, even at the animal level.

22 558. Further, each defendant has since publicly contended that the scant publicly-
 23 available information that suggests that the possibility for isocyanate skin contact to cause
 24 respiratory sensitization is anecdotal, inconclusive, and unreliable. For example, in a May 2002
 25 III paper entitled “Respiratory sensitization: the role of dermal contact with MDI and TDI,”
 26 defendants and other III member companies discussed the animal and human data relevant to the
 27 potential link between skin contact with MDI and respiratory sensitization. Exh. 2, at CHARM
 28

1 012422–012446. Each defendant was a co-author of that 2002 III paper. *Id.* at CHARM 12425,
2 Exh. 2.

3 559. The defendants neither published nor otherwise discussed in that paper the 1992
4 Human Cases SRI, even though that substantial risk information is directly relevant to the link
5 between human isocyanate skin contact and respiratory sensitization. Moreover, the defendants
6 concluded their May 2002 paper by contending that the link between respiratory sensitization
7 and MDI skin contact was not well-established and that the “available” human data was
8 insufficient to establish the link: “The available data do not provide sufficient evidence for a
9 clear correlation between skin exposure and occupational asthma.” *Id.* at CHARM 12442, Exh.
10 2. That statement directly contradicts the 1992 Human Cases SRI, which defendants knowingly
11 failed to report to the EPA and are continuing to conceal.

12 560. Furthermore, through the Diisocyanates Panel of the ACC, the defendants have
13 recently disputed the potential for dermal induction of respiratory sensitization directly to the
14 EPA. In April 2011, the EPA expressed its heightened interest in MDI and related chemicals by
15 issuing an “MDI Action Plan.” *Methylene Diphenyl Diisocyanate (MDI) and Related*
16 *Compounds Action Plan [RIN 2070-ZA15]*, U.S. Environmental Protection Agency, April 2011
17 (“MDI Action Plan”). On February 26, 2013, defendants submitted comments to the EPA’s
18 proposed MDI Action Plan through the ACC. Feb. 26, 2013 ACC Comments to MDI Action
19 Plan, Exh. 3. Disputing the EPA’s statement in the MDI Action Plan that “[b]oth inhalation and
20 dermal exposures to diisocyanates are thought to contribute to the development of isocyanate
21 asthma” (*id.* at 9, Exh. 3), the defendants contended “the role that dermal contact with
22 diisocyanates plays in the development of occupational asthma remains unresolved for humans.”
23 *Id.* at 10, Exh. 3. That statement directly contradicts the 1992 Human Cases SRI, which
24 defendants knowingly failed to report to the EPA and are continuing to conceal.

25 561. None of the defendants can contend that the 1992 Human Cases SRI was
26 “corroborative . . . of well-established adverse effects,” because they have contended afterward,
27 and directly to the EPA, that the effect is not well-established.
28

9. **In or shortly after April 1992, each defendant obtained the “1992 Specific Scenario SRI,” substantial risk information about MDI skin contact and low-level inhalation.**

a. **Each defendant separately obtained the information in or shortly after April 1992.**

562. In or shortly after April 1992, BASF, Bayer, Dow, and Huntsman each obtained substantial risk information about respiratory sensitization in humans caused by skin contact with or low-level inhalation of MDI. In April 1992, the III’s Scientific Director, D.S. Gilbert, provided a report to the III’s Board of Directors. Report to Board, 1992, BASF-040033-040073 at 040034, Exh. 19. In Section 4.1 of his report, Dr. Gilbert addressed “Sensitisation” under the general heading “MEDTOX ISSUES.” *Id.*, Exh. 19 at BASF-040043-040045. Under the subheading “MDI,” Dr. Gilbert stated:

The importance of mode of exposure has been questioned in a specific scenario: workers using MDI appear to have been subject to respiratory sensitization when occupied with a process giving rise to extremely low exposures of airborne MDI. This has again raised the question of such responses arising from skin contact. In terms of local concentrations there is a much higher potential for exposure via the skin than via the lung.

Id., Exh. 19 at BASF-040044 (emphasis in original).

b. **The 1992 Specific Scenario SRI was “substantial risk information.”**

563. This information, the “1992 Specific Scenario SRI,” comprised information relating to multiple “workers,” plural, whose MDI respiratory sensitization arose in a “specific scenario”: their MDI exposure occurred in the context of “a process giving rise to extremely low exposures of airborne MDI.” The III suspected that skin contact may have caused the respiratory sensitization, since the “local concentrations” provided “a much higher potential for exposure via the skin than via the lung.” *Id.*, Exh. 19 at BASF-040044.

564. The III’s Scientific Director indicated to the III’s Board of Directors that these workers’ respiratory sensitization had apparently been caused either by MDI skin contact or by “extremely” low-level inhalation exposures. *Id.*, Exh. 19 at BASF-040044. The Scientific

1 Director's confidence in the diagnosis of MDI respiratory sensitization indicates the analysis of
2 underlying medical data.

3 565. Further, the Scientific Director indicated knowledge about "local concentrations"
4 in the work environment that provided "a much higher potential for exposure via the skin than
5 via the lung." *Id.*, Exh. 19 at BASF-040044. The knowledge of these "local concentrations,"
6 and the exposure conclusions that the Scientific Director reached as a result of that knowledge,
7 indicates the analysis of underlying industrial hygiene data. Indeed, the Scientific Director stated
8 that the knowledge of airborne concentrations ("extremely low exposures of airborne MDI") had
9 "raised the question of such responses [respiratory sensitization] arising from skin contact." *Id.*,
10 Exh. 19 at BASF-040044.

11 566. The Report to the Board therefore establishes that the 1992 Specific Scenario SRI
12 comprised underlying medical and industrial hygiene data reported to the III's Board of
13 Directors as indicating an apparent causal relationship between confirmed human cases of MDI
14 respiratory sensitization and either MDI skin contact or inhalation of "extremely low exposures
15 of airborne MDI." *Id.*, Exh. 19 at BASF-040044.

16 567. TSCA defines substantial risk information as "information which reasonably
17 supports the conclusion that such substance or mixture presents a substantial risk of injury to
18 health or the environment." 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that
19 "'reasonably supports the conclusion' of substantial risk is not identical to a conclusive
20 demonstration of substantial risk." 1978 Policy Statement, 43 Fed. Reg. at 11110,
21 Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that "[a] person
22 is not to delay reporting until he obtains conclusive information that a substantial risk exists, but
23 is to immediately report any evidence which 'reasonably supports' that conclusion. Such
24 evidence will generally not be conclusive as to the substantiality of the risk; it should, however,
25 reliably ascribe the effect to the chemical." 1978 Policy Statement at 11112, Unit VI.

26 568. In its June 1991 Reporting Guide, the EPA reaffirmed the 1978 policy, providing
27 that "such information need not and most typically does not establish conclusively that a
28

1 substantial risk exists.” 1991 Reporting Guide at 2. The 1991 Reporting Guide provides that the
2 “decision-making process for Section 8(e)-reportability should focus primarily on whether the
3 toxicity or exposure information offers reasonable support for a conclusion of substantial risk
4 under the criteria described above, but should not focus at all on whether the information is
5 conclusive regarding the risk.” 1991 Reporting Guide at 2. Further, the 1991 Reporting Guide
6 directs that “[t]he evidence that offers reasonable support for a conclusion of substantial risk
7 need not be complete or definitive but should provide a plausible link between 1) an observed
8 serious effect and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific
9 product/activity and a previously unrecognized exposure to a chemical that is known or
10 reasonably anticipated to cause serious adverse health or environmental effects.” 1991
11 Reporting Guide at 7.

12 569. As established above, the 1992 Specific Scenario SRI “reliably ascribe[d] the
13 effect to the chemical,” and was therefore reportable substantial risk information. 1978 Policy
14 Statement at 11112, Unit VI. The Report to the Board establishes that the 1992 Specific
15 Scenario SRI comprised underlying medical and industrial hygiene data reported to the III’s
16 Board of Directors as indicating an apparent causal relationship between confirmed human cases
17 of MDI respiratory sensitization and either MDI skin contact or inhalation of “extremely low
18 exposures of airborne MDI.” *Id.*, Exh. 19 at BASF-040044.

19 570. The 1992 Specific Scenario SRI not only “reliably ascribe[d] the effect to the
20 chemical [MDI],” but it also characterized the effect in terms of MDI skin contact or low –level
21 inhalation, neither of which was known by the EPA to cause respiratory sensitization in humans.
22 Thus, the information “provide[d] a plausible link between . . . 2) a specific product/activity
23 [here, MDI (product) and MDI skin contact or low-level inhalation (activity)] and a previously
24 *unrecognized exposure* to a chemical [here, human skin contact or low-level inhalation] that is
25 known or reasonably anticipated to cause serious adverse health or environmental effects.” 1991
26 Reporting Guide at 7 (emphasis added). The 1992 Specific Scenario SRI was therefore
27 reportable substantial risk information under the 1991 Reporting Guide.

1 571. Indeed, each defendant expressly demonstrated its recognition that such
 2 information constitutes reportable substantial risk information. As referenced briefly above, on
 3 June 11, 1992, each defendant, through the III, reported to the EPA's TSCA Section 8(e)
 4 Coordinator the then-unpublished results of Dr. Ian Kimber's study of the dermal induction of
 5 respiratory hypersensitivity in guinea pigs. Exh. 16, Bice/Dow12306. According to the III's
 6 June 11, 1992 TSCA Section 8(e) submission, the animal data "indicate that respiratory
 7 hypersensitivity in guinea pigs *may result* from dermal exposure to MDI." *Id.* (emphasis added).
 8 Yet these defendants failed to report concurrently-received reports that multiple humans
 9 appeared to have sustained MDI respiratory sensitization from skin contact. Since the
 10 defendants correctly recognized the reportability of information that they claimed indicated the
 11 *possible* dermal induction of respiratory hypersensitivity in *animals*, they necessarily recognized
 12 the reportability of information that indicated the apparent dermal induction of respiratory
 13 sensitization in *humans*.

14 572. In other words, the defendants knowingly concealed the existence of the 1992
 15 Specific Scenario SRI from the EPA.

16 573. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
 17 determination: "the seriousness of the effect" and "the fact or probability of its occurrence."
 18 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
 19 factors are weighed differently for different effects. If the effects are among the human health
 20 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as "so
 21 serious that relatively little weight is given to exposure; the mere fact that the implicated
 22 chemical is in commerce constitutes sufficient evidence of exposure." 1978 Policy Statement,
 23 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a "serious" health
 24 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
 25 risk information.

26 574. The "serious" human health effects identified in unit V(a)(1) of the 1978 Policy
 27 include "[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
 28

1 inability to use a normal bodily function with a consequent relatively serious impairment of
2 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
3 43 Fed. Reg. at 11112, Unit V(a)(1). Respiratory sensitization, which can lead to occupational
4 asthma and permanent lung damage, is such a “serious” human health effect.

5 575. Accordingly, information about “[a]ny instance” of respiratory sensitization
6 “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few)
7 chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1).
8 Indeed, the EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an
9 effect is reportable: “It is anticipated here that reportable effects will generally occur in a
10 pattern, where a significant common feature is exposure to the chemical. However, a single
11 instance of . . . serious incapacitation in a human would be reportable if one (or a few)
12 chemical(s) was strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
13 VI(2).

14 576. The 1992 Specific Scenario SRI, which concerned the human health effect of
15 respiratory sensitization caused by either by MDI skin contact or low-level inhalation, was
16 therefore reportable substantial risk information. The 1992 Specific Scenario SRI involved
17 effects that “occur[ed] in a pattern, where a significant common feature [was] exposure to the
18 chemical,” here, exposure through skin contact or low-level inhalation. Indeed, the report calls
19 the pattern the “specific scenario,” in which the common pattern is respiratory sensitization
20 arising in a work environment involving a “process that gives rise to extremely low exposures of
21 airborne MDI.” 1992 Report to III Board, Exh. 19 at BASF-040044. And, as the 1992 Specific
22 Scenario SRI indicated a high degree of confidence that these workers had MDI respiratory
23 sensitization—in other words, respiratory sensitization caused by MDI exposure, “one . . .
24 chemical[] is strongly implicated.” The 1992 Specific Scenario SRI was reportable substantial
25 risk information.

26 577. Moreover, the Report to the Board confirms that the 1992 Specific Scenario SRI
27 added to a larger set of similar data that the III member companies had previously developed or
28

1 obtained. The III's Scientific Director reported to the III's Board of Directors that the
2 information about the apparent induction of human respiratory sensitization in an environment of
3 "extremely low" airborne MDI concentrations "has *again* raised the question of such responses
4 arising from skin contact." *Id.*, Exh. 19 at BASF-040044 (italicized emphasis added, underlined
5 emphasis in original). The fact that such information had "again" suggested the dermal
6 induction route emphasized the need for the defendants to report the information, as "reportable
7 effects will generally occur in a pattern." 1978 Policy Statement, 43 Fed. Reg. at 11112, Unite
8 VI(2).

9 578. The fact that the 1992 Specific Scenario SRI was consistent with other
10 information that the III member companies had previously developed or obtained also establishes
11 that the 1992 Specific Scenario SRI comprised underlying data that is different from the data
12 comprising the earlier substantial risk information that the defendants had obtained or developed
13 (and failed to report). For example, the "workers" whose injuries the 1992 Specific Scenario
14 SRI concerned are different from the "human cases of MDI sensitization" in the 1989 Human
15 Cases SRI. The 1992 Report to the III Board confirms that the defendants obtained or developed
16 numerous discrete and separate items of substantial risk information.

17 579. The 1992 Report to the Board therefore establishes that the defendants
18 intentionally concealed those numerous discrete and separate items of substantial risk
19 information. By recalling earlier similar reports, the 1992 Specific Scenario SRI, expressly
20 reminded the defendants of the accumulating evidence that MDI skin contact and/or low level
21 inhalation had caused, or at least was closely associated with, human respiratory sensitization.
22 The defendants' continuing refusal to report this human information, even as they reported the
23 animal data, establishes their conscious decision, either individually or in conspiracy, to conceal
24 the human data.

25 580. The EPA's 1978 Policy Statement provides that information that is reportable
26 under Section 8(e) may be obtained from sources other than designed, controlled studies,
27 although designed, controlled studies must be reported. 1978 Policy Statement, 43 Fed. Reg. at
28

1 11112, Unit VI(1). Indeed, in its 1978 Policy Statement, the EPA identifies the sources of
 2 information that “will often ‘reasonably support’ a conclusion of substantial risk.” 1978 Policy
 3 Statement, 43 Fed. Reg. at 11112, Unit VI. These sources include “reports concerning and
 4 studies of undesigned, uncontrolled circumstances.” 1978 Policy Statement, 43 Fed. Reg. at
 5 11112, Unit VI(2). Examples of “[r]eports and studies of undesigned circumstances include: (i)
 6 medical and health surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of*
 7 *effects in consumers, workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at
 8 11112, Unit VI(2) (emphasis added).

9 581. The defendants obtained the 1992 Specific Scenario SRI from “reports
 10 concerning . . . undesigned, uncontrolled circumstances,” including “reports concerning and
 11 evidence of effects in consumers, workers, or the environment.” The 1992 Human Cases SRI
 12 therefore comprises information that is reportable under TSCA Section 8(e).

13 **c. Each defendant separately obtained the 1992 Specific Scenario SRI.**

14 582. Under TSCA, a “business organization is considered to have obtained any
 15 information which any officer or employee capable of appreciating the significance of that
 16 information has obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II.

17 583. The III’s Scientific Director sent his report to the III Board of Directors in April
 18 1992. 1992 Report to the III Board, Exh. 19 at BASF-0040034.

19 584. As of April 2, 1992, each of the four defendants had a representative on the III’s
 20 Board of Directors. April 2, 1992 III Organizational Chart, Exh. 20, BASF-038636-038637 at
 21 038637. As of October 9, 1992, each of the four defendants still had a representative on the III’s
 22 Board of Directors. October 9, 1992 III Organization Chart, Exh. 21, BASF-038701-038702 at
 23 038702.

24 585. Thus, during the month of April 1992, the month in which the Scientific Director
 25 provided his Report to the Board, and in the six-month period following the provision of the
 26 report, each defendant had a representative on the III’s Board of Directors, to whom this report
 27 was distributed. By appointing these individuals as their representatives on the III Board of
 28

1 Directors, each defendant indicated its confidence in their respective employees' capability to
 2 appreciate the significance of isocyanate safety information that they would obtain as Board
 3 members. Through these representatives, each defendant separately obtained the 1992 Specific
 4 Scenario SRI when those representatives received the report. Although the Report to the Board
 5 does not indicate the exact distribution date, it was distributed during April 1992. Assuming
 6 distribution on the last day of April (April 30, 1992), and conservatively allowing two weeks for
 7 mailing, each defendant obtained the 1992 Specific Scenario SRI as of May 14, 1992.

8 **d. TSCA required that each defendant report the 1992 Specific Scenario**
 9 **SRI by June 4, 1992.**

10 586. The EPA's 1978 Policy Statement provides that "a person has 'immediately
 11 informed' the Administrator if information is received by EPA not later than the 15th working
 12 day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at
 13 11111, Unit IV.

14 587. As alleged more thoroughly above, each defendant obtained the 1992 Specific
 15 Scenario SRI by May 14, 1992, and TSCA required that each defendant report the 1992 Specific
 16 Scenario SRI to the EPA by June 4, 1992, the fifteenth working day after the date that each
 17 defendant separately obtained the information.

18 **e. Each defendant was subject to TSCA's reporting requirement when it**
 19 **separately obtained the 1992 Specific Scenario SRI.**

20 588. At the time that it obtained the 1992 Specific Scenario SRI, Bayer was a "person
 21 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
 22 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
 23 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
 24 and PMDI, and which concerned TDI either directly or as a closely related chemical.

25 589. At the time that it obtained the 1992 Specific Scenario SRI, BASF was a "person
 26 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
 27 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
 28

1 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
2 and PMDI, and which concerned TDI either directly or as a closely related chemical.

3 590. At the time that it obtained the 1992 Specific Scenario SRI, Dow was a "person
4 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
5 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
6 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
7 and PMDI, and which concerned TDI either directly or as a closely related chemical.

8 591. At the time that it obtained the 1992 Specific Scenario SRI, Huntsman was a
9 "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
10 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
11 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
12 and PMDI, and which concerned TDI either directly or as a closely related chemical.

13 f. **Each defendant failed to report the 1992 Specific Scenario SRI, even**
14 **though TSCA did not exempt its reporting obligation.**

15 592. BASF did not report the 1992 Specific Scenario SRI to the EPA "immediately"
16 after obtaining it.

17 593. BASF has never reported the 1992 Specific Scenario SRI to the EPA.

18 594. BASF did not have knowledge as of June 4, 1992 that some entity other than
19 BASF had submitted the 1992 Specific Scenario SRI to the EPA.

20 595. BASF has not acquired knowledge since June 4, 1992 that some entity other than
21 BASF has submitted the 1992 Specific Scenario SRI to the EPA.

22 596. BASF did not have actual knowledge as of June 4, 1992 that the EPA was
23 adequately informed of the 1992 Specific Scenario SRI.

24 597. BASF has not acquired actual knowledge since June 4, 1992 that the EPA has
25 become adequately informed of the 1992 Specific Scenario SRI.

26 598. Therefore, TSCA did not exempt BASF from its obligation to report the 1992
27 Specific Scenario SRI.

1 599. Bayer did not report the 1992 Specific Scenario SRI to the EPA “immediately”
2 after obtaining it.

3 600. Bayer has never reported the 1992 Specific Scenario SRI to the EPA.

4 601. Bayer did not have knowledge as of June 4, 1992 that some entity other than
5 Bayer had submitted the 1992 Specific Scenario SRI to the EPA.

6 602. Bayer has not acquired knowledge since June 4, 1992 that some entity other than
7 Bayer has submitted the 1992 Specific Scenario SRI to the EPA.

8 603. Bayer did not have actual knowledge as of June 4, 1992 that the EPA was
9 adequately informed of the 1992 Specific Scenario SRI.

10 604. Bayer has not acquired actual knowledge since June 4, 1992 that the EPA has
11 become adequately informed of the 1992 Specific Scenario SRI.

12 605. Therefore, TSCA did not exempt Bayer from its obligation to report the 1992
13 Specific Scenario SRI.

14 606. Dow did not report the 1992 Specific Scenario SRI to the EPA “immediately”
15 after obtaining it.

16 607. Dow has never reported the 1992 Specific Scenario SRI to the EPA.

17 608. Dow did not have knowledge as of June 4, 1992 that some entity other than Dow
18 had submitted the 1992 Specific Scenario SRI to the EPA.

19 609. Dow has not acquired knowledge since June 4, 1992 that some entity other than
20 Dow has submitted the 1992 Specific Scenario SRI to the EPA.

21 610. Dow did not have actual knowledge as of June 4, 1992 that the EPA was
22 adequately informed of the 1992 Specific Scenario SRI.

23 611. Dow has not acquired actual knowledge since June 4, 1992 that the EPA has
24 become adequately informed of the 1992 Specific Scenario SRI.

25 612. Therefore, TSCA did not exempt Dow from its obligation to report the 1992
26 Specific Scenario SRI.

1 613. Huntsman did not report the 1992 Specific Scenario SRI to the EPA
2 “immediately” after obtaining it.

3 614. Huntsman has never reported the 1992 Specific Scenario SRI to the EPA.

4 615. Huntsman did not have knowledge as of June 4, 1992 that some entity other than
5 Huntsman had submitted the 1992 Specific Scenario SRI to the EPA.

6 616. Huntsman has not acquired knowledge since June 4, 1992 that some entity other
7 than Huntsman has submitted the 1992 Specific Scenario SRI to the EPA.

8 617. Huntsman did not have actual knowledge as of June 4, 1992 that the EPA was
9 adequately informed of the 1992 Specific Scenario SRI.

10 618. Huntsman has not acquired actual knowledge since June 4, 1992 that the EPA has
11 become adequately informed of the 1992 Specific Scenario SRI.

12 619. Therefore, TSCA did not exempt Huntsman from its obligation to report the 1992
13 Specific Scenario SRI.

14 g. **The EPA’s guidance documents did not exempt any defendant’s**
15 **obligation to report the 1992 Specific Scenario SRI.**

16 620. Although the EPA’s guidance documents could be read to broaden TSCA’s
17 limited exemption, the EPA’s guidance documents cannot alter the scope of the statutory
18 exemption, and each defendant’s separate reporting obligation is exempted only if it had “actual
19 knowledge that the Administrator [of the EPA] has been adequately informed of such
20 information.” 15 U.S.C. § 2607(e).

21 621. Regardless, however, the EPA’s guidance documents did not exempt BASF,
22 Bayer, Dow, or Huntsman from the obligation to report the 1992 Specific Scenario SRI.

23 622. The EPA’s 1978 Policy Statement provided that substantial risk information was
24 exempted from reporting if the information: “(a) Has been published by EPA in reports; (b) Has
25 been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or
26 any other authority administered by EPA . . . ; (c) Has been published in the scientific literature
27 and referenced [by one of several listed abstract services]; (d) Is corroborative of well-

1 established adverse effects already documented in the scientific literature and referenced [by one
2 of the abstract services listed in (c) above]; or (e) [Is contained in an environmental notification
3 of spills].” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VII(a) through (e).

4 623. In its June 1991 Reporting Guide, EPA added two new exemptions, covering
5 information that (1) is contained in a formal report, publication, or public statement of another
6 Federal agency or (2) constitutes national security information based upon a determination by the
7 President of the United States. 1991 Reporting Guide at 8.

8 624. As of June 4, 1992, the latest date by which TSCA required BASF, Bayer, Dow,
9 and Huntsman to report the 1992 Specific Scenario SRI, the EPA’s 1991 Reporting Guide
10 provided that substantial risk information was exempted from reporting if the information:

- 11 (1) is contained in an EPA study or report.
- 12 (2) is published in the open scientific literature.
- 13 (3) has been submitted already to EPA under another mandatory
14 reporting provision of 1) TSCA, or 2) some other authority that is
15 administered by EPA.
- 16 (4) is contained in a formal publication/report or a formal statement
17 made available to the general public by another Federal agency.
- 18 (5) is corroborative (in terms of, for example, route of exposure, dose,
19 species, time to onset, severity, species, strain, etc.) of a well-
20 established adverse effect.
It is important to note, however, that information that newly
identifies a serious toxic effect **at a lower dose level** for example,
or **confirms a serious effect that was previously only suspected**,
is not considered by EPA to be corroborative and should be
reported under Section 8(e) of TSCA.
- 21 (6) [constitutes national security information based upon a
22 determination of the President of the United States.]

23 1991 Reporting Guide at 8 (emphasis in original). The EPA noted in a separate section of the
24 1991 Reporting Guide that information obtained at public scientific conferences or meetings is
25 exempt from reporting if there is a written record of the meeting that adequately describes the
26 information and is released to the public in a reasonable time frame. The EPA indicated,
27 however, that information obtained at a private conference or meeting is not exempt and should
28 be considered for reporting. 1991 Reporting Guide at 7.

625. The EPA's 1991 Reporting Guide expanded the exemption for published information to include "information that is obtained from major U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports." 1991 Reporting Guide at 9. The EPA clarified, however, that the published-information exemption exempted the reporting requirement only if the regulated company "obtained" the information from the published literature:

With regard to item (2) on the preceding page [that is, "published in the open scientific literature"], EPA believes that for the purposes of Section 8(e) reporting, a subject person need not report information that is *obtained from* well-established/well-recognized scientific journals, such as those typically abstracted in a) major computerized abstract data bases, or 2) [sic] publications such as Current Contents, published by the Institute for Scientific Information (ISI), Inc. (Philadelphia, Pennsylvania. Similarly, information that is *obtained from major* U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports typically need not be submitted to EPA under Section 8(e) of TSCA. However, with regard to information *obtained from* lesser known scientific journals, or from other magazines, newspapers, radio, or television reports, a subject person must have actual knowledge that EPA has been adequately informed about such information [to be exempt from the reporting obligation].

1991 Reporting Guide at 9 (italicized emphases added, other emphases in original).

626. The EPA's 1991 Reporting Guide did not exempt any defendant from its obligation to report the 1992 Specific Scenario SRI.

627. As of June 4, 1992, the 1992 Specific Scenario SRI was not "contained in an EPA study or report." 1991 Reporting Guide at 8, Item 1.

628. As of June 4, 1992, none of the defendants had "obtained" the 1992 Specific Scenario SRI from "well-established/well-recognized scientific journals," or "major U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports." 1991 Reporting Guide at 9, clarifying Item 2 on page 8.

629. As of June 4, 1992, the 1992 Specific Scenario SRI had not been “submitted already to EPA under another mandatory reporting provision of 1) TSCA, or 2) some other authority that is administered by EPA.” 1991 Reporting Guide at 8, Item 3.

630. As of June 4, 1992, the 1992 Specific Scenario SRI was not “contained in a formal publication/report or a formal statement made available to the general public by another Federal agency.” 1991 Reporting Guide at 8, Item 4.

631. As of June 4, 1992, the President of the United States had not determined that the 1992 Specific Scenario SRI was national security information. 1991 Reporting Guide at 8, Item 6.

632. As of June 4, 1992, the 1992 Specific Scenario SRI was not obtained from a *public* scientific conference or meeting, and the 1992 Specific Scenario SRI was not “captured accurately/adequately in a meeting transcript, abstract or other such written record or document *that is to be formally released to the public within a reasonable time frame.*” 1991 Reporting Guide at 7 (emphasis added).

633. The remaining exemption provided in the EPA’s 1991 Reporting Guide is for information that “is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a well-established adverse effect.” 1991 Reporting Guide at 8, Item 5 (emphasis in original). The EPA explained: “It is important to note, however, that information that newly identifies a serious toxic effect at a lower dose level for example, or confirms a serious effect that was previously only suspected, is not considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.” 1991 Reporting Guide at 8.

634. Thus, consistent with the statutory requirement to report information reasonably supporting a conclusion that the chemical presents a substantial *risk* of injury, the EPA defined “adverse effect” in the context of “risk”—not only whether a chemical causes a particular adverse effect, but how (route of exposure) or under what circumstances (dose levels or time to onset). As one company commented in response to the EPA’s proposals that preceded its 1978

1 Policy Statement, “[a] determination that information ‘reasonably supports the conclusion’ of
 2 substantial risk cannot be made independently of consideration of use, since the method and
 3 manner of using a chemical may influence the occurrence of an effect.” 1978 Policy Statement,
 4 43 Fed. Reg. at 11115, Comment 19. Although the company apparently offered the comment in
 5 the context of normal versus abnormal use (*id.*), the EPA agreed that “[t]he method and manner
 6 of using a chemical is one of several factors determining its exposure potential,” and further
 7 observed that “a definition of ‘normal’ use for a particular chemical will often depend upon a
 8 *knowledge of the risks* associated with the chemical.” *Id.* at 11115, Response to Comment 19.
 9 The EPA’s 1991 Reporting Guide confirmed that “the method and manner of use”—route of
 10 exposure and dose—was an integral part of the “adverse effect” being considered.

11 635. As of June 4, 1992, the 1992 Specific Scenario SRI was not corroborative (in
 12 terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain,
 13 etc.) of a well-established adverse effect.” 1991 Reporting Guide at 8, Item 5. Indeed, one
 14 week after June 4, 1992, the latest date by which TSCA required BASF, Bayer, Dow, and
 15 Huntsman to report the 1992 Specific Scenario SRI, those defendants, through the III, reported
 16 animal data that they claimed indicated the possibility that MDI dermal exposure could cause
 17 respiratory hypersensitivity in guinea pigs. June 11, 1992 TSCA Section 8(e) Submission, Exh.
 18 16 at Bice/Dow12306. By reporting the supposedly uncertain animal data, the defendants
 19 indicated that the effect they were reporting was *not* “corroborative . . . of a well-established
 20 adverse effect.” None of the defendants can contend that the 1992 Specific Scenario SRI
 21 corroborated a well-established adverse effect as of June 4, 1992, because they conceded one
 22 week later, on June 11, 1992 that that same adverse effect was not well-established, even at the
 23 animal level.

24 636. Further, each defendant has since publicly contended that the scant publicly-
 25 available information that suggests that the possibility for isocyanate skin contact to cause
 26 respiratory sensitization is anecdotal, inconclusive, and unreliable. For example, in a May 2002
 27 III paper entitled “Respiratory sensitization: the role of dermal contact with MDI and TDI,”
 28

1 defendants and other III member companies discussed the animal and human data relevant to the
2 potential link between skin contact with MDI and respiratory sensitization. Exh. 2, at CHARM
3 012422–012446. Each defendant was a co-author of that 2002 III paper. *Id.* at CHARM 12425,
4 Exh. 2.

5 637. The defendants neither published nor otherwise discussed in that paper the 1992
6 Specific Scenario SRI, even though that substantial risk information is directly relevant to the
7 link between human isocyanate skin contact and respiratory sensitization. Moreover, the
8 defendants concluded their May 2002 paper by contending that the link between respiratory
9 sensitization and MDI skin contact was not well-established and that the “available” human data
10 was insufficient to establish the link: “The available data do not provide sufficient evidence for a
11 clear correlation between skin exposure and occupational asthma.” *Id.* at CHARM 12442, Exh.
12 2. That statement contradicts the 1992 Specific Scenario SRI, which defendants knowingly
13 failed to report to the EPA and are continuing to conceal.

14 638. Furthermore, through the Diisocyanates Panel of the ACC, the defendants have
15 recently disputed the potential for dermal induction of respiratory sensitization directly to the
16 EPA. In April 2011, the EPA expressed its heightened interest in MDI and related chemicals by
17 issuing an “MDI Action Plan.” *Methylene Diphenyl Diisocyanate (MDI) and Related*
18 *Compounds Action Plan [RIN 2070-ZA15]*, U.S. Environmental Protection Agency, April 2011
19 (“MDI Action Plan”). On February 26, 2013, defendants submitted comments to the EPA’s
20 proposed MDI Action Plan through the ACC. Feb. 26, 2013 ACC Comments to MDI Action
21 Plan, Exh. 3. Disputing the EPA’s statement in the MDI Action Plan that “[b]oth inhalation and
22 dermal exposures to diisocyanates are thought to contribute to the development of isocyanate
23 asthma” (*id.* at 9, Exh. 3), the defendants contended “the role that dermal contact with
24 diisocyanates plays in the development of occupational asthma remains unresolved for humans.”
25 *Id.* at 10, Exh. 3. That statement contradicts the 1992 Specific Scenario SRI, which defendants
26 knowingly failed to report to the EPA and are continuing to conceal.

639. None of the defendants can contend that the 1992 Specific Scenario SRI was “corroborative . . . of well-established adverse effects,” because they have contended afterward, and directly to the EPA, that the effect is not well-established.

10. **In or shortly after March 1993, each defendant obtained the “1993 Especial Work Situation SRI,” which is substantial risk information about MDI skin contact and low-level inhalation.**

a. **Each defendant separately obtained the information in or shortly after March 1993.**

640. In or shortly after March 1993, BASF, Bayer, Dow, and Huntsman each obtained substantial risk information about respiratory sensitization in humans caused by skin contact with or low-level inhalation of MDI. In April 1993, the III’s Scientific Director, D.S. Gilbert, provided a report to the III’s Board of Directors. Report to Board, 1993, BASF-040074-040132 at 040075, Exh. 22. In Section 4.1.1 of his report, Dr. Gilbert addressed “Sensitisation” under the general heading 4.1 “Medtox Studies.” *Id.*, Exh. 22 at BASF-040083-040085. Under the subheading “MDI,” Dr. Gilbert stated:

Several years ago medical information from an especial work situation indicated that some workers had possibly become sensitized as a result of skin contact, because vapour exposure appeared to have been extremely low. These observations led to an III animal study (Kimber). The draft report of this study indicates that respiratory sensitization may be provoked by skin or intradermal (into the skin) contact with MDI. There has been considerable debate on this subject, with significant contribution from Member Companies having research experience in this area.

Id., Exh. 22 at BASF-040084 (emphasis in original).

b. **The 1993 Especial Work Situation SRI was “substantial risk information.”**

641. This information, the “1993 Especial Work Situation SRI,” comprised “medical information” relating to multiple “workers,” plural, whose MDI respiratory sensitization arose in an “especial work situation” involving “extremely low” inhalation exposure, indicating that the sensitization “possibly” arose from skin contact. *Id.*, Exh. 22 at BASF-040084.

1 642. The III's Scientific Director expressly stated that the 1993 Especial Work
 2 Situation SRI contained "medical information." Moreover, he stated that this "medical
 3 information . . . indicated that some workers had possibly become sensitized as a result of skin
 4 contact, because vapour exposure appeared to have been extremely low." *Id.*, Exh. 22 at BASF-
 5 040084. The syntax indicates that the "medical information" confirmed the sensitization
 6 diagnosis, while industrial hygiene data (measurements or other information indicating that
 7 vapour exposures were "extremely low") suggested that the sensitization arose not from
 8 inhalation but rather from skin contact.

9 643. The express reference to "medical information" indicates a high degree of
 10 confidence in the sensitization diagnosis. The statement that the "medical information . . .
 11 *indicated* [the diagnosis]" reveals an underlying analysis of the medical data that the III's
 12 Scientific Director either performed or reviewed.

13 644. The context confirms that these workers' diagnosis was *respiratory* sensitization.
 14 The Scientific Director began his report with the observation that, "It is widely accepted that
 15 under certain circumstances respiratory sensitisation to MDI can arise from inhalation of MDI."
 16 *Id.*, Exh. 22 at BASF-040084. He then described the information that indicated "that some
 17 workers had possibly become sensitised," which led the III to undertake an animal study, which
 18 concluded that "respiratory sensitisation can be provoked by skin or intradermal (into the skin)
 19 contact with MDI." *Id.* Logic compels the conclusion that the animal study investigated the
 20 same typed of sensitization (respiratory) involved in the human cases that caused the III to
 21 undertake the study.

22 645. Further, the Scientific Director indicated knowledge about the "vapour exposure"
 23 levels in the "especial work situation." *Id.*, Exh. 22 at BASF-040044. The knowledge of these
 24 inhalation exposure levels and the exposure conclusions that the Scientific Director reached as a
 25 result of that knowledge, indicates the analysis of underlying industrial hygiene data. Indeed, the
 26 Scientific Director stated that the knowledge of airborne concentrations ("extremely low") had
 27 suggested the possibility that the sensitization had been cause by skin contact. *Id.*

1 646. The 1993 Report to the Board therefore establishes that the 1993 Especial Work
2 Situation SRI comprised underlying medical and industrial hygiene data reported to the III's
3 Board of Directors as indicating a causal relationship between confirmed human cases of MDI
4 respiratory sensitization and either MDI skin contact or inhalation of "extremely low" inhalation
5 exposures. *Id.*, Exh. 22 at BASF-040084. Moreover, the report establishes that the III, through
6 its member companies, found the information to be compelling enough to commence an animal
7 study to investigate it. *Id.*

8 647. TSCA defines substantial risk information as "information which reasonably
9 supports the conclusion that such substance or mixture presents a substantial risk of injury to
10 health or the environment." 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that
11 "reasonably supports the conclusion" of substantial risk is not identical to a conclusive
12 demonstration of substantial risk." 1978 Policy Statement, 43 Fed. Reg. at 11110,
13 Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that "[a] person
14 is not to delay reporting until he obtains conclusive information that a substantial risk exists, but
15 is to immediately report any evidence which 'reasonably supports' that conclusion. Such
16 evidence will generally not be conclusive as to the substantiality of the risk; it should, however,
17 reliably ascribe the effect to the chemical." 1978 Policy Statement at 11112, Unit VI.

18 648. In its June 1991 Reporting Guide, the EPA reaffirmed the 1978 policy, providing
19 that "such information need not and most typically does not establish conclusively that a
20 substantial risk exists." 1991 Reporting Guide at 2. The 1991 Reporting Guide provides that the
21 "decision-making process for Section 8(e)-reportability should focus primarily on whether the
22 toxicity or exposure information offers reasonable support for a conclusion of substantial risk
23 under the criteria described above, but should not focus at all on whether the information is
24 conclusive regarding the risk." 1991 Reporting Guide at 2. Further, the 1991 Reporting Guide
25 directs that "[t]he evidence that offers reasonable support for a conclusion of substantial risk
26 need not be complete or definitive but should provide a plausible link between 1) an observed
27 serious effect and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific
28

1 product/activity and a previously unrecognized exposure to a chemical that is known or
 2 reasonably anticipated to cause serious adverse health or environmental effects.” 1991
 3 Reporting Guide at 7.

4 649. As established above, the 1993 Especial Work Situation SRI “reliably ascribe[d]
 5 the effect to the chemical,” and was therefore reportable substantial risk information. 1978
 6 Policy Statement at 11112, Unit VI. The 1993 Report to the Board establishes that the 1993
 7 Especial Work Situation SRI comprised underlying medical and industrial hygiene data reported
 8 to the III’s Board of Directors as indicating a causal relationship between confirmed human cases
 9 of MDI respiratory sensitization and either MDI skin contact or inhalation of “extremely low”
 10 airborne levels of MDI. *Id.*, Exh. 22 at BASF-040084.

11 650. The 1993 Especial Work Situation SRI not only “reliably ascribe[d] the effect to
 12 the chemical [MDI],” but it also characterized the effect in terms of MDI skin contact or low –
 13 level inhalation, neither of which was known by the EPA to cause respiratory sensitization in
 14 humans. Thus, the information “provide[d] a plausible link between . . . 2) a specific
 15 product/activity [here, MDI (product) and MDI skin contact or low-level inhalation (activity)]
 16 and a previously *unrecognized exposure* to a chemical [here, human skin contact or low-level
 17 inhalation] that is known or reasonably anticipated to cause serious adverse health or
 18 environmental effects.” 1991 Reporting Guide at 7 (emphasis added). The 1993 Especial Work
 19 Situation SRI was therefore reportable substantial risk information under the 1991 Reporting
 20 Guide.

21 651. Indeed, each defendant had recently demonstrated its recognition that such
 22 information constitutes reportable substantial risk information. On June 11, 1992, each
 23 defendant, through the III, reported to the EPA’s TSCA Section 8(e) Coordinator the then-
 24 unpublished results of Dr. Ian Kimber’s study of the dermal induction of respiratory
 25 hypersensitivity in guinea pigs. Exh. 16, Bice/Dow12306. According to the III’s June 11, 1992
 26 TSCA Section 8(e) submission, the animal data “indicate that respiratory hypersensitivity in
 27 guinea pigs *may result* from dermal exposure to MDI.” *Id.* (emphasis added). Yet these
 28

1 defendants then failed to report the 1993 Especial Work Situation SRI, which comprised reports
2 that multiple humans appeared to have sustained MDI respiratory sensitization from skin contact.
3 Since the defendants correctly recognized the reportability of information that they claimed
4 indicated the *possible* dermal induction of respiratory hypersensitivity in *animals*, they
5 necessarily recognized the reportability of information that indicated the apparent dermal
6 induction of respiratory sensitization in *humans*.

7 652. In other words, the defendants knowingly concealed the existence of the 1993
8 Especial Work Situation SRI from the EPA.

9 653. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
10 determination: “the seriousness of the effect” and “the fact or probability of its occurrence.”
11 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
12 factors are weighed differently for different effects. If the effects are among the human health
13 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so
14 serious that relatively little weight is given to exposure; the mere fact that the implicated
15 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
16 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
17 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
18 risk information.

19 654. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy
20 include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
21 inability to use a normal bodily function with a consequent relatively serious impairment of
22 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
23 43 Fed. Reg. at 11112, Unit V(a)(1). Respiratory sensitization, which can lead to occupational
24 asthma and permanent lung damage, is such a “serious” human health effect.

25 655. Accordingly, information about “[a]ny instance” of respiratory sensitization
26 “must be reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few)
27 chemical(s) is strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1).
28

1 Indeed, the EPA's 1978 Policy Statement elsewhere reiterates that a single instance of such an
 2 effect is reportable: "It is anticipated here that reportable effects will generally occur in a
 3 pattern, where a significant common feature is exposure to the chemical. However, a single
 4 instance of . . . serious incapacitation in a human would be reportable if one (or a few)
 5 chemical(s) was strongly implicated." 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit
 6 VI(2).

7 656. The 1993 Especial Work Situation SRI, which concerned the human health effect
 8 of respiratory sensitization caused by either by MDI skin contact or low-level inhalation, was
 9 therefore reportable substantial risk information. The 1993 Especial Work Situation SRI
 10 involved effects that "occur[ed] in a pattern, where a significant common feature [was] exposure
 11 to the chemical," here, exposure through skin contact or low-level inhalation. Indeed, the report
 12 calls the pattern an "especial work situation," in which the common pattern is respiratory
 13 sensitization in a work environment where "vapour exposure appeared to have been extremely
 14 low." 1993 Report to III Board, Exh. 22 at BASF-040084. And, as the 1993 Especial Work
 15 Situation SRI indicated a high degree of confidence that these workers had MDI respiratory
 16 sensitization—in other words, respiratory sensitization caused by MDI exposure, "one . . .
 17 chemical[] is strongly implicated." The 1992 Specific Scenario SRI was reportable substantial
 18 risk information.

19 657. The EPA's 1978 Policy Statement provides that information that is reportable
 20 under Section 8(e) may be obtained from sources other than designed, controlled studies,
 21 although designed, controlled studies must be reported. 1978 Policy Statement, 43 Fed. Reg. at
 22 11112, Unit VI(1). Indeed, in its 1978 Policy Statement, the EPA identifies the sources of
 23 information that "will often 'reasonably support' a conclusion of substantial risk." 1978 Policy
 24 Statement, 43 Fed. Reg. at 11112, Unit VI. These sources include "reports concerning and
 25 studies of undesigned, uncontrolled circumstances." 1978 Policy Statement, 43 Fed. Reg. at
 26 11112, Unit VI(2). Examples of "[r]eports and studies of undesigned circumstances include: (i)
 27 medical and health surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of*
 28

1 *effects in consumers, workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at
2 11112, Unit VI(2) (emphasis added).

3 658. The defendants obtained the 1993 Especial Work Situation SRI from “reports
4 concerning. . . undesigned, uncontrolled circumstances,” including “reports concerning and
5 evidence of effects in consumers, workers, or the environment.” The 1993 Especial Work
6 Situation SRI therefore comprises information that is reportable under TSCA Section 8(e).

7 c. **Each defendant separately obtained the 1993 Especial Work Situation**
8 **SRI.**

9 659. Under TSCA, a “business organization is considered to have obtained any
10 information which any officer or employee capable of appreciating the significance of that
11 information has obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II.

12 660. The III’s Scientific Director sent his 1993 report to the III Board of Directors in
13 March 1993. 1993 Report to the III Board, Exh. 22 at BASF-0040075.

14 661. As of January 12, 1993, each of the four defendants had a representative on the
15 III’s Board of Directors. January 12, 1993 III Organization Chart, Exh. 23, BASF-038739-
16 038740 at 038740. As of July 1993, each of the four defendants still had a representative on the
17 III’s Board of Directors. July 1993 III Organization Chart, Exh. 24, BASF-038784-038785 at
18 038785.

19 662. Thus, during the month of March 1993, the month in which the Scientific Director
20 provided his Report to the Board, and in the four-month period following the provision of the
21 report, each defendant had a representative on the III’s Board of Directors, to whom this report
22 was distributed. By appointing these individuals as their representatives on the III Board of
23 Directors, each defendant indicated its confidence in its respective employees’ capability to
24 appreciate the significance of isocyanate safety information that they would obtain as Board
25 members. Through these representatives, each defendant separately obtained the 1993 Especial
26 Work Situation SRI when those representatives received the report. Although the Report to the
27 Board does not indicate the exact distribution date, it was distributed during March 1993.
28

1 Assuming distribution on the last day of March (March 31, 1993), and conservatively allowing
 2 two weeks for mailing, each defendant obtained the 1993 Especial Work Situation SRI as of
 3 April 14, 1993.

4 d. **TSCA required that each defendant report the 1993 Especial Work**
 5 **Situation SRI by May 5, 1993.**

6 663. The EPA's 1978 Policy Statement provides that "a person has 'immediately
 7 informed' the Administrator if information is received by EPA not later than the 15th working
 8 day after the date the person obtained such information." 1978 Policy Statement, 43 Fed. Reg. at
 9 11111, Unit IV.

10 664. As alleged more thoroughly above, each defendant obtained the 1993 Especial
 11 Work Situation SRI by April 14, 1993, and TSCA required that each defendant report the 1993
 12 Especial Work Situation SRI to the EPA by May 5, 1993, the fifteenth working day after the date
 13 that each defendant separately obtained the information.

14 e. **Each defendant was subject to TSCA's reporting requirement when it**
 15 **separately obtained the 1993 Especial Work Situation SRI.**

16 665. At the time that it obtained the 1993 Especial Work Situation SRI, Bayer was a
 17 "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
 18 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
 19 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
 20 and PMDI, and which concerned TDI either directly or as a closely related chemical.

21 666. At the time that it obtained the 1993 Especial Work Situation SRI, BASF was a
 22 "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
 23 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
 24 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
 25 and PMDI, and which concerned TDI either directly or as a closely related chemical.

26 667. At the time that it obtained the 1993 Especial Work Situation SRI, Dow was a
 27 "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
 28 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the

1 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
2 and PMDI, and which concerned TDI either directly or as a closely related chemical.

3 668. At the time that it obtained the 1993 Especial Work Situation SRI, Huntsman was
4 a "person who manufactures, processes, or distributes in commerce [the] chemical substance[s]
5 or mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
6 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
7 and PMDI, and which concerned TDI either directly or as a closely related chemical.

8 f. **Each defendant failed to report the 1993 Especial Work Situation SRI,**
9 **even though TSCA did not exempt its reporting obligation.**

10 669. BASF did not report the 1993 Especial Work Situation SRI to the EPA
11 "immediately" after obtaining it.

12 670. BASF has never reported the 1993 Especial Work Situation SRI to the EPA.

13 671. BASF did not have knowledge as of May 5, 1993 that some entity other than
14 BASF had submitted the 1993 Especial Work Situation SRI to the EPA.

15 672. BASF has not acquired knowledge since May 5, 1993 that some entity other than
16 BASF has submitted the 1993 Especial Work Situation SRI to the EPA.

17 673. BASF did not have actual knowledge as of May 5, 1993 that the EPA was
18 adequately informed of the 1993 Especial Work Situation SRI.

19 674. BASF has not acquired actual knowledge since May 5, 1993 that the EPA has
20 become adequately informed of the 1993 Especial Work Situation SRI.

21 675. Therefore, TSCA did not exempt BASF from its obligation to report the 1993
22 Especial Work Situation SRI.

23 676. Bayer did not report the 1993 Especial Work Situation SRI to the EPA
24 "immediately" after obtaining it.

25 677. Bayer has never reported the 1993 Especial Work Situation SRI to the EPA.

26 678. Bayer did not have knowledge as of May 5, 1993 that some entity other than
27 Bayer had submitted the 1993 Especial Work Situation SRI to the EPA.

1 679. Bayer has not acquired knowledge since May 5, 1993 that some entity other than
2 Bayer has submitted the 1993 Especial Work Situation SRI to the EPA.

3 680. Bayer did not have actual knowledge as of May 5, 1993 that the EPA was
4 adequately informed of the 1993 Especial Work Situation SRI.

5 681. Bayer has not acquired actual knowledge since May 5, 1993 that the EPA has
6 become adequately informed of the 1993 Especial Work Situation SRI.

7 682. Therefore, TSCA did not exempt Bayer from its obligation to report the 1993
8 Especial Work Situation SRI.

9 683. Dow did not report the 1993 Especial Work Situation SRI to the EPA
10 “immediately” after obtaining it.

11 684. Dow has never reported the 1993 Especial Work Situation SRI to the EPA.

12 685. Dow did not have knowledge as of May 5, 1993 that some entity other than Dow
13 had submitted the 1993 Especial Work Situation SRI to the EPA.

14 686. Dow has not acquired knowledge since May 5, 1993 that some entity other than
15 Dow has submitted the 1993 Especial Work Situation SRI to the EPA.

16 687. Dow did not have actual knowledge as of May 5, 1993 that the EPA was
17 adequately informed of the 1993 Especial Work Situation SRI.

18 688. Dow has not acquired actual knowledge since May 5, 1993 that the EPA has
19 become adequately informed of the 1993 Especial Work Situation SRI.

20 689. Therefore, TSCA did not exempt Dow from its obligation to report the 1993
21 Especial Work Situation SRI.

22 690. Huntsman did not report the 1993 Especial Work Situation SRI to the EPA
23 “immediately” after obtaining it.

24 691. Huntsman has never reported the 1993 Especial Work Situation SRI to the EPA.

25 692. Huntsman did not have knowledge as of May 5, 1993 that some entity other than
26 Huntsman had submitted the 1993 Especial Work Situation SRI to the EPA.

693. Huntsman has not acquired knowledge since May 5, 1993 that some entity other than Huntsman has submitted the 1993 Especial Work Situation SRI to the EPA.

694. Huntsman did not have actual knowledge as of May 5, 1993 that the EPA was adequately informed of the 1993 Especial Work Situation SRI.

695. Huntsman has not acquired actual knowledge since May 5, 1993 that the EPA has become adequately informed of the 1993 Especial Work Situation SRI.

696. Therefore, TSCA did not exempt Huntsman from its obligation to report the 1993 Especial Work Situation SRI.

g. The EPA's guidance documents did not exempt any defendant's obligation to report the 1993 Especial Work Situation SRI.

697. Although the EPA's guidance documents could be read to broaden TSCA's limited exemption, the EPA's guidance documents cannot alter the scope of the statutory exemption, and each defendant's separate reporting obligation is exempted only if it had "actual knowledge that the Administrator [of the EPA] has been adequately informed of such information." 15 U.S.C. § 2607(e).

698. Regardless, however, the EPA's guidance documents did not exempt BASF, Bayer, Dow, or Huntsman from the obligation to report the 1993 Especial Work Situation SRI.

699. The EPA's 1978 Policy Statement provided that substantial risk information was exempted from reporting if the information: "(a) Has been published by EPA in reports; (b) Has been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA . . . ; (c) Has been published in the scientific literature and referenced [by one of several listed abstract services]; (d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced [by one of the abstract services listed in (c) above]; or (e) [Is contained in an environmental notification of spills]." 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VII(a) through (e).

700. In its June 1991 Reporting Guide, EPA added two new exemptions, covering information that (1) is contained in a formal report, publication, or public statement of another

1 Federal agency or (2) constitutes national security information based upon a determination by the
 2 President of the United States. 1991 Reporting Guide at 8.

3 701. As of May 5, 1993, the latest date by which TSCA required BASF, Bayer, Dow,
 4 and Huntsman to report the 1993 Especial Work Situation SRI, the EPA's 1991 Reporting Guide
 5 provided that substantial risk information was exempted from reporting if the information:

- 6 (1) is contained in an EPA study or report.
- 7 (2) is published in the open scientific literature.
- 8 (3) has been submitted already to EPA under another mandatory
 reporting provision of 1) TSCA, or 2) some other authority that is
 administered by EPA.
- 9 (4) is contained in a formal publication/report or a formal statement
 made available to the general public by another Federal agency.
- 10 (5) is corroborative (in terms of, for example, route of exposure, dose,
 species, time to onset, severity, species, strain, etc.) of a well-
 11 established adverse effect.
 It is important to note, however, that information that newly
 identifies a serious toxic effect **at a lower dose level** for example,
 or **confirms a serious effect that was previously only suspected**,
 is not considered by EPA to be corroborative and should be
 reported under Section 8(e) of TSCA.
- 12 (6) [constitutes national security information based upon a
 determination of the President of the United States.]

13 1991 Reporting Guide at 8 (emphasis in original). The EPA noted in a separate section of the
 14 1991 Reporting Guide that information obtained at public scientific conferences or meetings is
 15 exempt from reporting if there is a written record of the meeting that adequately describes the
 16 information and is released to the public in a reasonable time frame. The EPA indicated,
 17 however, that information obtained at a private conference or meeting is not exempt and should
 18 be considered for reporting. 1991 Reporting Guide at 7.

19 702. The EPA's 1991 Reporting Guide expanded the exemption for published
 20 information to include "information that is obtained from major U.S. news publications (e.g.,
 21 newspapers or news magazines with national circulation) or nationally broadcast U.S. radio
 22 and/or television news reports." 1991 Reporting Guide at 9. The EPA clarified, however, that
 23 the published-information exemption exempted the reporting requirement only if the regulated
 24 company "obtained" the information from the published literature:
 25
 26
 27
 28

With regard to item (2) on the preceding page [that is, “published in the open scientific literature”], EPA believes that for the purposes of Section 8(e) reporting, a subject person need not report information that is *obtained from* well-established/well-recognized scientific journals, such as those typically abstracted in a) major computerized abstract data bases, or 2) [sic] publications such as Current Contents, published by the Institute for Scientific Information (ISI), Inc. (Philadelphia, Pennsylvania. Similarly, information that is *obtained from* major U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports typically need not be submitted to EPA under Section 8(e) of TSCA. However, with regard to information *obtained from* lesser known scientific journals, or from other magazines, newspapers, radio, or television reports, a subject person must have actual knowledge that EPA has been adequately informed about such information [to be exempt from the reporting obligation].

1991 Reporting Guide at 9 (italicized emphases added, other emphases in original).

703. The EPA’s 1991 Reporting Guide did not exempt any defendant from its obligation to report the 1993 Especial Work Situation SRI.

704. As of May 5, 1993, the 1993 Especial Work Situation SRI was not “contained in an EPA study or report.” 1991 Reporting Guide at 8, Item 1.

705. As of May 5, 1993, none of the defendants had “obtained” the 1993 Especial Work Situation SRI from “well-established/well-recognized scientific journals,” or “major U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports.” 1991 Reporting Guide at 9, clarifying Item 2 on page 8.

706. As of May 5, 1993, the 1993 Especial Work Situation SRI had not been “submitted already to EPA under another mandatory reporting provision of 1) TSCA, or 2) some other authority that is administered by EPA.” 1991 Reporting Guide at 8, Item 3.

707. As of May 5, 1993, the 1993 Especial Work Situation SRI was not “contained in a formal publication/report or a formal statement made available to the general public by another Federal agency.” 1991 Reporting Guide at 8, Item 4.

708. As of May 5, 1993, the President of the United States had not determined that the 1993 Especial Work Situation SRI was national security information. 1991 Reporting Guide at 8, Item 6.

709. As of May 5, 1993, the 1993 Especial Work Situation SRI was not obtained from a *public* scientific conference or meeting, and the 1993 Especial Work Situation SRI was not “captured accurately/adequately in a meeting transcript, abstract or other such written record or document *that is to be formally released to the public within a reasonable time frame.*” 1991 Reporting Guide at 7 (emphasis added).

710. The remaining exemption provided in the EPA’s 1991 Reporting Guide is for information that “is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a well-established adverse effect.” 1991 Reporting Guide at 8, Item 5 (emphasis in original). The EPA explained: “It is important to note, however, that information that newly identifies a serious toxic effect at a lower dose level for example, or confirms a serious effect that was previously only suspected, is not considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.” 1991 Reporting Guide at 8.

711. Thus, consistent with the statutory requirement to report information reasonably supporting a conclusion that the chemical presents a substantial *risk* of injury, the EPA defined “adverse effect” in the context of “risk”—not only whether a chemical causes a particular adverse effect, but how (route of exposure) or under what circumstances (dose levels or time to onset). As one company commented in response to the EPA’s proposals that preceded its 1978 Policy Statement, “[a] determination that information ‘reasonably supports the conclusion’ of substantial risk cannot be made independently of consideration of use, since the method and manner of using a chemical may influence the occurrence of an effect.” 1978 Policy Statement, 43 Fed. Reg. at 11115, Comment 19. Although the company apparently offered the comment in the context of normal versus abnormal use (*id.*), the EPA agreed that “[t]he method and manner of using a chemical is one of several factors determining its exposure potential,” and further

1 observed that “a definition of ‘normal’ use for a particular chemical will often depend upon a
2 *knowledge of the risks* associated with the chemical.” *Id.* at 11115, Response to Comment 19.
3 The EPA’s 1991 Reporting Guide confirmed that “the method and manner of use”—route of
4 exposure and dose—was an integral part of the “adverse effect” being considered.

5 712. As of May 5, 1993, the 1993 Especial Work Situation SRI was not corroborative
6 (in terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain,
7 etc.) of a well-established adverse effect.” 1991 Reporting Guide at 8, Item 5 (emphasis in
8 original). Indeed, eleven months prior to May 5, 1993, the latest date by which TSCA required
9 BASF, Bayer, Dow, and Huntsman to report the 1993 Especial Work Situation SRI, those
10 defendants, through the III, had reported animal data that they claimed indicated the possibility
11 that MDI dermal exposure could cause respiratory hypersensitivity in guinea pigs. June 11, 1992
12 TSCA Section 8(e) Submission, Exh. 16 at Bice/Dow12306. By reporting the supposedly
13 uncertain animal data, the defendants indicated that the effect they were reporting was *not*
14 “corroborative . . . of a well-established adverse effect.” None of the defendants can contend that
15 the 1993 Especial Work Situation SRI corroborated a well-established adverse effect as of May
16 5, 1993, because they conceded eleven months earlier, on June 11, 1992 that that same adverse
17 effect was not well-established, even at the animal level.

18 713. Further, each defendant has since publicly contended that the scant publicly-
19 available information that suggests that the possibility for isocyanate skin contact to cause
20 respiratory sensitization is anecdotal, inconclusive, and unreliable. For example, in a May 2002
21 III paper entitled “Respiratory sensitization: the role of dermal contact with MDI and TDI,”
22 defendants and other III member companies discussed the animal and human data relevant to the
23 potential link between skin contact with MDI and respiratory sensitization. Exh. 2, at CHARM
24 012422–012446. Each defendant was a co-author of that 2002 III paper. *Id.* at CHARM 12425,
25 Exh. 2.

26 714. The defendants neither published nor otherwise discussed in that paper the 1993
27 Especial Work Situation SRI, even though that substantial risk information is directly relevant to
28

1 the link between human isocyanate skin contact and respiratory sensitization. Moreover, the
 2 defendants concluded their May 2002 paper by contending that the link between respiratory
 3 sensitization and MDI skin contact was not well-established and that the “available” human data
 4 was insufficient to establish the link: “The available data do not provide sufficient evidence for a
 5 clear correlation between skin exposure and occupational asthma.” *Id.* at CHARM 12442, Exh.

6 2. That statement contradicts the 1993 Especial Work Situation SRI, which defendants
 7 knowingly failed to report to the EPA and are continuing to conceal.

8 715. Furthermore, through the Diisocyanates Panel of the ACC, the defendants have
 9 recently disputed the potential for dermal induction of respiratory sensitization directly to the
 10 EPA. In April 2011, the EPA expressed its heightened interest in MDI and related chemicals by
 11 issuing an “MDI Action Plan.” *Methylene Diphenyl Diisocyanate (MDI) and Related*
 12 *Compounds Action Plan [RIN 2070-ZA15]*, U.S. Environmental Protection Agency, April 2011
 13 (“MDI Action Plan”). On February 26, 2013, defendants submitted comments to the EPA’s
 14 proposed MDI Action Plan through the ACC. Feb. 26, 2013 ACC Comments to MDI Action
 15 Plan, Exh. 2. Disputing the EPA’s statement in the MDI Action Plan that “[b]oth inhalation and
 16 dermal exposures to diisocyanates are thought to contribute to the development of isocyanate
 17 asthma” (*id.* at 9, Exh. 3), the defendants contended “the role that dermal contact with
 18 diisocyanates plays in the development of occupational asthma remains unresolved for humans.”
 19 *Id.* at 10, Exh. 3. That statement contradicts the 1993 Especial Work Situation SRI, which
 20 defendants knowingly failed to report to the EPA and are continuing to conceal.

21 716. None of the defendants can contend that the 1993 Especial Work Situation SRI
 22 was “corroborative . . . of well-established adverse effects,” because they have contended
 23 afterward, and directly to the EPA, that the effect is not well-established.

11. **By January 29, 2003, each defendant separately obtained the “2003 Isocyanate Asthma SRI,” which comprised substantial risk information about MDI and/or TDI skin contact.**

a. **Each defendant separately obtained the information by January 29, 2003.**

717. By January 29, 2003, BASF, Bayer, Dow, and Huntsman each obtained substantial risk information about respiratory sensitization in humans caused by skin contact with MDI and/or TDI. The minutes of the January 28-29, 2003 meeting of the III’s Americas Analytical Sub-Committee establish that the attendees discussed cases of isocyanate asthma: We continue to see cases of isocyanate asthma when there is no evidence of airborne exposure. Latex glove usage is a concern. Some companies are recommending to their customers to not use latex gloves.

The size of these files are [sic] extensive and are available on the Intranet for reference.

Minutes of the January 28-29, 2003 Meeting of the III Americas Analytical Sub-Committee, Exh. 25, III(Bice)019837-019848 at 019839-019840.

b. **The 2003 Isocyanate Asthma SRI was “substantial risk information.”**

718. This information, the “2003 Isocyanate Asthma SRI,” comprised “extensive files” that concerned “cases of isocyanate asthma when there is no evidence of airborne exposure.” *Id.*, Exh. 25 at III(Bice)019839.

719. The minutes do not itemize the content of the “extensive” files, but the context indicates that the files contained both medical and industrial hygiene information.

720. The minutes reflect conclusive confidence in the diagnosis of “isocyanate asthma.” That confidence indicates that the “extensive” files included medical data that prompted the isocyanate asthma diagnosis.

721. Additionally, the minutes reflect conclusive confidence in the exposure scenario. The statement that these isocyanate asthma cases arose in situations where “there is *no evidence* of airborne exposure” indicates the existence of sophisticated industrial hygiene data that excluded inhalation as a possible exposure route.

1 722. The minutes also establish that the attendees suspected that skin contact had
2 caused the cases of isocyanate asthma. The minutes indicate that the discussion of these cases
3 occurred in the context of discussing the “Biomonitoring workshop-Dermal Exposure.” *Id.*, Exh.
4 25 at III(Bice)019839. And immediately after noting the continuing occurrence of isocyanate
5 asthma in environments with no evidence of airborne exposure, the attendees discussed the use
6 or non-use of latex gloves as protection. Logic indicates that the attendees suspected dermal
7 exposure, in the absence of appropriate protective clothing, as the causal exposure that produced
8 the isocyanate asthma cases they continued to see.

9 723. The continuing occurrence of these cases might also account for the “extensive”
10 size of the files. The attendees discussed that “[w]e *continue* to see cases of isocyanate asthma,”
11 indicating that the recent cases of dermally-induced isocyanate asthma were consistent with prior
12 such cases. *Id.*, Exh. 25 at III(Bice)019839 (emphasis added). Indeed, the minutes suggest that
13 the III had accumulated these “extensive” files over a period of time during which it “continue[d]
14 to see” these cases of dermally-induced isocyanate asthma. The “extensive” files may well have
15 comprised all or a significant part of the earlier-obtained substantial risk information, including
16 the 1982 Japanese Skin Contact SRI, the 1988 Mineworkers SRI, the 1989 Human Cases SRI,
17 the 1989 German Mine SRI, the 1989 Nakata Papers SRI, the 1992 Human Cases SRI, the 1992
18 Specific Scenario SRI, and the 1993 Especial Work Situation SRI.

19 724. The minutes do not specify the particular isocyanate or isocyanates to which the
20 isocyanate asthma sufferers’ had been exposed. However, the III is and has been an association
21 of MDI and/or TDI manufacturers, with a proclaimed mission to promote the safe handling of
22 MDI and TDI. See www.diisocyanates.org (last visited May 2, 2015). Logic indicates that the
23 isocyanate exposures about which the III compiled these extensive files were exposures to the
24 two isocyanates that were the subject of the III’s mission.

25 725. The meeting minutes therefore establish that the 2003 Isocyanate Asthma SRI
26 comprised underlying medical and industrial hygiene data, stored by the III and available to its
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1 member companies on its intranet, that excluded the inhalation exposure route as the cause of
2 confirmed cases of isocyanate asthma, and therefore implicated the dermal exposure route.

3 726. TSCA defines substantial risk information as “information which reasonably
4 supports the conclusion that such substance or mixture presents a substantial risk of injury to
5 health or the environment.” 15 U.S.C. § 2607(e). The 1978 Policy Statement provides that
6 “‘reasonably supports the conclusion’ of substantial risk is not identical to a conclusive
7 demonstration of substantial risk.” 1978 Policy Statement, 43 Fed. Reg. at 11110,
8 Supplementary Information, ¶ (3). The 1978 Policy Statement further provides that “[a] person
9 is not to delay reporting until he obtains conclusive information that a substantial risk exists, but
10 is to immediately report any evidence which ‘reasonably supports’ that conclusion. Such
11 evidence will generally not be conclusive as to the substantiality of the risk; it should, however,
12 reliably ascribe the effect to the chemical.” 1978 Policy Statement at 11112, Unit VI.

13 727. In its June 1991 Reporting Guide, the EPA reaffirmed the 1978 policy, providing
14 that “such information need not and most typically does not establish conclusively that a
15 substantial risk exists.” 1991 Reporting Guide at 2. The 1991 Reporting Guide provides that the
16 “decision-making process for Section 8(e)-reportability should focus primarily on whether the
17 toxicity or exposure information offers reasonable support for a conclusion of substantial risk
18 under the criteria described above, but should not focus at all on whether the information is
19 conclusive regarding the risk.” 1991 Reporting Guide at 2. Further, the 1991 Reporting Guide
20 directs that “[t]he evidence that offers reasonable support for a conclusion of substantial risk
21 need not be complete or definitive but should provide a plausible link between 1) an observed
22 serious effect and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific
23 product/activity and a previously unrecognized exposure to a chemical that is known or
24 reasonably anticipated to cause serious adverse health or environmental effects.” 1991
25 Reporting Guide at 7.

26 728. As established above, the 2003 Isocyanate Asthma SRI “reliably ascribe[d] the
27 effect to the chemical,” and was therefore reportable substantial risk information. 1978 Policy
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1 Statement at 11112, Unit VI. The meeting minutes establish that the 2003 Isocyanate Asthma
 2 SRI comprised underlying medical and industrial hygiene data, stored by the III and available to
 3 its member companies on its intranet, that excluded the inhalation exposure route as the cause of
 4 confirmed cases of isocyanate asthma, and therefore implicated the dermal exposure route.

5 729. The 2003 Isocyanate Asthma SRI not only “reliably ascribe[d] the effect to the
 6 chemical [MDI],” but it also characterized the effect in terms of MDI skin contact, which was
 7 not known by the EPA to cause respiratory sensitization in humans. Thus, the information
 8 “provide[d] a plausible link between . . . 2) a specific product/activity [here, MDI (product) and
 9 MDI skin contact (activity)] and a previously *unrecognized exposure* to a chemical [here, human
 10 skin contact] that is known or reasonably anticipated to cause serious adverse health or
 11 environmental effects.” 1991 Reporting Guide at 7 (emphasis added). The 2003 Isocyanate
 12 Asthma SRI was therefore reportable substantial risk information under the 1991 Reporting
 13 Guide.

14 730. The 1978 Policy Statement identifies two factors to weigh in the substantial risk
 15 determination: “the seriousness of the effect” and “the fact or probability of its occurrence.”
 16 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit V. The 1978 Policy provides that these
 17 factors are weighed differently for different effects. If the effects are among the human health
 18 effects identified in unit V(a) of the 1978 Policy Statement, the EPA views the effects as “so
 19 serious that relatively little weight is given to exposure; the mere fact that the implicated
 20 chemical is in commerce constitutes sufficient evidence of exposure.” 1978 Policy Statement,
 21 43 Fed. Reg. at 11111, Unit V. Accordingly, if the information concerns a “serious” health
 22 effect identified in unit V(a) of the 1978 Policy Statement, the information constitutes substantial
 23 risk information.

24 731. The “serious” human health effects identified in unit V(a)(1) of the 1978 Policy
 25 include “[a]ny instance of . . . serious or prolonged incapacitation, including the loss of or
 26 inability to use a normal bodily function with a consequent relatively serious impairment of
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1 normal activities, if one (or a few) chemical(s) is strongly implicated.” 1978 Policy Statement,
2 43 Fed. Reg. at 11112, Unit V(a)(1). Isocyanate asthma is such a “serious” human health effect.

3 732. Accordingly, information about “[a]ny instance” of isocyanate asthma “must be
4 reported” under TSCA Section 8(e) (unless otherwise exempted) “if one (or a few) chemical(s) is
5 strongly implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit V(a)(1). Indeed, the
6 EPA’s 1978 Policy Statement elsewhere reiterates that a single instance of such an effect is
7 reportable: “It is anticipated here that reportable effects will generally occur in a pattern, where
8 a significant common feature is exposure to the chemical. However, a single instance of . . .
9 serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly
10 implicated.” 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VI(2).

11 733. The 2003 Isocyanate Asthma SRI, which concerned the human health effect of
12 isocyanate asthma caused by MDI skin contact, was therefore reportable substantial risk
13 information. The 2003 Isocyanate Asthma SRI involved effects that “occur[ed] in a pattern,
14 where a significant common feature [was] exposure to the chemical,” here, exposure through
15 skin contact. Indeed, the report groups the cases according to the pattern, which is cases of
16 isocyanate asthma arising in a work environment where “there is no evidence of airborne
17 exposure.” Minutes of January 28-29, 2003 III Americas Analytical Sub-Committee Meeting,
18 Exh. 25 at III(Bice)019839. And, as the 2003 Isocyanate Asthma SRI indicated a high degree of
19 confidence that these workers had isocyanate asthma—in other words, asthma caused by
20 exposure to either MDI or TDI, “one . . . chemical[] is strongly implicated.” The 2003
21 Isocyanate Asthma SRI was reportable substantial risk information.

22 734. The EPA’s 1978 Policy Statement provides that information that is reportable
23 under Section 8(e) may be obtained from sources other than designed, controlled studies,
24 although designed, controlled studies must be reported. 1978 Policy Statement, 43 Fed. Reg. at
25 11112, Unit VI(1). Indeed, in its 1978 Policy Statement, the EPA identifies the sources of
26 information that “will often ‘reasonably support’ a conclusion of substantial risk.” 1978 Policy
27 Statement, 43 Fed. Reg. at 11112, Unit VI. These sources include “reports concerning and
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1 studies of undesigned, uncontrolled circumstances.” 1978 Policy Statement, 43 Fed. Reg. at
 2 11112, Unit VI(2). Examples of “[r]eports and studies of undesigned circumstances include: (i)
 3 medical and health surveys, (ii) clinical studies, and (iii) *reports concerning and evidence of*
 4 *effects in consumers, workers, or the environment.*” 1978 Policy Statement, 43 Fed. Reg. at
 5 11112, Unit VI(2) (emphasis added).

6 735. The defendants obtained the 2003 Isocyanate Asthma SRI from “reports
 7 concerning. . . undesigned, uncontrolled circumstances,” including “reports concerning and
 8 evidence of effects in consumers, workers, or the environment.” The 2003 Isocyanate Asthma
 9 SRI therefore comprises information that is reportable under TSCA Section 8(e).

10 c. **Each defendant separately obtained the 2003 Isocyanate Asthma SRI.**

11 736. Under TSCA, a “business organization is considered to have obtained any
 12 information which any officer or employee capable of appreciating the significance of that
 13 information has obtained.” 1978 Policy Statement, 43 Fed. Reg. at 11111, Unit II.

14 737. Each defendant had representatives present at this January 28-29, 2003 meeting of
 15 the III Americas Analytical Sub-Committee meeting. Exh. 25, at III(Bice)019837 (attendance
 16 list)..

17 738. By appointing these individuals as their representatives on the III Americas
 18 Analytical Sub-Committee, each defendant indicated its confidence in its respective employees’
 19 capability to appreciate the significance of isocyanate safety information that they would obtain
 20 as members of the sub-committee. Through these representatives, each defendant separately
 21 obtained the 2003 Isocyanate Asthma SRI when those representatives attended the meeting.
 22 Thus, each defendant obtained the 2003 Isocyanate Asthma SRI as of January 29, 2003, the last
 23 day of the meeting.

24 d. **TSCA required that each defendant report the 2003 Isocyanate**
 25 **Asthma SRI by February 28, 2003.**

26 739. The EPA’s 1978 Policy Statement provides that “a person has ‘immediately
 27 informed’ the Administrator if information is received by EPA not later than the 15th working
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1 day after the date the person obtained such information.” 1978 Policy Statement, 43 Fed. Reg. at
2 11111, Unit IV.

3 740. On July 13, 1993, the EPA announced its intention “to change the current 15-
4 working day reporting deadline for the submission of written reports containing substantial risk
5 information to 30 calendar days.” 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37736. In
6 its 2003 TSCA Guidance Revisions, the EPA formally revised the reporting period to “the 30th
7 calendar day after the date the subject person obtained such information.” 2003 TSCA Guidance
8 Revisions at 33138, Section VIII, Unit IV.

9 741. As alleged more thoroughly above, each defendant obtained the 2003 Isocyanate
10 Asthma SRI by January 29, 2003, and TSCA required that each defendant report the 2003
11 Isocyanate Asthma SRI to the EPA by February 28, 2003, the thirtieth calendar day after the date
12 that each defendant separately obtained the information.

13 e. **Each defendant was subject to TSCA’s reporting requirement when it**
14 **separately obtained the 2003 Isocyanate Asthma SRI.**

15 742. At the time that it obtained the 2003 Isocyanate Asthma SRI, Bayer was a “person
16 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
17 mixture[s]” MDI, PMDI, and TDI, and thus was obligated to “immediately inform the
18 Administrator [of the EPA]” of the substantial risk information, which directly concerned MDI
19 and PMDI, and which concerned TDI either directly or as a closely related chemical.

20 743. At the time that it obtained the 2003 Isocyanate Asthma SRI, BASF was a
21 “person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
22 mixture[s]” MDI, PMDI, and TDI, and thus was obligated to “immediately inform the
23 Administrator [of the EPA]” of the substantial risk information, which directly concerned MDI
24 and PMDI, and which concerned TDI either directly or as a closely related chemical.

25 744. At the time that it obtained the 2003 Isocyanate Asthma SRI, Dow was a “person
26 who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
27 mixture[s]” MDI, PMDI, and TDI, and thus was obligated to “immediately inform the
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1 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
2 and PMDI, and which concerned TDI either directly or as a closely related chemical.

3 745. At the time that it obtained the 2003 Isocyanate Asthma SRI, Huntsman was a
4 "person who manufactures, processes, or distributes in commerce [the] chemical substance[s] or
5 mixture[s]" MDI, PMDI, and TDI, and thus was obligated to "immediately inform the
6 Administrator [of the EPA]" of the substantial risk information, which directly concerned MDI
7 and PMDI, and which concerned TDI either directly or as a closely related chemical.

8 f. **Each defendant failed to report the 2003 Isocyanate Asthma SRI, even**
9 **though TSCA did not exempt its reporting obligation.**

10 746. BASF did not report the 2003 Isocyanate Asthma SRI to the EPA "immediately"
11 after obtaining it.

12 747. BASF has never reported the 2003 Isocyanate Asthma SRI to the EPA.

13 748. BASF did not have knowledge as of February 28, 2003 that some entity other
14 than BASF had submitted the 2003 Isocyanate Asthma SRI to the EPA.

15 749. BASF has not acquired knowledge since February 28, 2003 that some entity other
16 than BASF has submitted the 2003 Isocyanate Asthma SRI to the EPA.

17 750. BASF did not have actual knowledge as of February 28, 2003 that the EPA was
18 adequately informed of the 2003 Isocyanate Asthma SRI.

19 751. BASF has not acquired actual knowledge since February 28, 2003 that the EPA
20 has become adequately informed of the 2003 Isocyanate Asthma SRI.

21 752. Therefore, TSCA did not exempt BASF from its obligation to report the 2003
22 Isocyanate Asthma SRI.

23 753. Bayer did not report the 2003 Isocyanate Asthma SRI to the EPA "immediately"
24 after obtaining it.

25 754. Bayer has never reported the 2003 Isocyanate Asthma SRI to the EPA.

26 755. Bayer did not have knowledge as of February 28, 2003 that some entity other than
27 Bayer had submitted the 2003 Isocyanate Asthma SRI to the EPA.

1 756. Bayer has not acquired knowledge since February 28, 2003 that some entity other
2 than Bayer has submitted the 2003 Isocyanate Asthma SRI to the EPA.

3 757. Bayer did not have actual knowledge as of February 28, 2003 that the EPA was
4 adequately informed of the 2003 Isocyanate Asthma SRI.

5 758. Bayer has not acquired actual knowledge since February 28, 2003 that the EPA
6 has become adequately informed of the 2003 Isocyanate Asthma SRI.

7 759. Therefore, TSCA did not exempt Bayer from its obligation to report the 2003
8 Isocyanate Asthma SRI.

9 760. Dow did not report the 2003 Isocyanate Asthma SRI to the EPA “immediately”
10 after obtaining it.

11 761. Dow has never reported the 2003 Isocyanate Asthma SRI to the EPA.

12 762. Dow did not have knowledge as of February 28, 2003 that some entity other than
13 Dow had submitted the 2003 Isocyanate Asthma SRI to the EPA.

14 763. Dow has not acquired knowledge since February 28, 2003 that some entity other
15 than Dow has submitted the 2003 Isocyanate Asthma SRI to the EPA.

16 764. Dow did not have actual knowledge as of February 28, 2003 that the EPA was
17 adequately informed of the 2003 Isocyanate Asthma SRI.

18 765. Dow has not acquired actual knowledge since February 28, 2003 that the EPA has
19 become adequately informed of the 2003 Isocyanate Asthma SRI.

20 766. Therefore, TSCA did not exempt Dow from its obligation to report the 2003
21 Isocyanate Asthma SRI.

22 767. Huntsman did not report the 2003 Isocyanate Asthma SRI to the EPA
23 “immediately” after obtaining it.

24 768. Huntsman has never reported the 2003 Isocyanate Asthma SRI to the EPA.

25 769. Huntsman did not have knowledge as of February 28, 2003 that some entity other
26 than Huntsman had submitted the 2003 Isocyanate Asthma SRI to the EPA.

1 770. Huntsman has not acquired knowledge since February 28, 2003 that some entity
2 other than Huntsman has submitted the 2003 Isocyanate Asthma SRI to the EPA.

3 771. Huntsman did not have actual knowledge as of February 28, 2003 that the EPA
4 was adequately informed of the 2003 Isocyanate Asthma SRI.

5 772. Huntsman has not acquired actual knowledge since February 28, 2003 that the
6 EPA has become adequately informed of the 2003 Isocyanate Asthma SRI.

7 773. Therefore, TSCA did not exempt Huntsman from its obligation to report the 2003
8 Isocyanate Asthma SRI.

9 g. **The EPA's guidance documents did not exempt any defendant's**
10 **obligation to report the 2003 Isocyanate Asthma SRI.**

11 774. Although the EPA's guidance documents could be read to broaden TSCA's
12 limited exemption, the EPA's guidance documents cannot alter the scope of the statutory
13 exemption, and each defendant's separate reporting obligation is exempted only if it had "actual
14 knowledge that the Administrator [of the EPA] has been adequately informed of such
15 information." 15 U.S.C. § 2607(e).

16 775. Regardless, however, the EPA's guidance documents did not exempt BASF,
17 Bayer, Dow, or Huntsman from the obligation to report the 2003 Isocyanate Asthma SRI.

18 776. The EPA's 1978 Policy Statement provided that substantial risk information was
19 exempted from reporting if the information: "(a) Has been published by EPA in reports; (b) Has
20 been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or
21 any other authority administered by EPA . . . ; (c) Has been published in the scientific literature
22 and referenced [by one of several listed abstract services]; (d) Is corroborative of well-
23 established adverse effects already documented in the scientific literature and referenced [by one
24 of the abstract services listed in (c) above]; or (e) [Is contained in an environmental notification
25 of spills]." 1978 Policy Statement, 43 Fed. Reg. at 11112, Unit VII(a) through (e).

26 777. In its June 1991 Reporting Guide, EPA added two new exemptions, covering
27 information that (1) is contained in a formal report, publication, or public statement of another
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1 Federal agency or (2) constitutes national security information based upon a determination by the
2 President of the United States. 1991 Reporting Guide at 8.

3 778. The EPA's 1991 Reporting Guide provided that substantial risk information was
4 exempted from reporting if the information:

- 5 (1) is contained in an EPA study or report.
- 6 (2) is published in the open scientific literature.
- 7 (3) has been submitted already to EPA under another mandatory
8 reporting provision of 1) TSCA, or 2) some other authority that is
9 administered by EPA.
- 10 (4) is contained in a formal publication/report or a formal statement
11 made available to the general public by another Federal agency.
- 12 (5) is corroborative (in terms of, for example, route of exposure, dose,
13 species, time to onset, severity, species, strain, etc.) of a well-
14 established adverse effect.
15 It is important to note, however, that information that newly
16 identifies a serious toxic effect **at a lower dose level** for example,
17 **or confirms a serious effect that was previously only suspected,**
18 is not considered by EPA to be corroborative and should be
19 reported under Section 8(e) of TSCA.
- 20 (6) [constitutes national security information based upon a
21 determination of the President of the United States.]

22 1991 Reporting Guide at 8 (emphasis in original). The EPA noted in a separate section of the
23 1991 Reporting Guide that information obtained at public scientific conferences or meetings is
24 exempt from reporting if there is a written record of the meeting that adequately describes the
25 information and is released to the public in a reasonable time frame. The EPA indicated,
26 however, that information obtained at a private conference or meeting is not exempt and should
27 be considered for reporting. 1991 Reporting Guide at 7.

28 779. The EPA's 1991 Reporting Guide expanded the exemption for published
information to include "information that is obtained from major U.S. news publications (e.g.,
newspapers or news magazines with national circulation) or nationally broadcast U.S. radio
and/or television news reports." 1991 Reporting Guide at 9. The EPA clarified, however, that
the published-information exemption exempted the reporting requirement only if the regulated
company "obtained" the information from the published literature:

With regard to item (2) on the preceding page [that is, “published in the open scientific literature”], EPA believes that for the purposes of Section 8(e) reporting, a subject person need not report information that is *obtained from* well-established/well-recognized scientific journals, such as those typically abstracted in a) major computerized abstract data bases, or 2) [sic] publications such as Current Contents, published by the Institute for Scientific Information (ISI), Inc. (Philadelphia, Pennsylvania. Similarly, information that is *obtained from major* U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports typically need not be submitted to EPA under Section 8(e) of TSCA. However, with regard to information *obtained from* lesser known scientific journals, or from other magazines, newspapers, radio, or television reports, a subject person must have actual knowledge that EPA has been adequately informed about such information [to be exempt from the reporting obligation].

1991 Reporting Guide at 9 (italicized emphases added, other emphases in original).

780. In its 1993 Proposed Policy Clarification, the EPA confirmed that the prior-publication exemption applied to information that the regulated company “obtained solely from” one of several sources. 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37739. Those sources include official federal reports, certain scientific publications, certain databases to which EPA has access, major written news publications, nationally-broadcast radio and television reports, or certain national public scientific conferences. 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37739 and 37741, Unit VII(a)(1)-(6).

781. As of February 28, 1993, the last day by which TSCA required BASF, Bayer, Dow, and Huntsman to report the 2003 Isocyanate Asthma SRI, the EPA’s 1993 Proposed Policy Clarification provided the following reporting exemptions:

“Substantial risk” information need not be reported if it:

(a) Is obtained from one of the following sources:

1. An official publication or official report published or made available to the general public by EPA or another Federal agency.
2. A scientific publication to which an EPA Headquarters library subscribes or that is referenced in a data base, including one which is computerized, to which an EPA Headquarters library subscribes.
3. A data base, including one which is computerized, to which an EPA Headquarters library subscribes.

Note: Specifically regarding paragraphs (2) and (3) above, general information concerning the data bases and publications to which the EPA Headquarters libraries subscribe is available from the Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection

Agency, 401 M. St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

4. A major written news publication (i.e., newspaper, news magazine, trade press) with national circulation in the U.S.

5. A radio or television news report broadcast nationally in the U.S. Note: Specifically regarding paragraphs (4) and (5) above, EPA anticipates that information will be obtained from news publications with less than national circulation, or radio or television news reports broadcast only on a local, State, or regional level. In such cases, the information must be reported under section 8(e) of TSCA unless the subject person has actual knowledge that EPA has been adequately informed of such information through that or another source.

6. A national public scientific conference or meeting held within the U.S., provided that the information is captured accurately by way of a meeting transcript, abstract, or other such record, and has been cited in a bibliographic/abstract computerized data base, publication, or report of the type cited in paragraphs (1), (2), (3), (4), or (5) above within 30 days of obtaining such information.

(b) Corroborates (i.e., substantially duplicates or confirms) in terms of, for example, route of exposure, dose, species, strain, sex, time to onset, and severity, a well-recognized/well-established serious adverse effect for the subject chemical(s), unless such information concerns effects observed in association with emergency incidents of environmental contamination as described in Part V(c).

(c) Is information that is reported to EPA within 30 calendar days for non-emergency information, or immediately (i.e., as soon as the subject person has knowledge of the incident) for emergency information, pursuant to a mandatory reporting requirement of any statutory authority that is administered by EPA [listing examples],

(d) [certain information reported to a State], or

(e) [certain information reported to a State].

1993 Proposed Policy Clarification, 58 Fed. Reg. at 37741, Unit VII.

782. The EPA's 1991 Reporting Guide did not exempt any defendant from its obligation to report the 2003 Isocyanate Asthma SRI.

783. As of February 28, 2003, none of the defendants had "obtained" the 2003 Isocyanate Asthma SRI "from . . . [a]n official publication or official report published or made available to the general public by EPA or another Federal agency." 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37741, Unit VII(a)(1).

784. As of February 28, 2003, none of the defendants had "obtained" the 2003 Isocyanate Asthma SRI "from . . . [a] scientific publication to which an EPA Headquarters

1 library subscribes or that is referenced in a data base, including one which is computerized, to
 2 which an EPA Headquarters library subscribes.” 1993 Proposed Policy Clarification, 58 Fed.
 3 Reg. at 37741, Unit VII(a)(2).

4 785. As of February 28, 2003, none of the defendants had “obtained” the 2003
 5 Isocyanate Asthma SRI “from . . . [a] data base, including one which is computerized, to which
 6 an EPA Headquarters library subscribes.” 1993 Proposed Policy Clarification, 58 Fed. Reg. at
 7 37741, Unit VII(a)(3).

8 786. As of February 28, 2003, none of the defendants had “obtained” the 2003
 9 Isocyanate Asthma SRI “from . . . [a] major written news publication (i.e., newspaper, news
 10 magazine, trade press) with national circulation in the U.S.” 1993 Proposed Policy Clarification,
 11 58 Fed. Reg. at 37741, Unit VII(a)(4).

12 787. As of February 28, 2003, none of the defendants had “obtained” the 2003
 13 Isocyanate Asthma SRI “from . . . [a] radio or television news report broadcast nationally in the
 14 U.S.” 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37741, Unit VII(a)(5).

15 788. As of February 28, 2003, none of the defendants had “obtained” the 2003
 16 Isocyanate Asthma SRI “from . . . [a] national public scientific conference or meeting held
 17 within the U.S., provided that the information is captured accurately by way of a meeting
 18 transcript, abstract, or other such record, and has been cited in a bibliographic/abstract
 19 computerized data base, publication, or report of the type cited in paragraphs (1), (2), (3), (4), or
 20 (5) above within 30 days of obtaining such information.” 1993 Proposed Policy Clarification, 58
 21 Fed. Reg. at 37741, Unit VII(a)(6).

22 789. As of February 28, 2003, the 2003 Isocyanate Asthma SRI was not information
 23 that had been reported to the EPA within thirty calendar days under some other mandatory
 24 reporting requirement. 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37741, Unit VII(c).

25 790. As of February 28, 2003, the 2003 Isocyanate Asthma SRI was not information
 26 that had been reported to a State within 30 calendar days under the circumstances specified in
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1 exemptions VII(d) and (e). 1993 Proposed Policy Clarification, 58 Fed. Reg. at 37741, Unit
2 VII(d) and (e).

3 791. The remaining exemption provided in the EPA's 1993 Proposed Policy
4 Clarification is for information that "[c]orroborates (i.e., substantially duplicates or confirms) in
5 terms of, for example, route of exposure, dose, species, strain, sex, time to onset, and severity, a
6 well-recognized/well-established serious adverse effect for the subject chemical(s)," with
7 environmental contamination exceptions not relevant here. 1993 Proposed Policy Clarification,
8 58 Fed. Reg. at 37741, Unit VII(b).

9 792. In its 1991 Reporting Guide, the EPA had explained this exemption: "It is
10 important to note, however, that information that newly identifies a serious toxic effect at a lower
11 dose level for example, or confirms a serious effect that was previously only suspected, is not
12 considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA."
13 1991 Reporting Guide at 8 (emphasis in original).

14 793. Thus, consistent with the statutory requirement to report information reasonably
15 supporting a conclusion that the chemical presents a substantial *risk* of injury, the EPA had
16 defined "adverse effect" in the context of "risk"—not only whether a chemical causes a
17 particular adverse effect, but how (route of exposure) or under what circumstances (dose levels
18 or time to onset). As one company commented in response to the EPA's proposals that preceded
19 its 1978 Policy Statement, "[a] determination that information 'reasonably supports the
20 conclusion' of substantial risk cannot be made independently of consideration of use, since the
21 method and manner of using a chemical may influence the occurrence of an effect." 1978 Policy
22 Statement, 43 Fed. Reg. at 11115, Comment 19. Although the company apparently offered the
23 comment in the context of normal versus abnormal use (*id.*), the EPA agreed that "[t]he method
24 and manner of using a chemical is one of several factors determining its exposure potential," and
25 further observed that "a definition of 'normal' use for a particular chemical will often depend
26 upon a *knowledge of the risks* associated with the chemical." *Id.* at 11115, Response to
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1 Comment 19. The EPA's 1991 Reporting Guide confirmed that "the method and manner of
2 use"—route of exposure and dose—was an integral part of the "adverse effect" being considered.

3 794. EPA further confirmed this policy in its 1993 Proposed Policy Clarification:

4 EPA maintains its position under Part VII(c) of the 1978 Policy Statement that
5 information need not be reported under section 8(e) of TSCA if the information
6 corroborates well established, serious adverse effects that are already
7 documented. The term "corroborates," in the context of this particular reporting
8 exclusion, means that the information *essentially duplicates and/or confirms an*
9 *existing and well-documented understanding of a serious adverse effect* of a
10 particular chemical substance or mixture. EPA has correctly received, and expects
11 to continue to receive, substantial risk reports that show adverse effects of a more
12 serious degree or of a different kind than are already established. In other words,
13 the Agency expects subject persons to immediately consider reporting
14 information on serious toxic effects (including but not limited to cancer,
15 developmental, reproductive toxicity, or neurotoxicity) if, for example: such
16 effects are substantially more serious in terms of the severity of the effects or the
17 number of animals affected; occur within a significantly shorter time frame
18 following exposure; *occur via a different route of exposure; occur at a*
19 *significantly lower dose or concentration*; or occur in a different species, strain, or
20 sex.

1993 Proposed Policy Clarification, 58 Fed. Reg. at 37739 (emphasis added).

21 795. As of February 28, 2003, the 2003 Isocyanate Asthma SRI did not
22 "[c]orroborate[]" (i.e., substantially duplicate[] or confirm[]) in terms of, for example, route of
23 exposure, dose, species, strain, sex, time to onset, and severity, a well-recognized/well-
24 established serious adverse effect for the subject chemical(s)." 1993 Proposed Policy
25 Clarification, 58 Fed. Reg. at 37741, Unit VII(b).

26 796. Indeed, nine months prior to February 28, 2003, the latest date by which TSCA
27 required BASF, Bayer, Dow, and Huntsman to report the 2003 Isocyanate Asthma SRI, those
28 defendants, through the III, had publicly contended that the scant publicly-available information
that suggests that the possibility for isocyanate skin contact to cause respiratory sensitization is
anecdotal, inconclusive, and unreliable. In a May 2002 III paper entitled "Respiratory
sensitization: the role of dermal contact with MDI and TDI," defendants and other III member
companies discussed the animal and human data relevant to the potential link between skin

1 contact with MDI and respiratory sensitization. Exh. 2, at CHARM 012422–012446. Each
2 defendant was a co-author of that 2002 III paper. *Id.* at CHARM 12425, Exh. 2.

3 797. The defendants neither published nor otherwise discussed in that paper the 2003
4 Isocyanate Asthma SRI, even though that substantial risk information is directly relevant to the
5 link between human isocyanate skin contact and respiratory sensitization. Moreover, the
6 defendants concluded their May 2002 paper by contending that the link between respiratory
7 sensitization and MDI skin contact was not well-established and that the “available” human data
8 was insufficient to establish the link: “The available data do not provide sufficient evidence for a
9 clear correlation between skin exposure and occupational asthma.” *Id.* at CHARM 12442, Exh.

10 2. That statement directly contradicts the 2003 Isocyanate Asthma SRI, which defendants
11 knowingly failed to report to the EPA and are continuing to conceal.

12 798. Furthermore, through the Diisocyanates Panel of the ACC, the defendants have
13 recently disputed the potential for dermal induction of respiratory sensitization directly to the
14 EPA. In April 2011, the EPA expressed its heightened interest in MDI and related chemicals by
15 issuing an “MDI Action Plan.” *Methylene Diphenyl Diisocyanate (MDI) and Related*
16 *Compounds Action Plan [RIN 2070-ZA15]*, U.S. Environmental Protection Agency, April 2011
17 (“MDI Action Plan”). On February 26, 2013, defendants submitted comments to the EPA’s
18 proposed MDI Action Plan through the ACC. Feb. 26, 2013 ACC Comments to MDI Action
19 Plan, Exh. 3. Disputing the EPA’s statement in the MDI Action Plan that “[b]oth inhalation and
20 dermal exposures to diisocyanates are thought to contribute to the development of isocyanate
21 asthma” (*id.* at 9, Exh. 3), the defendants contended “the role that dermal contact with
22 diisocyanates plays in the development of occupational asthma remains unresolved for humans.”
23 *Id.* at 10, Exh. 3. That statement directly contradicts the 2003 Isocyanate Asthma SRI, which
24 defendants knowingly failed to report to the EPA and are continuing to conceal.

25 799. None of the defendants can contend that the 2003 Isocyanate Asthma SRI was
26 “corroborative . . . of well-established adverse effects,” because they contended
27 contemporaneously with their receipt of the substantial risk information that the effect was not
28

1 well-established. And they continue to make the same contention, as recently as February 2013
2 directly to the EPA.

3 **12. Summary of SRI Obtained or Developed by Defendants.**

4 800. The following chart identifies the SRI each defendant obtained, the date by which
5 the defendant obtained the SRI, and the date by which TSCA required the defendant to report the
6 SRI.

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SRI Obtained by Each Defendant				
SRI	Defendant	Date Obtained	Report Deadline	Information
Bayer's 1979 Skin Contact SRI	Bayer	12/31/79	1/22/80	Information that skin contact with MDI could cause respiratory sensitization and reduced lung function, communicated in internal training by Bayer's industrial hygienists. Exh. 6 -- April 21, 2005 Deposition of David Hussey at 56-62, 66.
1982 Japanese Skin Contact SRI	Bayer	4/20/82	5/11/82	Analysis relevant to whether TDI or MDI skin absorption can cause pulmonary sensitization. Exh. 7 -- Minutes of the meeting of the III Safety Committee, April 19-20, 1982, at III(Bice) 003127.
	Dow	4/20/82	5/11/82	
1988 Mineworkers SRI	BASF	11/7/88	11/30/88	Cases of human respiratory sensitization conclusively caused either by MDI skin contact or low-level inhalation. Exh. 8 -- Minutes of the September 6-8, 1988 meeting of the III Safety Committee, at III(Bice)007178, Item 10.6.
	Bayer	11/7/88	11/30/88	
	Dow	9/8/88	9/29/88	
	Huntsman	9/8/88	9/29/88	
1989 Human Cases SRI	BASF	3/9/89	3/30/89	"Evidence" relating to multiple "cases," plural, of MDI respiratory sensitization in humans, caused by MDI exposure in what appeared to be a low-level ("negligible") inhalation exposure environment. Exh. 12 -- Minutes of the III Scientific Committee's March 6-9, 1989 meeting, at III(Bice)007425, Item 7.0(A).
	Bayer	5/8/89	5/30/89	
	Dow	3/9/89	3/30/89	
	Huntsman	3/9/89	3/30/89	
1989 German Mine SRI	BASF	3/9/89	3/30/89	Information relating to multiple "situations," plural, of "MDI respiratory sensitization" in humans, caused either by MDI skin contact or by low-level ("inordinately low") MDI inhalation exposure. Exh. 12 -- Minutes of the III Scientific Committee's March 6-9, 1989 meeting, at III(Bice)007436.
	Bayer	5/8/89	5/30/89	
	Dow	3/9/89	3/30/89	
	Huntsman	3/9/89	3/30/89	

SRI Obtained by Each Defendant

SRI	Defendant	Date Obtained	Report Deadline	Information
1989 Nakata Papers SRI	BASF	3/9/89	3/30/89	Several papers that analyzed medical and industrial hygiene data and determined, based on that analysis, an apparent causal relationship between documented MDI skin contact and confirmed human cases of MDI respiratory sensitization. Exh. 12 -- Minutes of the III Scientific Committee's March 6-9, 1989 meeting, at III(Bice)007436.
	Bayer	5/8/89	5/30/89	
	Dow	3/9/89	3/30/89	
	Huntsman	3/9/89	3/30/89	
1992 Human Cases SRI	All	3/16/92	4/6/92	Underlying medical and industrial hygiene data from which various III member companies had concluded a "likely" causal relationship between documented MDI skin contact and confirmed human cases of MDI respiratory sensitization. Exh. 15 -- Minutes of the III European Med-Tox (EU-MTX) Sub-Committee's January 16, 1992 meeting, at III(Bice)009472, Item 5.1.
1992 Specific Scenario SRI	All	5/14/92	6/4/92	Underlying medical and industrial hygiene data reported to the III's Board of Directors as indicating an apparent causal relationship between confirmed human cases of MDI respiratory sensitization and either MDI skin contact or inhalation of "extremely low exposures of airborne MDI." Exh. 19 -- 1992 Report to III Board, at BASF-040044.
1993 Especial Work Situation SRI	All	4/14/93	5/5/93	Underlying medical and industrial hygiene data reported to the III's Board of Directors as indicating a causal relationship between confirmed human cases of MDI respiratory sensitization and either MDI skin contact or inhalation of "extremely low" inhalation exposures. Exh. 22 -- 1993 Report to III Board, at BASF-040084.

SRI Obtained by Each Defendant

SRI	Defendant	Date Obtained	Report Deadline	Information
2003 Isocyanate Asthma SRI	All	1/29/03	2/28/03	Underlying medical and industrial hygiene data, stored by the III and available to its member companies on its intranet, that excluded the inhalation exposure route as the cause of confirmed cases of isocyanate asthma, and therefore implicated the dermal exposure route. Exh. 25 -- Minutes of the January 28-29, 2003 Meeting of the III Americas Analytical Sub-Committee, at III(Bice)019839-019840.

D. Each defendant's civil penalty obligations for TSCA reporting violations

801. TSCA originally imposed a "civil penalty" of up to \$25,000 for each TSCA violation (since adjusted upward, as detailed below), and specified that "[e]ach day such a violation continues shall . . . constitute a separate violation." 15 U.S.C. § 2615(a)(1).

802. In accordance with Congressional instruction, the EPA has adjusted TSCA's civil penalty from time to time for inflation, as reflected in the following chart:

Adjustments to TSCA Civil Penalty			
01/01/77 - 1/30/97	01/31/97 - 3/15/04	03/16/04 - 1/12/09	01/13/09 - Present
\$25,000 per violation	\$27,500 per violation	\$32,500 per violation	\$37,500 per violation

Civil Monetary Penalty Inflation Adjustment Rule, 73 Fed. Reg. 75340, 75345 (Dec. 11, 2008).

1. Determination of each defendant's "Gravity Based Penalty."

803. The EPA declared its current policy for assessing penalties for violations of TSCA's Section 8(e) reporting obligations in The Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13, United States Environmental Protection Agency, (1999) ("TSCA Enforcement Response Policy"). The EPA's policy designates Section 8(e) reporting violations as some of the most serious TSCA violations,

1 and therefore assesses such violations at the high end of the penalty assessment scale. *Id.* at 8-
2 14.

3 804. The EPA determines penalties in two stages. It first determines a “gravity based
4 penalty” (GBP) and then adjusts the GBP based on various factors. *Id.* at 5.

5 805. The EPA calculates the GBP based on four statutory factors: Nature,
6 Circumstances, Extent, and Gravity. *Id.*

7 806. The “Nature” of the Section 8, 12, and 13 record-keeping and reporting violations
8 addressed by the TSCA Enforcement Response Policy is “hazard assessment.” *Id.*

9 807. The EPA assesses the “Gravity” of the violation as a “dependent variable;” its
10 evaluation of the Nature, Circumstances, and Extent will determine the gravity. *Id.*

11 808. Thus, “[s]ince the statutory factor of ‘nature’ is a constant throughout this policy,
12 and the statutory factor of ‘gravity’ is a ‘dependent variable,’ the gravity based penalty is
13 determined by applying a matrix with ‘circumstances’ on the vertical axis and ‘extent’ along the
14 horizontal axis.” *Id.*

15 809. The TSCA Enforcement Response Policy provides that “[n]on reporting
16 violations under TSCA § 8 occur when information, studies, or reports are not submitted to
17 EPA.” *Id.* at 9. Each defendant’s failure to report the substantial risk information it obtained or
18 developed constitutes a “non reporting violation” under EPA’s TSCA Enforcement Response
19 Policy.

20 810. The EPA assesses “Non reporting for TSCA § 8(e)” as “Level 1,” the highest
21 “Circumstance Level,” and assesses the violation on a “per day” basis. *Id.* at 9.

22 811. As for the “Extent Level,” the EPA assesses Section 8(e) reporting violations as
23 either “Major” (the highest level) or “Significant.” The EPA assesses Section 8(e) violations
24 “involving human data” as “Major” violations. The EPA also assesses as “Major” violations
25 those Section 8(e) violations “which directly interfere with the Agency’s ability to address
26 situations involving potential imminent hazard, unreasonable risks, or substantial endangerment
27 to health or the environment.” *Id.* at 11. However, the TSCA Enforcement Response Policy
28

1 provides that the EPA's assessment of a Section 8(e) reporting violation as "Major" must have
 2 the written concurrence from EPA's Office of Prevention, Pesticides, and Toxic Substances
 3 (OPPTS). *Id.*

4 812. Each defendant's Section 8(e) reporting violations involved human data, and are
 5 thus "Major" violations.

6 813. Each defendant's Section 8(e) reporting violations "directly interfere[d] with the
 7 Agency's ability to address situations involving . . . unreasonable risks[] or substantial
 8 endangerment to health," (*id.* at 11) and are thus "Major" violations.

9 814. The EPA indicates that "incomplete and inaccurate information will have far-
 10 reaching effects on the Agency's risk assessment, regulatory priority setting, and regulation
 11 development process." *Id.* at 18.

12 815. For more than twenty-five years (thirty-five for Bayer), each defendant has
 13 willfully concealed from the EPA substantial risk information about an unusual and unexpected
 14 hazard—the potential for skin contact to cause respiratory sensitization and/or permanent
 15 pulmonary injury. As alleged thoroughly below in connection with each defendant's
 16 concealment of their statutory and contractual obligations, each defendant concealed and failed
 17 to report the substantial risk information to avoid and deflect the increased regulatory activity
 18 that the anticipated such reporting would prompt.

19 816. On February 1, 1991, the EPA announced the Compliance Audit Program (CAP).
 20 The program essentially operated as an amnesty for prior TSCA Section 8(e) reporting
 21 violations. Registration and Agreement for TSCA Section 8(e) Compliance Audit Program, 56
 22 Fed. Reg. 4128 (February 1, 1991) ("CAP Agreement"), Exh. 26.

23 817. The EPA instituted CAP based on its observation that regulated companies had
 24 been failing to report information that the EPA viewed as reportable under Section 8(e). CAP
 25 Agreement, Exh. 26, 56 Fed. Reg. at 4128, Unit I, Background.

26 818. In announcing the program, the EPA stated:
 27 Up-to-date information on hazard and exposure *is vital in supporting EPA efforts*
 28 *to protect human health and the environment from risks from toxic chemicals.*

1 *EPA has the responsibility under TSCA to perform needed risk assessments on*
2 *chemicals. Section 8(e) is a very important part of TSCA's section 8 information*
3 *reporting and recordkeeping provisions that enable EPA to obtain and disseminate*
4 *information needed to set priorities and perform risk assessments that may be*
5 *national in scope. Companies that do not report vital information are*
6 *undermining the effectiveness of the early warning system intended under section*
7 *8(e).*

8 *Id.*, CAP Agreement, Exh. 26, 56 Fed Reg. at 4128, Unit I, Background (emphasis added).

9 819. Thus, "to achieve the Agency's goal of obtaining any outstanding section 8(e)
10 data, EPA has developed this one-time voluntary compliance program designed to strongly
11 encourage companies to voluntarily audit their files for studies reportable under section 8(e)."

12 *Id.* at 4129.

13 820. As alleged thoroughly below in connection with their contractual obligations,
14 each defendant contractually agreed to provide their previously-unreported substantial risk
15 information to the EPA as information that was "vital in supporting EPA efforts to protect
16 human health and the environment from risks from toxic chemicals." *Id.* (emphasis added).

17 821. Even apart from their contractual agreements, each defendant knew or should
18 have known, as an EPA-regulated company, that the EPA needed each defendant's previously-
19 unreported substantial risk information as information that was "vital in supporting EPA efforts
20 to protect human health and the environment from risks from toxic chemicals." *Id.* (emphasis
21 added).

22 822. By failing to report its substantial risk information, each defendant thus thwarted,
23 rather than supported, the EPA's "efforts to protect human health and the environment from risks
24 from toxic chemicals," and "undermin[ed] the effectiveness of the early warning system intended
25 under section 8(e). *Id.*

26 823. For example, in April 1992, the EPA created a Hazard Summary for MDI, and
27 revised the Hazard Summary in January 2000. EPA Hazard Summary for MDI,
28 <http://www.epa.gov/ttnatw01/hlthef/methyl-d.html> (last visited May 6, 2015). As of and prior to
April 1992, when EPA created the Hazard Summary, BASF, Bayer, Dow, and Huntsman each

1 had obtained or developed substantial risk information that reasonably supported the conclusion
2 that skin contact with or low-level inhalation of MDI or PMDI could cause respiratory
3 sensitization or other pulmonary injury. Yet each defendant failed to report that substantial risk
4 information, and thus “directly interfere[d] with the Agency’s ability to address situations
5 involving . . . unreasonable risks[] or substantial endangerment to health,” by depriving the EPA
6 of that information in connection with its creation of the MDI Hazard Summary. TSCA
7 Enforcement Response Policy at 11.

8 824. Similarly, as of and prior to January 2000, when EPA revised the Hazard
9 Summary, BASF, Bayer, Dow, and Huntsman each had obtained or developed additional
10 substantial risk information that reasonably supported the conclusion that skin contact with or
11 low-level inhalation of MDI or PMDI could cause respiratory sensitization or other pulmonary
12 injury. Yet each defendant failed to report that substantial risk information, and thus “directly
13 interfere[d] with the Agency’s ability to address situations involving . . . unreasonable risks[] or
14 substantial endangerment to health,” by depriving the EPA of that information in connection
15 with its creation of the MDI Hazard Summary. TSCA Enforcement Response Policy at 11.

16 825. Indeed, the EPA’s Hazard Summary for MDI does not indicate the possibility that
17 skin contact with or low-level inhalation of MDI or PMDI could cause respiratory sensitization
18 or other pulmonary injury.

19 826. BASF, Bayer, Dow, and Huntsman similarly interfered with the EPA’s hazard
20 identification and risk assessment activities when the EPA prepared its “Toxicological Review of
21 MDI” in 1998. In and prior to 1998, each defendant had obtained or developed substantial risk
22 information that reasonably supported the conclusion that skin contact with or low-level
23 inhalation of MDI or PMDI could cause respiratory sensitization or other pulmonary injury. Yet
24 each defendant failed to report that substantial risk information, and thus “directly interfere[d]
25 with the Agency’s ability to address situations involving . . . unreasonable risks[] or substantial
26 endangerment to health,” by depriving the EPA of that information in connection with its
27
28

1 creation of the Toxicological Review of MDI in 1998. TSCA Enforcement Response Policy at
2 11.

3 827. Indeed, the EPA's 1998 Toxicological Review of MDI does not indicate the
4 possibility that skin contact with or low-level inhalation of MDI or PMDI could cause respiratory
5 sensitization or other pulmonary injury.

6 828. In April 2011, the EPA expressed its heightened interest in MDI and related
7 chemicals by issuing an "MDI Action Plan," in which it proposed increased scrutiny of MDI to
8 address its concerns about the chemical, and in particular "the potential health effects that may
9 result from exposures to the consumer or self-employed worker." MDI Action Plan at 1.

10 829. Although the EPA expressed concern about potential isocyanate health effects, it
11 characterized the potential for respiratory injury from skin exposure as uncertain. While
12 acknowledging several published reports in which respiratory injury had occurred where the
13 airborne exposure was either below established exposure levels, undetected with the measuring
14 systems used, or unmeasured (studies that these defendants have long criticized) (MDI Action
15 Plan at 6), the EPA cited to recent scientific articles in which "[b]oth inhalation and dermal
16 exposures to isocyanates *are thought to contribute* to the development of isocyanate asthma" (*id.*
17 at 5 (emphasis added)). In contrast to this uncertain human data, the EPA noted that MDI "*is a*
18 *respiratory sensitizer via both the dermal and inhalation routes of exposure in animals.*" *Id.*
19 (emphasis added).

20 830. To address its concerns, the EPA stated its intention to take several actions. First,
21 it stated that it would "[i]ssue a data call-in" under various TSCA regulations to obtain
22 "allegations of significant adverse effects" and "one-time reporting of relevant unpublished
23 health and safety studies for uncured MDI." *Id.* at 10. The EPA also stated that it would
24 consider requiring the industry to conduct exposure monitoring studies in both the consumer and
25 commercial settings. *Id.*

26 831. Based on the EPA's April 2011 issuance of the MDI Action Plan, BASF, Bayer,
27 Dow, and Huntsman knew or should have known at or around that time of the EPA's stated
28

1 interest in the health effects of MDI, including its interest in human data related to the potential
2 dermal induction of respiratory sensitization.

3 832. Each defendant's failure to report previously-obtained substantial risk information
4 in these circumstances thus "directly interfere[d] with the Agency's ability to address situations
5 involving . . . unreasonable risks[] or substantial endangerment to health," by depriving the EPA
6 of that information to inform its regulatory decisions. TSCA Enforcement Response Policy at
7 11.

8 833. Instead of reporting previously-obtained substantial risk information, on February
9 26, 2013, each defendant submitted comments to the EPA's proposed MDI Action Plan through
10 the ACC. Feb. 26, 2013 ACC Comments to MDI Action Plan, Exh. 3. Disputing the EPA's
11 statement in the MDI Action Plan that "[b]oth inhalation and dermal exposures to diisocyanates
12 are thought to contribute to the development of isocyanate asthma" (*id.* at 9, Exh. 3), each
13 defendant falsely represented that "the role that dermal contact with diisocyanates plays in the
14 development of occupational asthma remains unresolved for humans." *Id.* at 10, Exh. 3.

15 834. This statement directly contradicted the substantial risk information that each
16 defendant has failed to report and continues to conceal. By making this statement, each
17 defendant falsely implied that no other human data existed and falsely denied the existence of the
18 substantial risk information it was concealing.

19 835. By making this statement, each defendant "directly interfere[d] with the Agency's
20 ability to address situations involving . . . unreasonable risks[] or substantial endangerment to
21 health." TSCA Enforcement Response Policy at 11.

22 836. Based on the EPA's April 2011 issuance of the MDI Action Plan, BASF, Bayer,
23 Dow, and Huntsman knew or should have known at or around that time of the EPA's stated
24 interest in the health effects of MDI, "the potential health effects that may result from exposures
25 to the consumer or self-employed worker." MDI Action Plan at 1. Those types of exposures
26 necessarily included inhalation exposures at concentrations below the regulatory or
27 recommended limits.

1 837. But each defendant concealed their substantial risk information about the low-
2 level-inhalation-induction health effect, and instead falsely represented to the EPA that low-level
3 exposures were safe. In their comments to the EPA's MDI Action Plan, each defendant disputed
4 the EPA's statement in the MDI Action Plan that "[b]oth inhalation and dermal exposures to
5 diisocyanates are thought to contribute to the development of isocyanate asthma" (Feb. 26, 2013
6 ACC Comments to MDI Action Plan at 9, Exh. 3). In commenting on that statement, each
7 defendant represented to the EPA: "The ability of diisocyanates to induce respiratory
8 sensitization in some individuals, and asthma in some cases, is a known potential adverse health
9 effect in humans *after exposure to concentrations above workplace exposure limits.*" *Id.* at 10
10 (emphasis added), Exh. 3.

11 838. As alleged thoroughly above, in February 2013 each defendant possessed
12 substantial risk information about the low-level-inhalation health effect. By omitting this
13 information from their 2013 comments to the EPA's MDI Action Plan, BASF, Bayer, Dow, and
14 Huntsman each represented to the EPA that they neither possessed nor were aware of substantial
15 risk information about the low-level-inhalation health effect. By making such a false
16 representation to the EPA, each defendant "directly interfere[d] with the Agency's ability to
17 address situations involving . . . unreasonable risks[] or substantial endangerment to health."
18 TSCA Enforcement Response Policy at 11

19 839. The defendants' statement also misleadingly implies that exposures below the
20 "workplace exposure limits" did not have the ability to "induce respiratory sensitization," in
21 direct contradiction to the substantial risk information that each defendant has failed to report
22 and continues to conceal.

23 840. By making this misleading representation and continuing to conceal the
24 substantial risk information about the low-level-inhalation-induction health effect, each
25 defendant "directly interfere[d] with the Agency's ability to address situations involving . . .
26 unreasonable risks[] or substantial endangerment to health." TSCA Enforcement Response
27 Policy at 11.
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1 841. The penalty matrix provides that for violations occurring on or before January 30,
2 1997, a Level 1, Major violation results in the assessment of the maximum daily penalty of
3 \$25,000. For violations after January 30, 1997 (and prior to subsequent penalty inflation
4 adjustments), a Level 1, Major violation results in the assessment of the maximum daily penalty
5 of \$27,500.

6 842. In other words, a Level 1, Major violation results in a “base penalty” in the
7 amount of the maximum daily penalty allowed under the penalty amounts set by the penalty
8 inflation adjustments for the date or dates during which the violation continues.

9 843. Each defendant’s reporting violations are Level 1, Major violations. The EPA’s
10 TSCA Enforcement Response Policy therefore determines the “base penalty” to be assessed for
11 each violation as the maximum daily penalty allowed under the penalty amounts set by the
12 penalty inflation adjustments for the date or dates during which the violation continues.

13 844. The EPA has set “[n]o cap” on the number of days for a penalty to be assessed for
14 a TSCA Section 8(e) violation. *Id.* at 13 and 26. The EPA explains: The harm continues as
15 long as the violation continues.” *Id.* at 26.

16 845. Moreover, because the defendant’s violations have “directly interfere[d] with the
17 Agency’s ability to address situations involving . . . unreasonable risks[] or substantial
18 endangerment to health” (*id.* at 11), the penalty equals the base penalty times the number of days
19 in violation. *Id.* at 12.

20 846. Additionally, the EPA’s policy provides that “[m]ultiple penalties are to be used if
21 there is more than one violation of the same rule or violations of different rules.” *Id.* at 13. For
22 TSCA Section 8(e) violations, this policy means that violations will be determined “Per Type of
23 Reportable Effect or Event Per Chemical.” *Id.* at 14. The EPA explains that “[o]mission of one
24 significant adverse effect even if other effects are reported impedes the Agency’s risk
25 assessment.” *Id.* at 27.

1 847. Most of the defendants' reporting failures involved two significant adverse
2 effects: (1) the dermal-induction of respiratory sensitization or pulmonary injury and (2) the
3 low-level-inhalation-induction of respiratory sensitization or pulmonary injury.

4 848. In such cases, a defendant's failure to report the information constitutes two
5 separate violations under the EPA's TSCA Enforcement Response Policy, for each day of the
6 defendant's continuing failure to report.

7 849. Further, the defendants' reporting failures involved two and sometimes three
8 chemicals: (1) MDI; (2) PMDI; and (3) TDI.

9 850. Each defendant that obtained or developed substantial risk information about MDI
10 should have reported that information to the EPA for both MDI and PMDI. As each defendant
11 has acknowledged, PMDI is "a mixture of MDI and higher molecular weight oligomers of MDI,"
12 with MDI representing "[a]pproximately 50%" of that mixture. *Initial Submission: Letter from*
13 *International Isocyanate Institute to U.S. EPA submitting information on Monomeric and*
14 *Polymeric MDI*, Submitted March 14, 1984, EPA Document ID: FYI-OTS-0794-1027,
15 EPA00609-00626 at 00615, Exh. 1. Thus, because it is the primary component of PMDI,
16 substantial risk information about MDI (a "substance") is necessarily substantial risk information
17 about PMDI (a "mixture" comprised primarily of MDI).

18 851. Each defendant has acknowledged that substantial risk information reportable for
19 MDI is also reportable for PMDI. On March 14, 1984, the III responded to a request for
20 information about MDI from the TSCA Interagency Testing Committee (ITC). Although the
21 ITC had requested information about MDI (CAS numbers 101-68-8 and 26447-40-5), the III also
22 believed it necessary to make a PMDI submission of its MDI information: "However, since
23 MDI is mostly manufactured and sold in its polymeric form, we are also submitting information
24 on this third chemical group [identifying PMDI]." *Id.*, Exh.1 at EPA00613.

25 852. Further, because PMDI consists primarily of MDI, substantial risk information
26 about PMDI (a "mixture") is necessarily substantial risk information about MDI, the "substance"
27 that is the primary constituent of PMDI.

853. Thus, the majority of each defendant's reporting failures constitute four violations (two significant adverse effects for two chemicals—MDI and PMDI), and some constitute six violations (two significant adverse effects for three chemicals—MDI, PMDI, and TDI), for each day of the defendant's continuing failure to report.

854. TSCA's civil penalty provision affirms that TSCA reporting violations are continuing violations ("[e]ach day such a violation continues"), and provides that the penalty imposed for the continuing violation will increase each day the violation continues.

a. BASF's Gravity Based Penalty

855. TSCA imposed an obligation on BASF to report each adverse effect, with respect to each chemical, for each of the following separate items of substantial risk information that it obtained or developed:

- a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- c. 1989 German Mine SRI (two adverse effects, two chemicals);
- d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- h. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

856. BASF failed to fulfill each of these separate reporting obligations, and each such failure is a separate, continuing reporting violation that continues until BASF fulfills that reporting obligation. The penalty for each separate violation increases each day that the violation continues.

857. Because BASF has not fulfilled any of these reporting obligations, the penalties for each of its violations have continued to increase through the date of this complaint. The chart below summarizes the calculation of BASF's \$6,897,125,000 in civil penalties through the date

of this complaint. In the “Effect/Chemical” column, “Dermal” means “dermal-induction health effect,” and “LLI” means “low-level-inhalation-induction health effect.”

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TSCA Civil Penalties -- BASF								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1988 Mine-workers SRI			2,983 days	2,601 days	1,763 days	2,319 days		0
5	Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
6	Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
7	LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
8	LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
9								
1989 Human Cases SRI			2,863 days	2,601 days	1,763 days	2,319 days		0
10	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
11	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
12	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
13	LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
14								
1989 German Mine SRI				2,601 days	1,763 days	2,319 days		0
15	Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
16	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
17	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
18	LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
19								
1989 Nakata Papers SRI				2,601 days	1,763 days	2,319 days		0
20	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
21	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
22								
23								
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	2,319 days		0
24	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
25	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
26								

TSCA Civil Penalties -- BASF									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
1993 Special Work Situation SRI			1,366 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
2003 Separate Asthma SRI			0 days	381 days	1,763 days	2,319 days			0
	Dermal – MDI	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500		
	Dermal – PMDI	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500		
TOTAL							6,897,125,000		

b. Bayer's Gravity Based Penalty

858. TSCA imposed an obligation on Bayer report each adverse effect, with respect to each chemical, for each of the following separate items of substantial risk information that it obtained or developed:

- Bayer's 1979 Skin Contact SRI (one adverse effect, two chemicals);
- 1982 Japanese Skin Contact SRI (one adverse effect, three chemicals);
- 1988 Mineworkers SRI (two adverse effects, two chemicals);

- d. 1989 Human Cases SRI (two adverse effects, two chemicals);
- e. 1989 German Mine SRI (two adverse effects, two chemicals);
- f. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- g. 1992 Human Cases SRI (one adverse effect, two chemicals);
- h. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- i. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- j. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

859. Bayer failed to fulfill each of these separate reporting obligations, and each such failure is a separate, continuing reporting violation that continues until Bayer fulfills that reporting obligation. The penalty for each separate violation increases each day that the violation continues.

860. Because Bayer has not fulfilled any of these reporting obligations, the penalties for each of its violations have continued to increase through the date of this complaint. The chart below summarizes the calculation of Bayer's \$8,675,062,500 in civil penalties through the date of this complaint. In the "Effect/Chemical" column, "Dermal" means "dermal-induction health effect," and "LLI" means "low-level-inhalation-induction health effect."

TSCA Civil Penalties -- Bayer									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
Bayer's 1979 Skin Contact SRI			6,218 days	2,601 days	1,763 days	2,319 days		0	
	Dermal – MDI	1/22/80	155,450,000	71,527,500	57,297,500	86,962,500	371,237,500		
	Dermal - PMDI	1/22/80	155,450,000	71,527,500	57,297,500	86,962,500	371,237,500		

TSCA Civil Penalties -- Bayer									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1982 Japanese Skin Contact SRI				5,378 days	2,601 days	1,763 days	2,319 days		0
5		Dermal – MDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
6		Dermal – PMDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
7		Dermal – TDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
1988 Mine-workers SRI				2,983 days	2,601 days	1,763 days	2,319 days		0
9		Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
10		Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
11		LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
12		LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
13									
1989 Human Cases SRI				2,802 days	2,601 days	1,763 days	2,319 days		0
14		Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
15		Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
16		LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
17		LLI – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
18									
1989 German Mine SRI				2,802 days	2,601 days	1,763 days	2,319 days		0
20		Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
21		Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
22		LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
23		LLI – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
24									
1989 Nakata Papers SRI				2,802 days	2,601 days	1,763 days	2,319 days		0
25		Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
26		Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
27									

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TSCA Civil Penalties -- Bayer									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1992 Human Cases SRI				1,760 days	2,601 days	1,763 days	2,319 days		0
5		Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
6		Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
1992 Specific Scenario SRI				1,701 days	2,601 days	1,763 days	2,319 days		0
8		Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
9		Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
10		LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
11		LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
1993 Special Work Situation SRI				1,366 days	2,601 days	1,763 days	2,319 days		0
12		Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
13		Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
14		LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
15		LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
2003 Isocyanate Asthma SRI				0 days	381 days	1,763 days	2,319 days		0
19		Dermal – MDI	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500	
20		Dermal – PMDI	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500	
TOTAL								8,675,062,500	

c. Dow's Gravity Based Penalty

861. TSCA imposed an obligation on Dow to report each adverse effect, with respect to each chemical, for each of the following separate items of substantial risk information that it obtained or developed:

- a. 1982 Japanese Skin Contact SRI (one adverse effect, one chemical – Dow was not manufacturing, distributing, or processing MDI or PMDI in 1982);
- b. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- c. 1989 Human Cases SRI (two adverse effects, two chemicals);
- d. 1989 German Mine SRI (two adverse effects, two chemicals);
- e. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- f. 1992 Human Cases SRI (one adverse effect, two chemicals);
- g. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- h. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- i. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

862. Dow failed to fulfill each of these separate reporting obligations, and each such failure is a separate, continuing reporting violation that continues until Dow fulfills that reporting obligation. The penalty for each separate violation increases each day that the violation continues.

863. Because Dow has not fulfilled any of these reporting obligations, the penalties for each of its violations have continued to increase through the date of this complaint. The chart below summarizes the calculation of Dow's \$7,253,562,500 in civil penalties through the date of this complaint. In the "Effect/Chemical" column, "Dermal" means "dermal-induction health effect," and "LLI" means "low-level-inhalation-induction health effect."

TSCA Civil Penalties -- Dow									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1982 Japanese Skin Contact SRI				5,378 days	2,601 days	1,763 days	2,319 days		0
		Dermal - TDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
1988 Mine-workers SRI				3,045 days	2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	
		Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	
		LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	
		LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	
1989 Human Cases SRI				2,863 days	2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
		LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
1989 German Mine SRI					2,601 days	1,763 days	2,319 days		0
		Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
		LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
1989 Nakata Papers SRI					2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	

TSCA Civil Penalties -- Dow									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1992 Human Cases SRI				1,760 days	2,601 days	1,763 days	2,319 days		0
5		Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
6		Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
1992 Specific Scenario SRI				1,701 days	2,601 days	1,763 days	2,319 days	0	
8		Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
9		Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
10		LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
11		LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
12									
1993 Special Work Situation SRI				1,366 days	2,601 days	1,763 days	2,319 days		0
13		Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
14		Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
15		LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
16		LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
17									
18									
2003 Isocyanate Asthma SRI				0 days	381 days	1,763 days	2,319 days		0
19		Dermal – MDI	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500	
20		Dermal – PMDI	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500	
21									
TOTAL								7,253,562,500	

d. Huntsman's Gravity Based Penalty

864. TSCA imposed an obligation on Huntsman to report each adverse effect, with respect to each chemical, for each of the following separate items of substantial risk information that it obtained or developed:

- a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- c. 1989 German Mine SRI (two adverse effects, two chemicals);
- d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- h. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

865. Huntsman failed to fulfill each of these separate reporting obligations, and each such failure is a separate, continuing reporting violation that continues until Huntsman fulfills that reporting obligation. The penalty for each separate violation increases each day that the violation continues.

866. Because Huntsman has not fulfilled any of these reporting obligations, the penalties for each of its violations have continued to increase through the date of this complaint. The chart below summarizes the calculation of Huntsman's \$6,903,325,000 in civil penalties through the date of this complaint. In the "Effect/Chemical" column, "Dermal" means "dermal-induction health effect," and "LLI" means "low-level-inhalation-induction health effect."

TSCA Civil Penalties -- Huntsman									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1988 Mine- workers SRI			3,045 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		
	Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		
	LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		
	LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		

TSCA Civil Penalties -- Huntsman									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1989 Human Cases SRI				2,863 days	2,601 days	1,763 days	2,319 days		0
5		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
6		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
7		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
8		LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
1989 German Mine SRI					2,601 days	1,763 days	2,319 days		0
10		Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
11		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
12		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
13		LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
14									
1989 Nakata Papers SRI					2,601 days	1,763 days	2,319 days		0
15		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
16		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
1992 Human Cases SRI				1,760 days	2,601 days	1,763 days	2,319 days		0
19		Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
20		Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
1992 Specific Scenario SRI				1,701 days	2,601 days	1,763 days	2,319 days		0
21		Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
22		Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
23		LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
24		LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
25									
26									

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TSCA Civil Penalties -- Huntsman									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1994				1,366 days	2,601 days	1,763 days	2,319 days		0
Special		Dermal –	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
Work		MDI							
Situation	SRI	Dermal –	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
6		PMDI							
7		LLI –	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
8		MDI							
9		LLI -	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
		PMDI							
2000				0 days	381 days	1,763 days	2,319 days		0
Isocyanate		Dermal –	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500	
Atmospheric	SRI	MDI							
12		Dermal -	2/28/03	0	10,477,500	57,297,500	86,962,500	154,737,500	
		PMDI							
TOTAL								6,903,325,000	

2. **The adjustment factors justify an upward adjustment to each defendant's Gravity Based Penalty**

867. After determining the Gravity Based Penalty, the EPA assesses several additional factors to determine whether the GBP should be adjusted upward or downward. Those factors are (1) the violator's degree of culpability; (2) the violator's history of prior violations; (3) the violator's ability to pay; (4) the violator's ability to continue in business; and (5) such other matters as justice may require. TSCA Enforcement Response Policy at 6.

868. Here, each defendant has a high degree of culpability. As alleged thoroughly below, each defendant willfully refused to report multiple items of substantial risk information obtained or developed over a lengthy time period, willfully concealed its violations and the substantial risk information from the EPA, and has publicly disputed (including directly to the EPA) the very adverse health effects indicated by the substantial risk information it continues to conceal.

1 869. KBT&F is not aware of each defendant's history of prior violations. However,
2 each defendant here committed multiple violations over a lengthy period of time, and has
3 actively concealed those violations from the EPA.

4 870. Each defendant is a large, very profitable chemical company, capable of paying
5 the maximum penalty and continuing in business.

6 871. Among the "other factors as justice may require," the EPA considers whether the
7 violator voluntarily disclosed the violation, the violator's exposure reduction efforts, the
8 violator's attitude, and the economic benefit the violator gained from non-compliance. *Id.* at 15-
9 17.

10 872. The defendants have not voluntarily disclosed their violations. Instead, each
11 defendant has actively concealed its multiple violations over a lengthy period of time, and
12 implicitly represented to the EPA that the data that comprises the concealed substantial risk
13 information does not exist.

14 873. Each defendant's attitude justifies an upward adjustment to the GBP. The EPA
15 looks to "whether the violator is making good faith efforts to comply with the appropriate
16 regulations" as one factor in assessing the violator's attitude. *Id.* at 16. As alleged thoroughly
17 below, each defendant violated its reporting obligations in bad faith. Each defendant reported
18 *animal* data that reasonably supported the conclusion of an adverse health effect, but concealed
19 and failed to report *human* data that reasonably supported (sometimes more conclusively) that
20 very same adverse health effect. And each defendant thereafter told the EPA that the human
21 evidence for that adverse health effect was "inconclusive," even as that defendant continued to
22 conceal such human evidence from the EPA. None of the defendants made good faith efforts to
23 comply with TSCA's reporting obligations.

24 874. The EPA indicates that an "upward adjustment of a maximum of 15% may be
25 justified where company officials . . . do not act in good faith, hinder EPA's progress, cause
26 increased government expenditures, or are otherwise uncooperative." *Id.* at 16. Each
27
28

1 defendant's actions here justify such an upward adjustment. Each defendant has acted in bad
2 faith, has hindered EPA's ability to conduct its regulatory activities, and has been uncooperative.

3 875. The EPA also assesses the economic benefit that the violator gained from its non-
4 compliance:

5 In no case should the final penalty imposed be less than the economic benefit. In
6 those cases where the initial gravity based penalty is less than the economic
7 benefit derived from non-compliance, EPA reserves the right to impose penalties
8 up to the maximum of \$25,000 per day [or the maximum penalty as adjusted for
inflation for the date or dates during which the violation continues] to assure that
the penalty is not less than the economic benefit.

9 *Id.* at 16.

10 876. The EPA discussed the calculation of the economic benefit component in A
11 Framework for Statute-Specific Approaches to Penalty Assessments: Implementing EPA's
12 Policy on Civil Penalties, EPA General Enforcement Policy #GM-22, at 2, February 16, 1984
13 ("Framework for Penalty Assessments"). The EPA indicated that some violations allow the
14 violator to sell products that "are more attractive to the consumer," and lists as an example
15 "[s]elling products without required labelling or warnings." Framework for Penalty Assessments
16 at 10. In those cases, the economic benefit includes "the net profits made from the improper
17 transactions." *Id.*

18 877. As alleged thoroughly below, as each defendant failed to report the substantial
19 risk information to the EPA, it also omitted from its product labels and warnings the health-effect
20 conclusions reasonably supported by the substantial risk information. Each defendant concealed
21 this information to avoid or deflect anticipated regulatory scrutiny and to maintain its substantial
22 isocyanate profits by avoiding customer "de-selection" of its products.

23 878. Each defendant knew from the substantial risk information it was concealing that
24 its MDI, PMDI, and TDI products posed serious and unusual hazards that customers could avoid
25 only by using specific, expensive, and cumbersome protective equipment.

1 879. Each defendant knew that skin contact with those products could cause
2 respiratory sensitization and permanent pulmonary injury. To avoid that hazard the worker
3 should:

- 4 a. cover all exposed skin with protective clothing made of specific,
5 chemical-resistant material;
- 6 b. replace that protective clothing before the “breakthrough time” expires
7 and the isocyanate “breaks through” the clothing to the skin; and
- 8 c. follow specific and cumbersome procedures, possibly involving a
9 suitably-attired assistant, to remove the protective clothing.

10 880. Each defendant also knew that low-level inhalation of those products could cause
11 respiratory sensitization and permanent pulmonary injury. To avoid that hazard the worker
12 should use a supplied-air respirator or, at a minimum, an air-purifying respirator with an
13 approved cartridge that is replaced before its useful service-life expires.

14 881. Each defendant feared that its disclosure of the dermal-induction or the low-level-
15 inhalation hazard could prompt its customers to “de-select” its products, and therefore concealed
16 those hazards to protect its products.

17 882. Thus, each defendant’s non-compliance provided it with a significant economic
18 benefit comprising all or some of its net profits from the sale of MDI, PMDI, and TDI products
19 during the period of its non-compliance.

20 883. Bayer’s non-compliance period began on or before January 22, 1980, the date by
21 which it was required to report Bayer’s 1979 Skin Contact SRI, and continues through the
22 present. KBT&F does not possess sufficient information at this time to calculate Bayer’s net
23 profits from MDI, PMDI, and TDI sales during that period.

24 884. Dow’s non-compliance period began on or before May 11, 1982, the date by
25 which it was required to report the 1982 Japanese Skin Contact SRI, and continues through the
26 present. KBT&F does not possess sufficient information at this time to calculate Dow’s net
27 profits from MDI, PMDI, and TDI sales during that period.

1 885. Huntsman's non-compliance period began on or before September 29, 1988, the
2 date by which it was required to report the 1988 Mineworkers SRI, and continues through the
3 present. KBT&F does not possess sufficient information at this time to calculate BASF's net
4 profits from MDI, PMDI, and TDI sales during that period.

5 886. BASF's non-compliance period began on or before November 30, 1988, the date
6 by which it was required to report the 1988 Mineworkers SRI, and continues through the present.
7 KBT&F does not possess sufficient information at this time to calculate BASF's net profits from
8 MDI, PMDI, and TDI sales during that period.

9 887. Each defendant also feared that its disclosure of the dermal-induction or the low-
10 level-inhalation hazard could prompt the EPA or other regulatory authorities to restrict or ban the
11 sale or use of its products, and therefore concealed those hazards to avoid or deflect such
12 regulation.

13 888. Thus, each defendant's violations directly interfered with the EPA's hazard
14 identification and risk assessment activities, and each defendant concealed the substantial risk
15 information to prevent or thwart those activities.

16 889. None of the EPA's adjustment factors justify a downward adjustment in BASF,
17 Bayer, Dow, or Huntsman's Gravity Based Penalty.

18 890. The Attitude factor justifies an upward adjustment of 15% in BASF, Bayer, Dow,
19 and Huntsman's Gravity Based Penalty.

20 891. The Economic Benefit factor requires that the final penalty imposed on each
21 defendant at least equal the value of the economic benefit that the defendant obtained from its
22 non-compliance.

23 892. BASF's TSCA reporting violations obligate it to pay \$6,897,125,000 to the
24 United States government as of May 20, 2015, as shown in chart set out in the Gravity Based
25 Penalty subsection above.

893. Bayer's TSCA reporting violations obligate it to pay \$8,675,062,500 to the United States government as of May 20, 2015, as shown in chart set out in the Gravity Based Penalty subsection above.

894. Dow's TSCA reporting violations obligate it to pay \$7,253,562,500 to the United States government as of May 20, 2015, as shown in chart set out in the Gravity Based Penalty subsection above.

895. Huntsman's TSCA reporting violations obligate it to pay \$6,903,325,000 to the United States government as of May 20, 2015, as shown in chart set out in the Gravity Based Penalty subsection above.

E. Defendants' contractual obligations.

896. On February 1, 1991, the EPA announced the Compliance Audit Program (CAP). The program essentially operated as an amnesty for prior TSCA Section 8(e) reporting violations. Registration and Agreement for TSCA Section 8(e) Compliance Audit Program, 56 Fed. Reg. 4128 (February 1, 1991) ("CAP Agreement"), Exh. 26.

897. In response to industry complaints that it had changed its interpretation of the reporting requirements and that its high monetary penalties created a disincentive for companies to audit their hazard information for compliance, the EPA developed CAP to "encourage companies to audit their files for studies reportable under [TSCA] Section 8(e)." *Id.*, Exh. 26 at 4128-4129, Section I.3.

898. The EPA required each participating company to sign the CAP contract, the text of which is published in the Federal Register. *Id.*, Exh. 26 at 4129-4131, Section II. (The EPA twice slightly revised the text of the contract: Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification, 56 Fed. Reg. 19514 (April 26, 1991) ("CAP Modification 1"), Exh. 27, and Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification, 56 Fed. Reg. 28458 (June 20, 1991) ("CAP Modification 2"), Exh. 28.)

1 899. Each participating company agreed to audit its substantial risk reporting
2 compliance and to submit all previously unsubmitted substantial risk information, in return for
3 which the EPA agreed to reduce significantly the reporting penalties for each submitted report,
4 and to cap the total reporting penalties for all previously unsubmitted information at \$1 million.
5 CAP Agreement, 56 Fed. Reg. at 4129-4130, Section II.B.1 – II.B.3. The contract further
6 required each participating company to certify its completion of the audit program at the
7 program's conclusion. *Id.* at 4130, Section II.B.4.

8 900. In a Freedom of Information Act (FOIA) request, KBT&F requested that the EPA
9 produce the CAP contracts and associated documents executed by any of the defendants, as well
10 as documents that identified the companies that participated in CAP. The EPA responded that its
11 document retention schedule for the CAP documents had expired and it could not locate the
12 contracts and associated documents. However, the EPA provided KBT&F with a "Final
13 Summary Chart" for the TSCA Section 8(e) Compliance Audit Program. EPA's March 4, 2015
14 FOIA Response, Exh. 29.

15 901. The Final Summary Chart for CAP establishes that defendants BASF, Bayer
16 (through its predecessor-in-interest Miles), and Dow each participated in CAP.

17 902. While that chart also shows that an entity identified as "Zeneca, Inc., f/k/a ICI
18 America, Inc." participated in CAP, that reference did not provide evidence sufficient for
19 KBT&F to allege that Huntsman participated in CAP through its predecessor-in-interest ICI
20 Americas, but rather appeared to indicate just the opposite. In 1993, prior to the EPA's May 15,
21 1996 termination of the CAP program, ICI Americas' parent company, Imperial Chemical
22 Industries plc, sold its pharmaceuticals business (including the pharmaceutical division of ICI
23 Americas) to Zeneca Group, which later became AstraZeneca plc. ICI Americas, however,
24 continued to operate its chemical business as ICI Americas until Huntsman acquired ICI
25 Americas in 2000, as part of its acquisition of the world-wide chemical business of Imperial
26 Chemical Industries plc. Thus, when the EPA completed the CAP Final Summary Chart at the
27 program's termination in May 1996, its identification of "Zeneca, Inc., f/k/a ICI America, Inc."

1 as a CAP participant appeared to include (as relates to ICI Americas) only those pharmaceutical
2 operations acquired by and being operated then by Zeneca. Since ICI Americas was continuing
3 to operate its chemical business in May 1996 under the name ICI Americas, the “formerly
4 known as” designation in the EPA’s Final Summary Chart appeared to exclude the ongoing
5 chemical operations of ICI Americas, and include only those operations acquired by Zeneca.

6 903. In a separate FOIA request, KBT&F had requested that the EPA produce, among
7 other items, all information about MDI, PMDI, or TDI submitted to the EPA under TSCA. After
8 obtaining several extensions, the EPA served an interim FOIA response on July 30, 2015, in
9 which it produced documents that establish Huntsman’s participation in CAP. Specifically, the
10 EPA produced two documents in which Huntsman’s predecessor-in-interest, ICI Americas,
11 submitted TDI information to the EPA under CAP. EPA’s July 30, 2015 Interim FOIA
12 Response, Exh. 82; EPA Document Identification Number 8EHQ-0892-8337, Exh. 83; and EPA
13 Document Identification Number 8EHQ-0892-8381, Exh. 84. The CAP Identification Number
14 that ICI Americas referenced in these two CAP submissions (8ECAP-0040) corresponds to the
15 CAP Identification Number shown on the EPA’s Final Summary Chart as belonging to “Zeneca,
16 Inc., f/k/a ICI America, Inc.” Thus, the summary information in the EPA’s Final Summary
17 Chart about “Zeneca, Inc., f/k/a ICI America, Inc.” either comprises or includes the summary
18 information about Huntsman’s participation in CAP through its predecessor-in-interest, ICI
19 Americas.

20 904. By virtue of its participation in CAP, BASF entered a contract with the EPA in
21 the form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
22 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

23 905. By virtue of its participation in CAP, Bayer entered a contract with the EPA in the
24 form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
25 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

1 906. By virtue of its participation in CAP, Dow entered a contract with the EPA in the
2 form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
3 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

4 907. By virtue of its participation in CAP, Huntsman entered a contract with the EPA
5 in the form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by
6 CAP Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28)

7 908. In their respective contracts with the EPA, each defendant agreed and was
8 contractually required to audit its substantial risk reporting compliance and to submit all
9 previously unsubmitted substantial risk information, in return for which the EPA agreed to
10 reduce significantly the reporting penalties for each submitted report, and to cap the total
11 reporting penalties for all previously unsubmitted information at \$1 million. CAP Agreement,
12 Exh. 26, 56 Fed. Reg. at 4129-4130, Section II.B.1 – II.B.3.

13 909. In their respective contracts with the EPA, each defendant agreed and was
14 contractually required to certify its completion of the audit program at the program's conclusion.
15 CAP Agreement, Exh. 26, 56 Fed. Reg. at 4130, Section II.B.4.

16 910. In their respective contracts with the EPA, each defendant agreed that its failure to
17 comply with its contractual obligations would authorize the EPA to impose full penalties for any
18 substantial risk information it had submitted under CAP and received a reduced or "capped"
19 amnesty penalty. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4130, Section II.D.4.

20 911. In their respective contracts with the EPA, each defendant agreed that its failure to
21 comply with its contractual obligations would authorize the EPA to pursue full penalties for the
22 company's failure to submit substantial risk information that it should have submitted under the
23 CAP Agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Section II.A.5.

24 912. Shortly after it instituted CAP, the EPA amended the contract to extend through
25 February 28, 1992 the deadline for participating companies to submit substantial risk
26 information, and also inserted a provision that allowed for additional extensions to be assessed
27 on a case-by-case basis. CAP Modification 1, Exh. 26, 56 Fed. Reg. at 19514.

1 913. In response to questions about EPA's guidance about the reportability of
 2 information concerning environmental distribution and contamination, the EPA announced on
 3 June 20, 1991 that it would provide more specific guidance about the reportability of such
 4 information. CAP Modification 2, Exh. 28, 56 Fed Reg. at 28459, Unit 3.D. The EPA issued
 5 that guidance on July 13, 1993. 1993 Proposed Policy Clarification, 58 Fed. Reg. 37735. The
 6 CAP reporting deadline appears to have been extended as the EPA issued this guidance and
 7 analyzed the comments received about the revised guidance. 2003 TSCA Guidance Revisions,
 8 68 Fed. Reg. 33129, June 3, 2003. After terminating CAP on May 15, 1996, the EPA "reached
 9 final settlements with CAP participants, announced those settlements on October 15, 1996, and
 10 collected payment for stipulated penalties." *Id.*, 68 Fed. Reg. at 33131, Unit II.D.

11 914. Thus, the CAP Agreement required BASF, Bayer, Dow, and Huntsman to audit
 12 its files for unreported substantial risk information and to submit such information to the EPA by
 13 May 15, 1996.

14 915. BASF, Bayer, Dow, and Huntsman each breached both of these obligations.
 15 **F. Defendants' obligation to pay damages for breach of the CAP Agreement.**

16 916. The CAP Agreement authorized the EPA to obtain at least two categories of
 17 damages for a participating company's failure to submit previously unreported substantial risk
 18 information.

19 917. First, the EPA is authorized to impose full TSCA Section 8(e) civil penalties for
 20 any substantial risk information for which the participating company received a reduced or
 21 capped "amnesty" penalty. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4130, Unit II.D.4.

22 918. The EPA was unable to locate the Consent Agreement or Consent Order that
 23 summarized the results of the program with respect to BASF, Bayer, Dow, or Huntsman.
 24 Although the EPA's TSCA Section 8(e) Final Summary Chart establishes that each defendant
 25 submitted substantial risk information under CAP for which they each received reduced or
 26 "amnesty" penalties (Exh. 29), KBT&F is not currently able to calculate the differential between
 27 the full penalties that would have been due for those submissions absent the amnesty reduction.
 28

1 919. Second, the CAP Agreement authorizes the EPA to pursue full penalties for a
 2 participating company's failure to submit substantial risk information that it should have
 3 submitted under the CAP Agreement:

4 EPA reserves its rights under TSCA Section 16 to take appropriate enforcement
 5 action if EPA determines later that Regulatee was required to submit under TSCA
 6 section 8(e) a study or report determined by the Regulatee to be not reportable and
 7 therefore not submitted under the TSCA Section 8(e) Compliance Audit Program.
 In such event, the terms of the EPA TSCA Sections 8, 12, and 13 Enforcement
 Response Policy will apply to such proceeding.

8 CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.

9 920. Under this contractual damages provision, the civil penalties for the substantial
 10 risk information "not submitted under the TSCA Section 8(e) Compliance Audit Program" are
 11 calculated under the TSCA Enforcement Response Policy as of the date the "appropriate
 12 enforcement action" that EPA initiates after it has "determine[d] later" that the participating
 13 company breached the agreement.

14 921. As alleged thoroughly above, the terms of the EPA's enforcement policy require
 15 each defendant to pay the maximum daily penalty for each reporting violation.

16 922. Thus, the EPA is and has been entitled to damages separately against BASF,
 17 Bayer, Dow, and Huntsman for the accumulated civil penalties for each company's multiple
 18 reporting violations as to each separate piece of substantial risk information that the defendant
 19 should have provided, but failed to provide, under the CAP Agreement.

20 **1. Damages for BASF's breach of the CAP Agreement.**

21 923. BASF violated its contractual duty to submit the following unreported substantial
 22 risk information:

- 23 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 24 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- 25 c. 1989 German Mine SRI (two adverse effects, two chemicals);
- 26 d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- 27 e. 1992 Human Cases SRI (one adverse effect, two chemicals);

- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

924. Because BASF failed to submit these separate items of substantial risk information, it is liable in contract damages to the United States Government in the amount of \$6,587,650,000, the TSCA civil penalties, accumulated through the date of this complaint, for its multiple failures to report these separate items of substantial risk information. The chart below summarizes the calculation of BASF's breach of contract damages through the date of this complaint. In the "Effect/Chemical" column, "Dermal" means "dermal-induction health effect," and "LLI" means "low-level-inhalation-induction health effect."

CAP Breach of Contract Damages -- BASF									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1988 Mine- workers SRI			2,983 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500		
	Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500		
	LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500		
	LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500		
1989 Human Cases SRI			2,863 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		

CAP Breach of Contract Damages -- BASF									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1989 German Mine SRI					2,601 days	1,763 days	2,319 days		0
5		Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
6		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
7		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
8		LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
9									
1989 Nakata Paper SRI					2,601 days	1,763 days	2,319 days		0
10		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
11		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
12									
1992 Human Cases SRI				1,760 days	2,601 days	1,763 days	2,319 days		0
13		Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
14		Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
15									
1992 Specific Scenario SRI				1,701 days	2,601 days	1,763 days	2,319 days		0
16		Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
17		Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
18		LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
19		LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
20									
1993 Especial Work Situation SRI				1,366 days	2,601 days	1,763 days	2,319 days		0
21		Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
22		Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
23		LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
24		LLI - PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
25									
26									
TOTAL								6,587,650,000	

28

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2. Damages for Bayer's breach of the CAP Agreement.

925. Bayer violated its contractual duty to submit the following unreported substantial risk information:

- a. Bayer's 1979 Skin Contact SRI (one adverse effect, two chemicals);
- b. 1982 Japanese Skin Contact SRI (one adverse effect, three chemicals);
- c. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- d. 1989 Human Cases SRI (two adverse effects, two chemicals);
- e. 1989 German Mine SRI (two adverse effects, two chemicals);
- f. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- g. 1992 Human Cases SRI (one adverse effect, two chemicals);
- h. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
- i. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

926. Because Bayer failed to submit these separate items of substantial risk information, it is liable in contract damages to the United States Government in the amount of \$8,365,587,500, the TSCA civil penalties, accumulated through the date of this complaint, for its multiple failures to report these separate items of substantial risk information. The chart below summarizes the calculation of Bayer's breach of contract damages through the date of this complaint. In the "Effect/Chemical" column, "Dermal" means "dermal-induction health effect," and "LLI" means "low-level-inhalation-induction health effect."

CAP Breach of Contract Damages -- Bayer									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
Bayer's 1979 Skin Contact SRI			6,218 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	1/22/80	155,450,000	71,527,500	57,297,500	86,962,500	371,237,500		
	Dermal - PMDI	1/22/80	155,450,000	71,527,500	57,297,500	86,962,500	371,237,500		

CAP Breach of Contract Damages -- Bayer									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1982 Japanese Skin Contact SRI				5,378 days	2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
		Dermal – PMDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
		Dermal - TDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
1988 Mine-workers SRI				2,983 days	2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
		Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
		LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
		LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	86,962,500	290,362,500	
1989 Human Cases SRI				2,802 days	2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
		Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
		LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
		LLI – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
1989 German Mine SRI				2,802 days	2,601 days	1,763 days	2,319 days		0
		Dermal - MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
		Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
		LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
		LLI - PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
1989 Nakata Papers SRI				2,802 days	2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	
		Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	86,962,500	285,837,500	

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CAP Breach of Contract Damages -- Bayer									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	2,319 days			0
5	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500		
6	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500		
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	2,319 days			0
8	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
9	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
10	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
11	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500		
1993 Special Work Situation SRI			1,366 days	2,601 days	1,763 days	2,319 days			0
12	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
13	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
14	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
15	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
16	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
17	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500		
18									
TOTAL							8,365,587,500		

3. Damages for Dow's breach of the CAP Agreement.

927. Dow violated its contractual duty to submit the following unreported substantial risk information:

- 1982 Japanese Skin Contact SRI (one adverse effect, one chemical);
- 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 1989 Human Cases SRI (two adverse effects, two chemicals);
- 1989 German Mine SRI (two adverse effects, two chemicals);

- e. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- f. 1992 Human Cases SRI (one adverse effect, two chemicals);
- g. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- h. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

928. Because Dow failed to submit these separate items of substantial risk information, it is liable in contract damages to the United States Government in the amount of \$6,944,087,500, the TSCA civil penalties, accumulated through the date of this complaint, for its multiple failures to report these separate items of substantial risk information. The chart below summarizes the calculation of Dow's breach of contract damages through the date of this complaint. In the "Effect/Chemical" column, "Dermal" means "dermal-induction health effect," and "LLI" means "low-level-inhalation-induction health effect."

CAP Breach of Contract Damages -- Dow

Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
		\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
		5,378 days	2,601 days	1,763 days	2,319 days		0
Dermal - TDI	5/11/82	134,450,000	71,527,500	57,297,500	86,962,500	350,237,500	
		3,045 days	2,601 days	1,763 days	2,319 days		0
Dermal – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	
Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	
LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	
LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500	

CAP Breach of Contract Damages -- Dow									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1989 Human Cases SRI				2,863 days	2,601 days	1,763 days	2,319 days		0
5		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
6		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
7		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
8		LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
9									
1989 German Mine SRI					2,601 days	1,763 days	2,319 days		0
10		Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
11		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
12		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
13		LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
14									
1989 Nakata Papers SRI					2,601 days	1,763 days	2,319 days		0
15		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
16		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500	
17									
1992 Human Cases SRI				1,760 days	2,601 days	1,763 days	2,319 days		0
18		Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
19		Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
20									
1992 Specific Scenario SRI				1,701 days	2,601 days	1,763 days	2,319 days		0
21		Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
22		Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
23		LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
24		LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
25									
26									
27									

CAP Breach of Contract Damages -- Dow									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1994 Especial Work Situation SRI				1,366 days	2,601 days	1,763 days	2,319 days		0
		Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
		Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
		LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
		LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
TOTAL								6,944,087,500	

4. Damages for Huntsman's breach of the CAP Agreement.

929. Huntsman violated its contractual duty to submit the following unreported substantial risk information:

- a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- c. 1989 German Mine SRI (two adverse effects, two chemicals);
- d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

930. Because Huntsman failed to submit these separate items of substantial risk information, it is liable in contract damages to the United States Government in the amount of \$6,593,850,000, the TSCA civil penalties, accumulated through the date of this complaint, for its multiple failures to report these separate items of substantial risk information. The chart below summarizes the calculation of Huntsman's breach of contract damages through the date of this

complaint. In the "Effect/Chemical" column, "Dermal" means "dermal-induction health effect," and "LLI" means "low-level-inhalation-induction health effect."

CAP Breach of Contract Damages -- Huntsman									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1988 Mine-workers SRI			3,045 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		
	Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		
	LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		
	LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	86,962,500	291,912,500		
1989 Human Cases SRI			2,863 days	2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
1989 German Mine SRI				2,601 days	1,763 days	2,319 days			0
	Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
1989 Nakata Papers SRI				2,601 days	1,763 days	2,319 days			0
	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	86,962,500	287,362,500		

CAP Breach of Contract Damages -- Huntsman								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/15	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	2,319 days		0
5	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
6	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	86,962,500	259,787,500	
1997 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	2,319 days		0
8	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
9	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
10	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
11	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	86,962,500	258,312,500	
1993 Special Work Situation SRI			1,366 days	2,601 days	1,763 days	2,319 days		0
12	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
13	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
14	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
15	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
16	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
17	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
18	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	86,962,500	249,937,500	
TOTAL							6,593,850,000	

V. EACH DEFENDANT CONCEALED ITS VIOLATIONS OF ITS STATUTORY, REGULATORY, AND CONTRACTUAL OBLIGATIONS

931. BASF, Bayer, Dow, and Huntsman, individually and in conspiracy, have actively and knowingly concealed both the existence of and their failure to report to the EPA about the extensive quantity of substantial risk information they have obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI. As more thoroughly alleged below, each defendant, individually and in conspiracy with the other defendants, has:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it is concealing;

932. BASF, Bayer, and Dow, individually and in conspiracy, have each concealed both the existence of the substantial risk information and their failure to report it by refusing to report the substantial risk information to the EPA, even after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May 2010 that identified some of the defendants’ Section 8(e) reporting violations identified in this complaint. Although Huntsman was not a party to the *Bice* case, Huntsman was a co-defendant with BASF, Bayer, and Dow in a related case filed in West Virginia state court. KBT&F believes that BASF, Bayer, and Dow notified Huntsman of the *Bice* case testimony, and discussed its implications with Huntsman.

1 **A. Each defendant demonstrated its intention to conceal the SRI by its refusal to report**
2 **the SRI even as it obtained additional SRI and received communications that**
3 **prompted reminders of previously-obtained SRI.**

4 933. Starting in the 1970s (Bayer) and from the early 1980s (BASF, Bayer, and Dow),
5 the late 1980s (BASF, Bayer, Dow, and Huntsman), and continuing into the 2000s (and perhaps
6 even through the present day), defendants BASF, Bayer, Dow, and Huntsman have obtained
7 and/or developed several separate and discrete items of substantial risk information that each
8 contain different medical, scientific, and/or industrial hygiene data that points to and reasonably
9 supports the same conclusion: skin contact with and/or low-level inhalation of TDI, MDI, and/or
10 TDI can cause and has caused in specific instances respiratory sensitization and/or pulmonary
11 injury in humans.

12 934. As each defendant obtained and/or developed new substantial risk information
13 that corroborated the more-likely-than-not or stronger conclusions drawn from the previously-
14 obtained or –developed information, TSCA required that it evaluate the Section 8(e) reportability
15 of not only the newly-obtained or –developed substantial risk information, but also the
16 previously-obtained or –developed information. As the magnitude of each defendant’s
17 knowledge of corroborating substantial risk information continued to build, each defendant’s
18 willfulness in refusing to report the substantial risk information, and thus its intention to conceal
19 that information from the EPA, became more and more evident.

20 935. Further, certain events or communications should have reminded each defendant
21 of its reporting obligation. By refusing to report the substantial risk information despite these
22 reminders, each defendant again demonstrated its willful refusal to report the substantial risk
23 information, as well as its intention to conceal the information from the EPA.

24 936. As alleged more thoroughly above, by December 31, 1979 at the latest, Bayer had
25 obtained or developed Bayer’s 1979 Skin Contact SRI, which comprised information
26 communicated in training by Bayer’s industrial hygienists that skin contact with MDI could
27 cause respiratory sensitization and reduced lung function.
28

1 937. When in December 1980 Dr. Meryl Karol presented to the III the findings of her
2 seminal study in which she had demonstrated that a minimal amount (as small as a single drop)
3 of TDI on the skin of guinea pigs resulted in respiratory hypersensitivity, Bayer had
4 representatives in the audience. May 6, 2008 Dow-Woolhiser Depo at 120-121, Exh. 5.

5 938. After presenting the results of her animal study to the III member representatives,
6 Dr. Karol responded to a question in which one of the attendees suggested that Dr. Karol's TDI
7 animal results should prompt efforts to protect against human workers having skin exposure not
8 only for TDI, but also for MDI. Dr. Karol responded that the study's findings indicated that
9 users should avoid skin contact with any of these isocyanates. May 6, 2008 Dow-Woolhiser
10 Depo at 131, Exh. 5.

11 939. Despite obtaining information that corroborated in the animal setting instruction
12 that Bayer was providing to its employees, Bayer failed to report Bayer's 1979 Skin Contact SRI
13 to the EPA. Bayer's failure to report in these circumstances demonstrates that its failure was
14 willful and calculated to conceal the substantial risk information from the EPA.

15 940. In 1982, Bayer and Dow obtained the 1982 Japanese Skin Contact SRI, which
16 comprised analysis relevant to whether TDI or MDI skin absorption can cause pulmonary
17 sensitization. Once again, Bayer's receipt of this information should have prompted it to report
18 Bayer's 1979 Skin Contact SRI to the EPA. Bayer's failure to report in these circumstances
19 demonstrates that its failure was willful and calculated to conceal the substantial risk information
20 from the EPA.

21 941. In or shortly after September 1988, BASF, Bayer, Dow, and Huntsman obtained
22 or developed the 1988 Mineworkers SRI, which comprised cases of human respiratory
23 sensitization conclusively caused either by MDI skin contact or low-level inhalation.

24 942. Even though the 1988 Mineworkers SRI conclusively corroborated Bayer's 1979
25 Skin Contact SRI and the 1982 Japanese Skin Contact SRI, Bayer refused to report any of these
26 previously-obtained items of substantial risk information. Bayer's failure to report in these
27
28

1 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
2 risk information from the EPA.

3 943. Even though the 1988 Mineworkers SRI conclusively corroborated the 1982
4 Japanese Skin Contact SRI, Dow refused to report this previously-obtained substantial risk
5 information. Dow's failure to report in these circumstances demonstrates that its failure was
6 willful and calculated to conceal the substantial risk information from the EPA.

7 944. In or shortly after March 1989, BASF, Bayer, Dow, and Huntsman obtained or
8 developed the 1989 Human Cases SRI and the 1989 German Mine SRI, each of which comprised
9 data of human subjects whose confirmed MDI respiratory sensitization appeared to have been
10 caused either by MDI skin contact or low-level inhalation.

11 945. Even through the 1989 Human Cases SRI and the 1989 German Mine SRI each
12 corroborated the other and were reported to the defendants concurrently, each of the defendants
13 refused to report the substantial risk information. Each defendant's failure to report in these
14 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
15 risk information from the EPA.

16 946. Further, even though the 1989 Human Cases SRI and the 1989 German Mine SRI
17 each corroborated separate items of substantial risk information that each defendant had
18 previously obtained, each defendant refused to report the previously-obtained substantial risk
19 information. Bayer refused to report Bayer's 1979 Skin Contact SRI, the 1982 Japanese Skin
20 Contact SRI, and the 1988 Mineworkers SRI. Dow refused to report the 1982 Japanese Skin
21 Contact SRI and the 1988 Mineworkers SRI. BASF and Huntsman each refused to report the
22 1988 Mineworkers SRI.

23 947. Each defendant's failure to report in these circumstances demonstrates that its
24 failure was willful and calculated to conceal the substantial risk information from the EPA.

25 948. In or shortly after March 1989, each defendant obtained the 1989 Nakata Papers
26 SRI, which comprised several papers that analyzed medical and industrial hygiene data and
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1 determined, based on that analysis, an apparent causal relationship between documented MDI
2 skin contact and confirmed human cases of MDI respiratory sensitization.

3 949. Even though the 1989 Nakata Papers SRI corroborated separate items of
4 substantial risk information that each defendant had previously obtained, each defendant refused
5 to report the previously-obtained substantial risk information. Bayer refused to report Bayer's
6 1979 Skin Contact SRI, the 1982 Japanese Skin Contact SRI, the 1988 Mineworkers SRI, the
7 1989 Human Cases SRI, and the 1989 German Mine SRI. Dow refused to report the 1982
8 Japanese Skin Contact SRI, the 1988 Mineworkers SRI, the 1989 Human Cases SRI, and the
9 1989 German Mine SRI. BASF and Huntsman each refused to report the 1988 Mineworkers
10 SRI, the 1989 Human Cases SRI, and the 1989 German Mine SRI.

11 950. Each defendant's failure to report in these circumstances demonstrates that its
12 failure was willful and calculated to conceal the substantial risk information from the EPA.

13 951. As alleged thoroughly above, on February 1, 1991, the EPA announced CAP, a
14 program essentially operated as an amnesty for prior TSCA Section 8(e) reporting violations.

15 952. As companies regulated by the EPA under TSCA and other statutes, BASF,
16 Bayer, Dow, and Huntsman each knew or should have known that the EPA instituted CAP based
17 on its observation that regulated companies had been failing to report information that the EPA
18 viewed as reportable under Section 8(e). CAP Agreement, Exh. 26, 56 Fed. Reg. at 4128, Unit I,
19 Background. Further, each defendant knew or should have known that, "to achieve the Agency's
20 goal of obtaining any outstanding section 8(e) data, EPA has developed this one-time voluntary
21 compliance program designed to strongly encourage companies to voluntarily audit their files for
22 studies reportable under section 8(e)." *Id.* at 4129.

23 953. Each defendant knew or should have known EPA's position on companies that
24 failed to participate in CAP: "Companies that do not participate in the TSCA Section 8(e)
25 Compliance Audit Program should be aware that EPA intends to actively pursue violations of the
26 TSCA section 8(e) reporting requirement." *Id.*, Exh. 26, 56 Fed. Reg. at 4129, Unit I.

1 954. Even if a defendant did not participate in CAP, its failure to report its previously-
2 obtained substantial risk information in these circumstances demonstrates that its failure was
3 willful and calculated to conceal the substantial risk information from the EPA.

4 955. Each defendant knew or should have known EPA's position on companies that
5 participated in CAP but failed to comply with CAP's contractual auditing and reporting
6 obligations:

7 EPA reserves its rights under TSCA section 16 to take appropriate enforcement
8 action if EPA determines later that the Regulatee was required to submit under
9 TSCA section 8(e) a study or report determined by the Regulatee to be not
10 reportable and therefore not submitted under the TSCA Section 8(e) Compliance
11 Audit Program. In such event, the terms of the EPA TSCA Sections 8, 12, and 13
12 Enforcement Response Policy will apply to such proceeding.

13 *Id.*, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.

14 956. In their respective contracts with the EPA, each defendant agreed and was
15 contractually required to audit its substantial risk reporting compliance and to submit all
16 previously unsubmitted substantial risk information, in return for which the EPA agreed to
17 reduce significantly the reporting penalties for each submitted report, and to cap the total
18 reporting penalties for all previously unsubmitted information at \$1 million. CAP Agreement,
19 Exh. 26, 56 Fed. Reg. at 4129-4130, Section II.B.1 – II.B.3.

20 957. In their respective contracts with the EPA, each defendant agreed and was
21 contractually required to certify its completion of the audit program at the program's conclusion.
22 CAP Agreement, Exh. 26, 56 Fed. Reg. at 4130, Section II.B.4.

23 958. In their respective contracts with the EPA, each defendant agreed that its failure to
24 comply with its contractual obligations would authorize the EPA to impose full penalties for any
25 substantial risk information it had submitted under CAP and received a reduced or "capped"
26 amnesty penalty. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4130, Section II.D.4.

27 959. In their respective contracts with the EPA, each defendant agreed that its failure to
28 comply with its contractual obligations would authorize the EPA to pursue full penalties for the

1 company's failure to submit substantial risk information that it should have submitted under the
2 CAP Agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Section II.A.5.

3 960. BASF's failure to report its previously-obtained substantial risk information in
4 these circumstances demonstrates that its failure was willful and calculated to conceal the
5 substantial risk information from the EPA.

6 961. Bayer's failure to report its previously-obtained substantial risk information in
7 these circumstances demonstrates that its failure was willful and calculated to conceal the
8 substantial risk information from the EPA.

9 962. Dow's failure to report its previously-obtained substantial risk information in
10 these circumstances demonstrates that its failure was willful and calculated to conceal the
11 substantial risk information from the EPA.

12 963. Huntsman's failure to report its previously-obtained substantial risk information
13 in these circumstances demonstrates that its failure was willful and calculated to conceal the
14 substantial risk information from the EPA.

15 964. In March 1992, each defendant obtained the 1992 Human Cases SRI, which
16 comprised underlying medical and industrial hygiene data from which various III member
17 companies had concluded a "likely" causal relationship between documented MDI skin contact
18 and confirmed human cases of MDI respiratory sensitization.

19 965. Even though the 1992 Human Cases SRI corroborated separate items of
20 substantial risk information that each defendant had previously obtained, each defendant refused
21 to report the previously-obtained substantial risk information. Bayer refused to report Bayer's
22 1979 Skin Contact SRI, the 1982 Japanese Skin Contact SRI, the 1988 Mineworkers SRI, the
23 1989 Human Cases SRI, the 1989 German Mine SRI, and the 1989 Nakata Papers SRI. Dow
24 refused to report the 1982 Japanese Skin Contact SRI, the 1988 Mineworkers SRI, the 1989
25 Human Cases SRI, the 1989 German Mine SRI, and the 1989 Nakata Papers SRI. BASF and
26 Huntsman each refused to report the 1988 Mineworkers SRI, the 1989 Human Cases SRI, the
27 1989 German Mine SRI, and the 1989 Nakata Papers SRI.
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1 966. Each defendant's failure to report in these circumstances demonstrates that its
2 failure was willful and calculated to conceal the substantial risk information from the EPA.

3 967. In April 1992, each defendant obtained the 1992 Specific Scenario SRI, which
4 comprised underlying medical and industrial hygiene data reported to the III's Board of
5 Directors as indicating an apparent causal relationship between confirmed human cases of MDI
6 respiratory sensitization and either MDI skin contact or inhalation of "extremely low exposures
7 of airborne MDI."

8 968. Even though the 1992 Specific Scenario SRI corroborated separate items of
9 substantial risk information that each defendant had previously obtained, each defendant refused
10 to report the previously-obtained substantial risk information. Bayer refused to report Bayer's
11 1979 Skin Contact SRI, the 1982 Japanese Skin Contact SRI, the 1988 Mineworkers SRI, the
12 1989 Human Cases SRI, the 1989 German Mine SRI, the 1989 Nakata Papers SRI, and the 1992
13 Human Cases SRI. Dow refused to report the 1982 Japanese Skin Contact SRI, the 1988
14 Mineworkers SRI, the 1989 Human Cases SRI, the 1989 German Mine SRI, the 1989 Nakata
15 Papers SRI, and the 1992 Human Cases SRI. BASF and Huntsman each refused to report the
16 1988 Mineworkers SRI, the 1989 Human Cases SRI, the 1989 German Mine SRI, the 1989
17 Nakata Papers SRI, and the 1992 Human Cases SRI.

18 969. Each defendant's failure to report in these circumstances demonstrates that its
19 failure was willful and calculated to conceal the substantial risk information from the EPA.

20 970. In or shortly after April 1993, each defendant obtained the 1993 Especial Work
21 Situation SRI, which comprised underlying medical and industrial hygiene data reported to the
22 III's Board of Directors as indicating a causal relationship between confirmed human cases of
23 MDI respiratory sensitization and either MDI skin contact or inhalation of "extremely low"
24 inhalation exposures.

25 971. Even though the 1993 Especial Work Situation SRI corroborated separate items
26 of substantial risk information that each defendant had previously obtained, each defendant
27 refused to report the previously-obtained substantial risk information. Bayer refused to report
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1 Bayer's 1979 Skin Contact SRI, the 1982 Japanese Skin Contact SRI, the 1988 Mineworkers
2 SRI, the 1989 Human Cases SRI, the 1989 German Mine SRI, the 1989 Nakata Papers SRI, the
3 1992 Human Cases SRI, and the 1992 Specific Scenario SRI. Dow refused to report the 1982
4 Japanese Skin Contact SRI, the 1988 Mineworkers SRI, the 1989 Human Cases SRI, the 1989
5 German Mine SRI, the 1989 Nakata Papers SRI, the 1992 Human Cases SRI, and the 1992
6 Specific Scenario SRI. BASF and Huntsman each refused to report the 1988 Mineworkers SRI,
7 the 1989 Human Cases SRI, the 1989 German Mine SRI, the 1989 Nakata Papers SRI, the 1992
8 Human Cases SRI, and the 1992 Specific Scenario SRI.

9 972. Each defendant's failure to report in these circumstances demonstrates that its
10 failure was willful and calculated to conceal the substantial risk information from the EPA.

11 973. In or shortly after April 1994, each defendant received the III Scientific Director's
12 1994 Report to the Board. Report to Board, 1994, Exh. 30, BASF040133-040186. The III's
13 Scientific Director distributed the 1994 Report to the Board in April 1994. *Id.*, Exh. 30 at BASF-
14 040134. All four defendants had representatives on the III Board of Directors in April 1994.
15 April 1994 III Organizational Chart, Exh. 31, BASF-038843-038844, at 038844. And all four
16 defendants still had a representative on the III Board of Directors as of July 11, 1994. July 11,
17 1994 III Organizational Chart, Exh. 32, BASF-038863-038864 at 038864. Accordingly, each
18 defendant received the 1994 Report to the III Board through the representative it had appointed
19 to represent it on the III's Board of Directors.

20 974. Section 2.4.2 of the 1994 Report to the III Board is entitled "Respiratory Effects."
21 *Id.*, Exh. 30 at BASF-040154-140158. Under the first subheading "Acute respiratory effects of
22 MDI and TDI" (*id.* at BASF-040154), the III's Scientific Director reported to the III Board of
23 Directors as follows:

24 Studies on acute respiratory effects associated with skin (only) exposure continue.
25 These were established by the Institute, to explore the sensitization of individuals
26 who had apparently had only exceptionally low lung exposure to MDI.

27 *Id.*, Exh. 30 at BASF-040156 (emphasis in original).
28

1 975. When BASF, Bayer, Dow, and Huntsman each received the 1994 Report to the III
2 Board in or shortly after April 1994, this statement provided either a new item of reportable
3 substantial risk information or, at a minimum, a reminder that each had previously received
4 substantial risk information comprised of data concerning human cases of MDI or PMDI
5 respiratory sensitization caused either by MDI skin contact or low-level inhalation.

6 976. Each defendant's failure to report in these circumstances demonstrates that its
7 failure was willful and calculated to conceal the substantial risk information from the EPA.

8 977. The III's Scientific Director also provided the defendants with information about
9 human cases of TDI respiratory sensitization resulting either from TDI skin contact or low-level
10 inhalation:

11 Allport has drafted his analysis of levels of sensitization found in the Clark study
12 of the UK flexible foam industry [TDI], re-exploring the raw data. He used a
13 more meaningful criterion than the original authors. . . . It was noted that
14 sensitization was found in some subjects who had apparently had minimal
15 exposure.

16 Studies on acute respiratory effects associated with skin (only) exposure continue.
17 These were established by the Institute, to explore the sensitization of individuals
18 who had apparently had only exceptionally low lung exposure to MDI. *A similar*
19 *observation amongst TDI workers may also be relevant (see above).*

20 1994 Report to III Board, Exh. 30 at BASF-040156 (underline emphasis in original, italics
21 added).

22 978. When BASF, Bayer, Dow, and Huntsman each received the 1994 Report to the III
23 Board in or shortly after April 1994, this statement provided either a new item of reportable
24 substantial risk information or, at a minimum, a reminder that each had previously received
25 substantial risk information comprised of data concerning human cases of isocyanate respiratory
26 sensitization caused either by isocyanate skin contact or low-level inhalation.

27 979. Each defendant's failure to report previously-obtained substantial risk information
28 in these circumstances demonstrates that its failure was willful and calculated to conceal the
substantial risk information from the EPA.

1 980. EPA terminated CAP on May 15, 1996, “reached final settlements with CAP
2 participants, announced those settlements on October 15, 1996, and collected payment for
3 stipulated penalties.” 2003 TSCA Guidance Revisions, 68 Fed. Reg. at 33131, Unit II.D.

4 981. When EPA terminated the CAP program and began reaching final settlements
5 with the participating companies, BASF, Bayer, Dow, and Huntsman each knew or should have
6 known that its failure to submit all previously-obtained but unsubmitted substantial risk
7 information would breach its contractual obligation to the EPA and subject it to substantial
8 penalties.

9 982. Each defendant’s failure to report previously-obtained substantial risk information
10 in these circumstances demonstrates that its failure was willful and calculated to conceal the
11 substantial risk information from the EPA.

12 983. By June 2001, each defendant had obtained information that one drop (50
13 microliters) of isocyanate on the skin, even assuming a 1% absorption rate, would create
14 systemic exposure comparable to “4 hours at the [20 ppb] PEL.” See April 5, 2001 internal Dow
15 e-mail, Bice/Dow73220-73221 at 73220, Exh. 68; June 13, 2001 e-mail to representatives of
16 BASF, Bayer, Dow, and Huntsman, BASF-57083-57086 at 57085, Exh. 69.; April 30, 2008
17 Deposition of Dow through its Rule 30(b)(6) witness Mark Spence at 510-511, Exh. 70 (Dow-
18 Spence Depo).

19 984. Thus, by June 2001, and almost certainly well before that date, BASF, Bayer,
20 Dow, and Huntsman knew that very slight skin exposures to isocyanates could represent a
21 greater health-effect hazard than high-level inhalation exposures. Each defendant’s receipt or
22 development of this information represented either a new item of reportable substantial risk
23 information or, at a minimum, a reminder that each had previously received substantial risk
24 information comprised of data concerning human cases of isocyanate respiratory sensitization
25 caused either by isocyanate skin contact or low-level inhalation. Further the “one-drop”
26 information should have provided each defendant with a heightened awareness of the
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1 significance of the dermal-induction health effect substantial risk information each had
2 previously obtained or developed.

3 985. Each defendant's failure to report previously-obtained substantial risk information
4 in these circumstances demonstrates that its failure was willful and calculated to conceal the
5 substantial risk information from the EPA

6 986. In or shortly after January 2003, each defendant obtained the 2003 Isocyanate
7 Asthma SRI, which comprised underlying medical and industrial hygiene data, stored by the III
8 and available to its member companies on its intranet, that excluded the inhalation exposure
9 route as the cause of confirmed cases of isocyanate asthma, and therefore implicated the dermal
10 exposure route.

11 987. During the meeting at which the 2003 Isocyanate Asthma SRI was reported, the
12 defendants' representatives who attended the meeting discussed that "[w]e *continue* to see cases
13 of isocyanate asthma," indicating that the recent cases of dermally-induced isocyanate asthma
14 were consistent with prior such cases. *Id.*, Exh. 25 at III(Bice)019839 (emphasis added).
15 Indeed, the minutes suggest that the III member companies had accumulated these "extensive"
16 files over a period of time during which they "continue[d] to see" these cases of dermally-
17 induced isocyanate asthma. The "extensive" files may well have comprised all or a significant
18 part of the earlier-obtained substantial risk information, including the 1982 Japanese Skin
19 Contact SRI, the 1988 Mineworkers SRI, the 1989 Human Cases SRI, the 1989 German Mine
20 SRI, the 1989 Nakata Papers SRI, the 1992 Human Cases SRI, the 1992 Specific Scenario SRI,
21 and the 1993 Especial Work Situation SRI.

22 988. Each defendant's receipt (or reminder) of knowledge that the III member
23 companies possessed extensive files of data that corroborated the dermal- or low-level-induction
24 of respiratory sensitization or pulmonary injury should have prompted each to report the
25 substantial risk information it had previously obtained or developed.

1 989. Even though the 2003 Isocyanate Asthma SRI corroborated separate items of
2 substantial risk information that each defendant had previously obtained, each defendant refused
3 to report the previously-obtained substantial risk information.

4 990. Bayer refused to report Bayer's 1979 Skin Contact SRI, the 1982 Japanese Skin
5 Contact SRI, the 1988 Mineworkers SRI, the 1989 Human Cases SRI, the 1989 German Mine
6 SRI, the 1989 Nakata Papers SRI, the 1992 Human Cases SRI, the 1992 Specific Scenario SRI,
7 and the 1993 Especial Work Situation SRI.

8 991. Dow refused to report the 1982 Japanese Skin Contact SRI, the 1988
9 Mineworkers SRI, the 1989 Human Cases SRI, the 1989 German Mine SRI, the 1989 Nakata
10 Papers SRI, the 1992 Human Cases SRI, the 1992 Specific Scenario SRI, and the 1993 Especial
11 Work Situation SRI.

12 992. BASF and Huntsman each refused to report the 1988 Mineworkers SRI, the 1989
13 Human Cases SRI, the 1989 German Mine SRI, the 1989 Nakata Papers SRI, the 1992 Human
14 Cases SRI, the 1992 Specific Scenario SRI, and the 1993 Especial Work Situation SRI.

15 993. Each defendant's failure to report previously-obtained substantial risk information
16 in these circumstances demonstrates that its failure was willful and calculated to conceal the
17 substantial risk information from the EPA.

18 994. In April 2011, the EPA expressed its heightened interest in MDI and related
19 chemicals by issuing an "MDI Action Plan," in which it proposed increased scrutiny of MDI to
20 address its concerns about the chemical, and in particular "the potential health effects that may
21 result from exposures to the consumer or self-employed worker." MDI Action Plan at 1.

22 995. Although the EPA expressed concern about potential isocyanate health effects, it
23 characterized the potential for respiratory injury from skin exposure as uncertain. While
24 acknowledging several published reports in which respiratory injury had occurred where the
25 airborne exposure was either below established exposure levels, undetected with the measuring
26 systems used, or unmeasured (studies that these defendants have long criticized) (*id.* at 6), the
27 EPA cited to recent scientific articles in which "[b]oth inhalation and dermal exposures to
28

1 isocyanates *are thought to contribute* to the development of isocyanate asthma” (*id.* at 5
2 (emphasis added)). In contrast to this uncertain human data, the EPA noted that MDI “*is a*
3 respiratory sensitizer via both the dermal and inhalation routes of exposure in animals.” *Id.*
4 (emphasis added).

5 996. To address its concerns, the EPA stated its intention to take several actions. First,
6 it stated that it would “[i]ssue a data call-in” under various TSCA regulations to obtain
7 “allegations of significant adverse effects” and “one-time reporting of relevant unpublished
8 health and safety studies for uncured MDI.” *Id.* at 10. The EPA also stated that it would
9 consider requiring the industry to conduct exposure monitoring studies in both the consumer and
10 commercial settings. *Id.*

11 997. Based on the EPA’s April 2011 issuance of the MDI Action Plan, BASF, Bayer,
12 Dow, and Huntsman knew or should have known at or around that time of the EPA’s stated
13 interest in the health effects of MDI, including its interest in human data related to the potential
14 dermal induction of respiratory sensitization.

15 998. Each defendant’s failure to report previously-obtained substantial risk information
16 in these circumstances demonstrates that its failure was willful and calculated to conceal the
17 substantial risk information from the EPA.

18 999. Instead of reporting previously-obtained substantial risk information, on February
19 26, 2013, each defendant submitted comments to the EPA’s proposed MDI Action Plan through
20 the ACC. Feb. 26, 2013 ACC Comments to MDI Action Plan, Exh. 3. Disputing the EPA’s
21 statement in the MDI Action Plan that “[b]oth inhalation and dermal exposures to diisocyanates
22 are thought to contribute to the development of isocyanate asthma” (*id.* at 9, Exh. 3), each
23 defendant contended “the role that dermal contact with diisocyanates plays in the development of
24 occupational asthma remains unresolved for humans.” *Id.* at 10, Exh. 3.

25 1000. This statement directly contradicted the substantial risk information that each
26 defendant has failed to report and continues to conceal. By making this statement, each
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1 defendant falsely implied that no other human data existed and falsely denied the existence of the
2 substantial risk information it was concealing.

3 1001. By making this statement, each defendant demonstrated its intent to conceal the
4 substantial risk information from the EPA.

5 1002. Based on the EPA's April 2011 issuance of the MDI Action Plan, BASF, Bayer,
6 Dow, and Huntsman knew or should have known at or around that time of the EPA's stated
7 interest in the health effects of MDI, "the potential health effects that may result from exposures
8 to the consumer or self-employed worker." MDI Action Plan at 1. Those types of exposures
9 necessarily included inhalation exposures at concentrations below the regulatory or
10 recommended limits.

11 1003. But each defendant concealed their substantial risk information about the low-
12 level-inhalation-induction health effect, and instead falsely represented to the EPA that low-level
13 exposures were safe. In their comments to the EPA's MDI Action Plan, each defendant disputed
14 the EPA's statement in the MDI Action Plan that "[b]oth inhalation and dermal exposures to
15 diisocyanates are thought to contribute to the development of isocyanate asthma" (Feb. 26, 2013
16 ACC Comments to MDI Action Plan at 9, Exh. 3). In commenting on that statement, each
17 defendant represented to the EPA: "The ability of diisocyanates to induce respiratory
18 sensitization in some individuals, and asthma in some cases, is a known potential adverse health
19 effect in humans *after exposure to concentrations above workplace exposure limits.*" *Id.* at 10
20 (emphasis added), Exh. 3.

21 1004. As alleged thoroughly above, in February 2013 each defendant possessed
22 substantial risk information about the low-level-inhalation health effect. By omitting this
23 information from their 2013 comments to the EPA's MDI Action Plan, BASF, Bayer, Dow, and
24 Huntsman each represented to the EPA that they neither possessed nor were aware of substantial
25 risk information about the low-level-inhalation health effect. By making such a false
26 representation to the EPA, each defendant falsely implied that no other human data existed and
27 falsely denied the existence of the substantial risk information it was concealing.

1005. By making this statement, each defendant demonstrated its intent to conceal the substantial risk information from the EPA.

1006. The defendants' statement also misleadingly implies that exposures below the "workplace exposure limits" did not have the ability to "induce respiratory sensitization," in direct contradiction to the substantial risk information that each defendant has failed to report and continues to conceal.

1007. By making this misleading representation and continuing to conceal the substantial risk information about the low-level-inhalation-induction health effect, each defendant demonstrated its intent to conceal the substantial risk information from the EPA.

B. Each defendant demonstrated its intention to conceal the SRI by its refusal to report the SRI even as it reported similar but less certain animal data.

1008. On February 6, 1990, ICI Americas, Huntsman's predecessor-in-interest, submitted Dr. Phil Botham's paper, "Animal Models for Predicting Hypersensitivity Reactions to Small Molecules," as well as a document entitled, "Table 1, Serological, pulmonary and dermal responses in Guinea Pigs injected intradermally with MDI." ICI Americas' February 6, 1990 Section 8(e) Submission, Bice/Dow12242-12265, Exh. 33. ICI Americas stated in its submission:

Data on MDI, shown in Table 1, indicated that MDI injected intradermally in guinea pigs can elicit a sensitization reaction including pulmonary response as measured by respiratory rate. While it is well known that inhalation of MDI can induce pulmonary sensitization in animal models and humans, *these animal data on intradermal injections indicate new information regarding route of exposure.*

Id., Exh. 33 at Bice/Dow12242 (emphasis added).

1009. On February 9, 1990, ICI Americas forwarded its Section 8(e) submission to the "AM-AB Subcommittee Members." February 9, 1990 Memorandum, BAY018458-018459, Exh. 34.

1010. As of January 30, 1990, the III's AM-AB Sub-Committee included representatives of BASF, Mobay (Bayer's predecessor-in-interest), Dow, and ICI Americas (Huntsman's predecessor-in-interest). Minutes of the January 30, 1990 meeting of the III AM-

1 AB Sub-Committee, Exh. 35, BASF-028583-028592 at 028590-028591. Thus, BASF, Bayer,
 2 and Dow each received a copy of ICI Americas' February 6, 1990 Section 8(e) submission
 3 through its representative on the sub-committee.

4 1011. As of February 6, 1990, each of these defendants had obtained or developed
 5 multiple separate items of substantial risk information that indicated that either skin contact with
 6 or low-level inhalation of MDI or PMDI could cause or had caused respiratory sensitization or
 7 pulmonary injury. Specifically, each defendant had separately obtained or developed:

- 8 a. 1988 Mineworkers SRI, which comprised cases of human respiratory
 9 sensitization conclusively caused either by MDI skin contact or low-level
 10 inhalation;
- 11 b. 1989 Human Cases SRI, which comprised "evidence" relating to multiple
 12 "cases," plural, of MDI respiratory sensitization in humans, caused by MDI
 13 exposure in what appeared to be a low-level ("negligible") inhalation
 14 exposure environment;
- 15 c. 1989 German Mine SRI, which comprised information relating to multiple
 16 "situations," plural, of "MDI respiratory sensitization" in humans, caused
 17 either by MDI skin contact or by low-level ("inordinately low") MDI
 18 inhalation exposure; and
- 19 d. 1989 Nakata Papers SRI, which comprised several papers that analyzed
 20 medical and industrial hygiene data and determined, based on that analysis,
 21 an apparent causal relationship between documented MDI skin contact and
 22 confirmed human cases of MDI respiratory sensitization;
 23

24 1012. Additionally, Bayer had also obtained or developed:

- 25 a. Bayer's 1979 Skin Contact SRI, which comprised information
 26 communicated in training by Bayer's industrial hygienists that skin contact
 27

1 with MDI could cause respiratory sensitization and reduced lung function;
2 and

- 3 b. 1982 Japanese Skin Contact SRI, which comprised analysis relevant to
4 whether TDI or MDI skin absorption can cause pulmonary sensitization.
5

6 1013. Additionally, BASF had obtained or developed the 1982 Japanese Skin Contact
7 SRI.

8 1014. By stating in its February 6, 1990 Section 8(e) submission that “these animal data
9 on intradermal injections indicate new information regarding route of exposure,” ICI Americas
10 demonstrated its knowledge that the substantial risk information set out above, which it had
11 obtained or developed prior to submitting the animal data, was reportable Section 8(e)
12 information because it, too, “indicate[d] new information regarding route of exposure,” but in
13 humans rather than animals. ICI Americas’ February 6, 1990 Section 8(e) Submission, Exh. 33
14 at Bice/Dow12242.

15 1015. ICI Americas’ failure to report previously-obtained substantial risk information in
16 these circumstances demonstrates that its failure was willful and calculated to conceal the
17 substantial risk information from the EPA.

18 1016. When BASF, Bayer, and Dow each received its copy of ICI Americas February
19 6, 1990 Section 8(e) Submission, they knew or should have known that the substantial risk
20 information set out above, which it had obtained or developed prior to submitting the animal
21 data, was reportable Section 8(e) information because it, too, “indicate[d] new information
22 regarding route of exposure,” but in humans rather than animals. ICI Americas’ February 6,
23 1990 Section 8(e) Submission, Exh. 33 at Bice/Dow12242.

24 1017. BASF’s failure to report previously-obtained substantial risk information in these
25 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
26 risk information from the EPA.
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1 1018. Bayer's failure to report previously-obtained substantial risk information in these
2 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
3 risk information from the EPA.

4 1019. Dow's failure to report previously-obtained substantial risk information in these
5 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
6 risk information from the EPA.

7 1020. On October 29, 1991, ICI Americas submitted to EPA under TSCA Section 8(e)
8 an abstract that reported "some results from a study conducted at the Fraunhofer Institute of
9 Toxicology and Aerosol Research, Hannover, Germany." ICI Americas' October 29, 1991
10 Section 8(e) Submission, Exh. 36, BAY018360-018361 at 018360. BASF, Bayer, and Dow each
11 received a copy of ICI Americas' submission shortly after ICI Americas submitted it, as each
12 produced a copy of the document during the *Bice* case.

13 1021. ICI Americas stated in its submission:

14 We have reviewed our product literature and believe the present TLV for MDI
15 (0.05 mg/m³) offers sufficient protection against long terms and short term
16 effects.

17 *Id.*, Exh. 36 at BAY018361.

18 1022. As alleged thoroughly above, by October 29, 1991 each of these defendants had
19 obtained or developed multiple separate items of substantial risk information that indicated that
20 either skin contact with or low-level inhalation of MDI or PMDI could cause or had caused
21 respiratory sensitization or pulmonary injury.

22 1023. ICI America's statement that it "believe[s] the present TLV for MDI (0.05
23 mg/m³) offers sufficient protection against long terms and short term effects," is directly contrary
24 to the substantial risk information it had received. Indeed, ICI Americas made this statement
25 while possessing knowledge of numerous different cases in which either low-level inhalation of
26 or skin contact with MDI had caused respiratory sensitization or pulmonary injury.

1 1024. This statement directly contradicted the substantial risk information that ICI
2 Americas had failed to report and continues to conceal. By making this statement, ICI Americas
3 falsely implied that no human data of low-level inhalation injury existed and falsely denied the
4 existence of the substantial risk information it was concealing.

5 1025. By making this statement, ICI Americas demonstrated its intent to conceal the
6 substantial risk information from the EPA.

7 1026. When BASF, Bayer, and Dow each received ICI Americas' October 29, 1991
8 Section 8(e) Submission, it knew or reasonably should have known that ICI America's statement
9 that it "believe[s] the present TLV for MDI (0.05 mg/m³) offers sufficient protection against long
10 terms and short term effects," was directly contrary to the substantial risk information it had
11 received. Indeed, BASF, Bayer, and Dow possessed knowledge of numerous different cases in
12 which either low-level inhalation of or skin contact with MDI had caused respiratory
13 sensitization or pulmonary injury.

14 1027. This statement should have prompted BASF, Bayer, and Dow each to report the
15 substantial risk information that they possessed and knew directly contradicted ICI Americas'
16 statement to the EPA.

17 1028. BASF's failure to report previously-obtained substantial risk information in these
18 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
19 risk information from the EPA.

20 1029. Bayer's failure to report previously-obtained substantial risk information in these
21 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
22 risk information from the EPA.

23 1030. Dow's failure to report previously-obtained substantial risk information in these
24 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
25 risk information from the EPA.

26 1031. On June 11, 1992, on behalf of its member companies including BASF, Bayer,
27 Dow, and Huntsman, the III submitted to EPA under TSCA Section 8(e) findings from a III
28

1 animal study. The III Managing Director stated in his submission that the data from the study
2 “indicate that respiratory hypersensitivity in guinea pigs may result from dermal exposure to
3 MDI.” III June 11, 1992 Section 8(e) Submission, Exh. 16, Bice/Dow12306.

4 1032. At the time that BASF, Bayer, Dow, and Huntsman submitted these findings to
5 the EPA through the III, each had previously obtained or developed the extensive substantial risk
6 information as set out above, indicating that either skin contact with or low-level inhalation of
7 MDI or PMDI could cause or had caused respiratory sensitization or pulmonary injury.
8 Furthermore, in the three months prior to the III’s submission, each defendant had just obtained
9 or developed two additional and separate items of substantial risk information:

- 10 a. 1992 Human Cases SRI, which comprised underlying medical and industrial
11 hygiene data from which various III member companies had concluded a
12 “likely” causal relationship between documented MDI skin contact and
13 confirmed human cases of MDI respiratory sensitization; and
- 14 b. 1992 Specific Scenario SRI, which comprised underlying medical and
15 industrial hygiene data reported to the III’s Board of Directors as indicating
16 an apparent causal relationship between confirmed human cases of MDI
17 respiratory sensitization and either MDI skin contact or inhalation of
18 “extremely low exposures of airborne MDI.”
19

20 1033. During the six months prior to submitting the III June 11, 1992 Section 8(e)
21 Submission, BASF, Bayer, Dow, and Huntsman each failed to report information about *human*
22 cases in which certain III member companies had determined that “dermal contact *was the likely*
23 *source* of human sensitisation to MDI.” 1992 Human Cases SRI, January 16, 1992 EU-MTX
24 meeting minutes, Exh. 15 at III(Bice)009472 (emphasis added). Each defendant’s failure to
25 report the “likely” dermal induction of respiratory sensitization in *humans* even as they reported
26 the *possible* dermal induction of respiratory hypersensitivity in *animals*, demonstrates that its
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1 failure to report was willful and was calculated to conceal the previously-obtained substantial
2 risk information from the EPA.

3 1034. The III June 11, 1992 Section 8(e) Submission demonstrates that each defendant
4 knew or reasonably should have known that the reports it had previously obtained or developed,
5 concerning multiple humans who appeared to have sustained MDI respiratory sensitization from
6 skin contact, were reportable under TSCA Section 8(e).

7 1035. BASF's failure to report previously-obtained substantial risk information in these
8 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
9 risk information from the EPA.

10 1036. Bayer's failure to report previously-obtained substantial risk information in these
11 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
12 risk information from the EPA.

13 1037. Dow's failure to report previously-obtained substantial risk information in these
14 circumstances demonstrates that its failure was willful and calculated to conceal the substantial
15 risk information from the EPA.

16 1038. Huntsman's failure to report previously-obtained substantial risk information in
17 these circumstances demonstrates that its failure was willful and calculated to conceal the
18 substantial risk information from the EPA.

19 **C. Each defendant demonstrated its intention to conceal the SRI when, individually**
20 **and in conspiracy, it issued health-effect disclosures in its MSDSs and labels that**
implicitly or explicitly denied the existence of the SRI it was concealing.

21 **a. Each defendant agreed to harmonize its health-effects disclosures with**
22 **the disclosures of the other defendants.**

23 1039. A Material Safety Data Sheet (MSDS) is a hazard communication document that
24 the federal Hazard Communication Standard (HazCom) requires each chemical manufacturer
25 and importer to develop or obtain for each hazardous chemical it produces or imports. Hazard
26 Communication Standard, 29 CFR § 1910.1200(g). HazCom requires that the MSDS (now
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1 called simply an SDS) disclose the chemical's hazards and the appropriate protective measures
2 to avoid those hazards. *Id.* at Appendix D, Table D.1, Headings 2 and 8.

3 1040. On May 1, 1980, BASF, Bayer, Dow, and other III member companies
4 "recommended" to the American III members that they exclude from their MSDSs for PMDI
5 certain specific hazard information about the toxic effects of PMDI exposure. April 30, 2008
6 Deposition of Dow through its Rule 30(b)(6) witness Mark Spence (Dow-Spence Depo) at 136,
7 138-142, Exh. 37.

8 1041. BASF, Dow, and Mobay, Bayer's predecessor-in-interest, had representatives on
9 this sub-committee when it issued this recommendation. *Id.*, Exh. 37 at 141-142.

10 1042. Thus, in May 1980, BASF, Bayer, and Dow each recommended, through the III
11 North American Transportation and Handling Sub-Committee, that American III member
12 companies harmonize certain health-effects disclosures in their respective isocyanate MSDSs.

13 1043. During the 1980s and 1990s, BASF, Bayer, Dow, and Huntsman continued to
14 cooperate in harmonizing the language they would use in disclosing—or rather concealing—
15 various health effects in their TDI, MDI, and PMDI MSDSs.

16 1044. On January 19, 1982, the III North American Transportation and Handling Sub-
17 Committee discussed its review of "label information from the major producers." Minutes of the
18 January 19, 1982 meeting of the III North American Transportation and Handling Sub-
19 Committee, Exh. 38, III(Bice)003009-003013 at 003012, Item III.C. After expressing concern
20 about how "most labels" disclosed a particular health effect, the sub-committee reached a
21 decision:

22 It was recommended that the safety committee, toxicology, and health committees
23 should review this item. The transportation committee suggested use of words
24 and general format of the Mobay label.

25 *Id.*, Exh. 38 at 003012, Item III.C.

26 1045. BASF and Dow had representatives on this sub-committee when it issued this
27 recommendation. *Id.*, Exh. 38 at 003010.
28

1 1046. Thus, in January 1982, BASF and Dow, through the North American
2 Transportation and Handling Sub-Committee, recommended that American III member
3 companies harmonize certain health-effects disclosures in their isocyanate product labels.

4 1047. Through the sub-committee, BASF and Dow also recommended that the III
5 member companies thoroughly vet the content of member companies' health-effects disclosures
6 in several different III committees ("safety committee, toxicology, and health committees"),
7 some with international membership. *Id.*, Exh. 38 at 003012.

8 1048. On August 25, 1982, members of the III's North American Environmental
9 Committee meeting heard a report from BASF's Bob Drake about the Transportation and
10 Handling Sub-Committee's continuing MSDS- harmonization activities. Mr. Drake reported:
11 '*Material Safety and Data' sheets will be traded among member companies to*
12 *assure that the environmental sections contain information that is current and*
13 *complete.*

14 Minutes of the August 25, 1982 meeting of the III North American Environmental Committee,
15 Exh. 39, III(Bice)003279-003283 at 03280 (emphasis added).

16 1049. BASF, Dow, and Mobay, Bayer's predecessor-in-interest, each had a
17 representative present at the III's North American Environmental Committee's August 25, 1982
18 meeting, and each of those defendants received this report about the harmonization efforts. *Id.*,
19 Exh. 39 at III(Bice)003280.

20 1050. Thus, in August 1982, BASF, Bayer, Dow, and other American III member
21 companies agreed to exchange their MSDSs "to assure" the harmony of the content, at least as it
22 related to the "environmental sections."

23 1051. By February 1987, Huntsman's predecessor-in-interest, ICI Americas, had joined
24 the III and was cooperating with its fellow American III member companies to harmonize the
25 language they would use in disclosing or concealing various health effects in their TDI, MDI,
26 and PMDI MSDSs.

27 1052. The minutes of the February 3, 1987 meeting of the III North American
28 Environmental Committee confirm that "[m]ember companies agreed to exchange Material

1 Safety Data Sheets (MSDS) on their isocyanate products.” Minutes of the February 3, 1987
2 meeting of the III North American Environmental Committee, Exh. 40, III(Bice)006153-006176
3 at 006156, Item 18..0.

4 1053. BASF, Mobay (Bayer’s predecessor-in-interest), Dow, and ICI Americas
5 (Huntsman’s predecessor-in-interest), each had a representative at this meeting. *Id.*, Exh. 40, at
6 III(Bice)006154.

7 1054. On January 10, 1988, the members of the III’s European “CE” Sub-Committee
8 discussed the desire of the III’s member companies to harmonize MSDSs across Europe and
9 America. Dr. D.S. Gilbert of the III first introduced the “TDI Manual, Part 1,” which was to
10 operate as a “bible” from which “member companies could abstract.” Minutes of the January 10,
11 1988 meeting of the III European CE Sub-Committee, Exh. 41, III(Bice)006583-006591 at
12 006590. The sub-committee then discussed the desired harmonization of MSDSs:

13 An additional point was that an III agreed position on acute toxicity data should
14 be strived for, and as European and/or U.S.A. harmonised MSDS’s would be
15 included in Part 2 of the Manual preferred figures need to be quoted.

16 *Id.*, Exh. 41 at III(Bice)006590.

17 1055. First, these European III member companies, as well as the III’s Scientific
18 Director (D.S. Gilbert, who made the presentation), envisioned the III member companies
19 striving for “an III agreed position on acute toxicity data.” *Id.*, Exh. 41 at III(Bice)006590.
20 These committee members were discussing this desire just as the III member companies were
21 obtaining a significant amount of substantial risk information about the potential for dermal
22 induction of respiratory sensitization, including the 1988 Mineworkers SRI, the 1989 Human
23 Cases SRI, the 1989 German Mine SRI, and the 1989 Nakata Papers SRI. The fact that the III
24 member companies all failed to report these separate items of substantial risk information to the
25 EPA, to disclose it in published reports about potential MDI, PMDI, and/or TDI hazards, and to
26 disclose it in their MDI, PMDI, and/or TDI labels or MSDSs, strongly suggests that the III’s
27 “agreed position” was to conceal that information.
28

1 1056. Second, these European member companies, as well as the III's Scientific
2 Director (D.S. Gilbert, who made the presentation), envisioned "European and/or U.S.A.
3 harmonized MSDS's" to be included in the TDI Manual, which was to be the "bible" from which
4 "member companies could abstract." *Id.*, Exh. 41 at III(Bice)006590.

5 1057. The minutes indicate that copies were distributed to the "Safety Committee," the
6 "AM-E Chairman [American Environmental Committee Chairman]," and through an "Alerting
7 Note to . . . AM-E members." *Id.*, Exh. 41 at III(Bice)006584.

8 1058. As of June 16, 1987, BASF, Bayer (through its predecessor-in-interest Mobay),
9 Dow, and Huntsman (through its predecessor in-interest ICI Americas) each had representatives
10 on the III Americas Environmental Committee. Minutes of the June 16, 1987 meeting of the III
11 Americas Environmental Committee, Exh. 42, III(Bice)006387-006393 at 006390. As of June 8,
12 1988, Bayer, Dow, and Huntsman each had representatives on the III Americas Environmental
13 Committee. Minutes of the June 8, 1988 meeting of the III Americas Environmental Committee,
14 Exh. 43, III(Bice)007028-007034 at 007033. It also appears that BASF had a representative on
15 the committee (Mr. Keith Fray), who is included in the distribution of the minutes but apparently
16 inadvertently omitted from the list of committee members at the end of the minutes. *Id.*, Exh. 43
17 at 007029.

18 1059. Thus, BASF, Bayer, Dow, and Huntsman each received a copy of the minutes of
19 the January 10, 1988 meeting of the III's European CE Sub-Committee, at which the sub-
20 committee members discussed the desire of the III's member companies to harmonize MSDSs
21 across Europe and America and reach an agreed position about certain toxicity information.

22 1060. Within six months of the European CE Sub-Committee's meeting, the BASF,
23 Bayer, and Dow, through the III Americas Transportation and Handling Sub-Committee, were
24 again coordinating the exchange of the American III member companies' MSDSs and product
25 labels:

26 Dow and Mobay supplied copies of MSDS and product precautionary labels to all
27 members. Other members are to distribute theirs by mail no later than June 30,
28 1988.

Minutes of the June 7, 1988 meeting of the III Americas Transportation and Handling Sub-Committee, Exh. 14, III(Bice)007108-007113 at 007111.

1061. BASF, Bayer (through its predecessor-in-interest Mobay), and Dow each had representatives on this sub-committee who were present at this meeting. *Id.*, Exh. 14 at III(Bice)007109.

1062. On January 31, 1990, BASF, Bayer, Dow, and Huntsman discussed their continuing efforts to harmonize their MSDSs and labels. The minutes of III Americas Environmental Committee meeting record the discussion about “MSDS/Labels – State Activities”: “CMA [Chemical Manufacturers Association] has a task group to standardize ‘language’ and format. Should be finalized in early February.” Minutes of the January 30-31, 1990 meeting of the III Americas Environmental Committee, Exh. 44, III(Bice)008044-008049 at 008046, Item 4.

1063. BASF, Bayer (through its predecessor-in-interest Mobay), Dow, and Huntsman (through its predecessor-in-interest ICI Americas) each had a representative at this meeting. *Id.*, Exh. 44 at III(Bice)008046, Item 2.

1064. As BASF has conceded, through its original Rule 30(b)(6) witness Mr. Bill Robert, this description in the meeting minutes suggests that defendants were colluding. January 19, 2006 Deposition of BASF through its Rule 30(b)(6) witness Bill Robert, Exh. 45, at 197-198.

1065. As BASF’s supplemental Rule 30(b)(6) witness conceded, the CMA and III defendants agreed, at a minimum, to standardize “signal words” indicating to end-users the relevant level of danger posed by exposure to a product, and that “there may have been” an attempt “to standardize the language regarding health effects.” January 11, 2008 Deposition of BASF through Dan Steinmetz, Exh. 46 at 158-163.

b. **In the early to late 1990s, defendants harmonized the health-effects disclosures in their MSDSs to conceal the substantial risk information.**

1066. Despite obtaining and/or developing a significant quantity of substantial risk information that skin contact with or low-level inhalation of MDI or PMDI had caused

1 respiratory sensitization in humans, defendants failed to disclose this information in their
2 MSDSs, and instead included disclosures that suggested the non-existence of such information.

3 1067. By March 1989, BASF, Bayer, Dow, and Huntsman had each separately obtained
4 or developed at least three separate and discrete items of information about human cases of
5 “respiratory sensitization” that had “resulted” from either PMDI/MDI skin contact or low-level
6 inhalation, including the 1988 Mineworkers SRI, the 1989 Human Cases SRI, and the 1989
7 German Mine SRI.

8 1068. Since 1989, BASF, Bayer, Dow, and Huntsman, individually and in conspiracy,
9 have omitted from their PMDI, MDI, and TDI product labels and MSDSs any disclosure of the
10 potential for low-level inhalation to induce or cause respiratory sensitization or other pulmonary
11 injury. By omitting this disclosure from their product labels and MSDSs, BASF, Bayer, Dow,
12 and Huntsman falsely imply that there is no reliable data that associates human respiratory
13 sensitization or other pulmonary injury with inhalation of TDI, MDI, and/or PMDI below the
14 regulatory or recommended exposure limits.

15 1069. As alleged above, on February 6, 1990, Huntsman’s predecessor-in-interest ICI
16 Americas submitted a TSCA Section 8(e) report of Dr. Botham’s animal study which “indicated
17 that MDI injected intradermally in guinea pigs can elicit a sensitization reaction including a
18 pulmonary response as measured by respiratory rate.” ICI Americas February 6, 1990 Section
19 8(e) Submission, Exh. 33 at Bice/Dow 12242.

20 1070. Having reported these animal results to the EPA in February 1990 (Exh. 33) while
21 concealing the human substantial risk information that they had each separately obtained or
22 developed, and having met in January 1990 to “standardize ‘language’ and format of MSDSs”
23 (Exh. 44), the defendants agreed to harmonize their MSDS health-effect disclosures at both the
24 “wholesale” and “retail” levels. The defendants agreed to conceal the dermal-induction health
25 effect at the retail level (formulated products to be sold to end-users) while down-playing the
26 effect at the wholesale level (“raw” MDI or PMDI sold to distributor or formulators). The
27
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1 defendants agreed to conceal the low-level-inhalation-induction health effect at both the
2 wholesale and retail levels.

3 1071. In the early 1990s, BASF, Bayer, and Huntsman each made similar revisions to
4 their “wholesale-level” MSDSs (those for MDI and PMDI chemicals sold to distributors and
5 formulators). Specifically, rather than disclose the potential dermal induction hazard in the
6 context of human data, BASF, Bayer, and Huntsman each couched its disclosure of this risk in
7 language which referenced only to animal studies and not to any human data. These “animal-
8 study-only” disclosures falsely implied that no corroborating human data existed. In other
9 words, through these MSDS disclosures, BASF, Bayer, and Huntsman publicly and falsely
10 denied the existence of the substantial risk information they were concealing.

11 1072. By August 17, 1990, Huntsman’s predecessor-in-interest ICI Americas added an
12 animal-study-only hazard disclosure to its PMDI MSDS:

13 Preliminary data from a research study indicates that MDI in corn oil injected
14 intradermally in guinea pigs can elicit a respiratory sensitization reaction. The
15 potential for MDI to induce respiratory sensitization in humans and animals by
16 inhalation is well known; however, this new data indicates that this effect may be
17 induced by skin contact.

18 August 17, 1990 MSDS for Rubinate M (Polymeric MDI), Exh. 47, FP/Bice35614-35618 at
19 35615, Section 6, Health Hazards, Skin Contact.

20 1073. Huntsman’s animal-study-only disclosure falsely implied that no corroborating
21 human data existed and falsely denied the existence of the substantial risk information it was
22 concealing.

23 1074. Huntsman further concealed the existence of the human substantial risk
24 information by falsely indicating human skin contact was probably not dangerous:

25 Skin absorption:

26 Systemically toxic concentrations of this produce will probably not be absorbed
27 through human skin.

28 *Id.*, Exh. 47 at FP/Bice35615.

1 1075. Bayer added an animal-study-only disclosure to its PMDI MSDS on November
2 20, 1990, and buried it in the “Animal Toxicity Data” section. November 20, 1990 Mobay
3 MSDS for Mondur, Exh. 48, FP/Bice09719-09728 at 09725, Section XII, Animal Toxicity Data..

4 1076. In September 1992, Bayer moved the animal-study-only disclosure to the Human
5 Health Effects section of its MSDS, but continued to couch its disclosure of this risk in language
6 which referenced only to animal studies and not to any human data:

7 Animal tests have indicated that respiratory sensitization can result from skin
8 contact with MDI. This data reinforces the need to prevent direct skin contact
9 with MDI. (See Section XII Animal Toxicity Data, SENSITIZATION.)

10 September 17, 1992 Miles MSDS for Mondur, Exh. 49, FP/Bice09708-09718 at 09710, Section
11 V, Chronic Skin Contact.

12 1077. Bayer’s animal-study-only disclosure falsely implied that no corroborating human
13 data existed and falsely denied the existence of the substantial risk information it was concealing.

14 1078. BASF added an animal-study-only disclosure beginning March 19, 1992: “An
15 animal study indicates that MDI may induce respiratory hypersensitivity following dermal
16 exposure.” March 19, 1992 BASF MSDS for Lupranate, Exh. 50, BASF000271-000281 at
17 000274.

18 1079. BASF’s animal-study-only disclosure falsely implied that no corroborating human
19 data existed and falsely denied the existence of the substantial risk information it was concealing.

20 1080. Although BASF had added an “animal-study-only” disclosure to its wholesale-
21 level PMDI MSDS on March 19, 1992, it failed to disclose the dermal-induction animal study
22 information in its retail-level MSDSs from the same period. October 13, 2005 Deposition of
23 BASF through its Rule 30(b)(6) witness Bill Robert at 403-407, 415-416, Exh. 64. During this
24 time, BASF concealed the dermal-induction human data in both its wholesale and retail MSDSs
25 for MDI and PMDI, and it failed even to disclose the animal study information in its retail-level
26 MSDSs for PMDI-containing products.

1 1081. As alleged more thoroughly below, beginning in September 1998, BASF removed
2 the animal-study-only disclosure from its wholesale-level MSDSs for MDI and PMDI, and made
3 no disclosure at all about the potential for skin contact to induce respiratory sensitization.

4 1082. Between August 28, 1990 and November 1999, Dow included the following skin
5 contact disclosure in its PMDI MSDSs:

6 May cause allergic skin reaction in susceptible individuals. Prolonged or repeated
7 exposure may cause skin irritation. May stain skin. Skin contact may result in
8 allergic skin reactions or respiratory sensitization but is not expected to result in
absorption of amounts sufficient to cause other adverse effects.

9 August 28, 1990 Dow MSDS for PAPI 27 Polymeric MDI, Exh. 51 Bice/Dow 83037-83045 at
10 83040, Section 6, Skin Contact.

11 1083. Dow did not disclose or refer to the significant substantial risk information it had
12 obtained and/or developed. Further, similarly to Huntsman's predecessor-in-interest ICI
13 Americas, Dow concealed the existence of the human substantial risk information by falsely
14 indicating that human skin contact would probably not result in absorption of amounts that
15 would be dangerous.

16 1084. Further, BASF, Bayer, Dow, and Huntsman have each described the potential
17 health effect from PMDI or MDI skin contact as "respiratory sensitization" rather than asthma, in
18 accordance with BASF, Bayer, and Dow's May 1, 1980 recommendation to "avoid the statement
19 causes asthma in material safety data sheets." Dow-Spence Depo at 139:16-140:3, Exh. 37.

20 c. **In the late 1990s, defendants harmonized the health-effects disclosures**
21 **in their MSDSs to conceal the substantial risk information, to deflect**
regulatory scrutiny, and to protect their profits.

22 1085. In 1998 and 1999, BASF and Dow each changed their skin contact disclosures to
23 harmonize with Bayer's disclosures. Concerned that United States regulators were increasing
24 scrutiny about the dermal induction route, and that increased scrutiny could result in their
25 isocyanate products being "de-selected," the defendants and their fellow III member companies
26 coordinated a strategy to deflect regulatory scrutiny.

1 1086. On or about September 29, 1998, BASF removed the “animal study only”
2 warning from its Lupranate MSDSs. January 15, 2008 Deposition of BASF through its Rule
3 30(b)(6) witness Ralph Parod at 237-249, Exh. 52 (Jan. 15, 2008 BASF Parod Depo). By late
4 1999 or 2000, BASF had removed the animal study language from between eighty-five and
5 ninety percent of its MSDSs for PMDI products. March 11, 2008 Deposition of BASF through
6 its Rule 30(b)(6) witness Ralph Parod at 125-128, Exh. 53 (Mar. 11, 2008 BASF-Parod Depo).

7 1087. BASF changed from its internal “MDI 2” MSDS phrase, which contained the
8 “animal-study-only” warning, to its internal “NL 24” phrase, which has no reference to the
9 potential respiratory hazard of skin contact exposure, in response to a request from BASF’s
10 coatings division. Jan. 15, 2008 BASF-Parod Depo at 65-67, Exh. 52; Mar. 11, 2008 BASF-
11 Parod Depo at 300-301, 303-304, Exh. 53. Moreover, BASF based the new language on a Bayer
12 MSDS — not for PMDI but, interestingly, for HDI (a different isocyanate). Jan. 15, 2008
13 BASF-Parod Depo at 65-67, Exh. 52.

14 1088. BASF’s November 28, 1998 revision to its skin contact disclosure falsely
15 indicated that there is no evidence, human or animal, of a respiratory hazard from MDI or PMDI
16 skin contact, and falsely denied the existence of the substantial risk information it was
17 concealing.

18 1089. In January 2000, Dow acquired Flexible Products Company (Flexible Products), a
19 formulator of “retail-level” PMDI products. Flexible Products’ MSDS for its PMDI-containing
20 products did not disclose the dermal-induction health effect, in animal or human terms. Flexible
21 Products’ November 1999 MSDS for Froth-Pak 180 (A Component), FP/Bice09750-09751,
22 Section 3, Hazards Identification, Exh. 65.

23 1090. Between its acquisition of Flexible Products in January 2000 and December 2000,
24 Dow sold Flexible Products’ retail-level products (RokLok and FrothPak/FoamPak) with
25 Flexible Products’ name on the MSDS and product label. May 29, 2008 Deposition of Dow
26 through its Rule 30(b)(6) witness Jeffery Haynes, at 141-145, (Dow-Haynes Depo), Exh. 66.

1 1091. In December of 2000, Dow issued new MSDSs for Flexible Products' "retail-
2 level" products in which it continued to conceal the dermal-induction health effect. Dow-Haynes
3 Depo at 139-141, 145-162, Exh. 66; Dow's 12/00 MSDS for RokLok BE-1000,
4 Bice/Dow93732-93733, Exh. 67.

5 1092. Thus, as BASF had done in 1992, Dow issued a retail-level MSDS for PMDI-
6 containing products in which it failed to disclose the dermal-induction health effect in animal or
7 human terms, while, as alleged below, it issued a wholesale-level MSDS for PMDI and MDI in
8 which it downplayed the dermal-induction health effect by concealing the human data and
9 disclosing only the animal data.

10 1093. In 1999, Dow significantly downgraded its wholesale-level disclosure regarding
11 the dermal-induction health effect. Specifically, Dow downgraded its warning to imitate Bayer's
12 "animal-study-only" warning and then added an additional sentence indicating that skin contact
13 was not harmful in the human context. January 24, 2008 Deposition of Dow through its Rule
14 30(b)(6) witness Hal Kirk at 145-146, Exh. 54 (Dow-Kirk Depo). Beginning on November 29,
15 1999, Dow's skin contact disclosure read:

16 Prolonged or repeated exposure may cause slight skin irritation ... Animal studies
17 have shown that skin contact with isocyanate may play a role in respiratory
18 sensitization ... A single prolonged exposure is not likely to result in the material
19 being absorbed in harmful amounts.

20 November 29, 1999 Dow MSDS for PAPI 27 Polymeric MDI, Exh. 55, Bice/Dow 83135-83150
21 at 83135-83136.

22 1094. Dow's November 29, 1999 revision to its skin contact disclosure falsely implied
23 that that no corroborating human data existed, and falsely denied the existence of the substantial
24 risk information it was concealing.

25 1095. Dow consulted a Bayer MSDS in connection with its 1999 revision to its skin
26 contact warning. Dow's Response to Plaintiff's Fifth Request for Production of Documents, No.
27 2, Exh. 56.
28

1 1096. And Dow revised its skin contact disclosure in 1999 “[t]o accommodate European
2 requests.” Dow-Kirk Depo. at 362-363, Exh. 54. The European requests did not provide an
3 appropriate toxicological basis for Dow’s revision of this disclosure. May 8, 2008 Deposition of
4 Dow through its Rule 30(b)(6) witness Michael Woolhiser (May 8, 2008 Dow-Woolhiser Depo),
5 at 680-689, Exh. 57.

6 1097. The “European requests” likely came from the Europe III member companies that
7 had discussed a desire, in the January 1988 III European CE meeting, to strive for an “agreed
8 position on acute toxicity data” and for “European and/or U.S.A. harmonised MSDSs” from
9 which “member companies could abstract.” Minutes of the January 10, 1988 meeting of the III
10 European CE Committee, Exh. 41 at III(Bice)0006590, Item 9.

11 1098. In the time period immediately preceding BASF and Dow’s revisions to their skin
12 contact disclosures, the European III member companies were concerned about European Union
13 regulatory scrutiny. Specifically, in a letter dated April 22, 1997 to the Scientific Committee the
14 European MedTox Committee, the European Environmental Committee, and the Health
15 Advisory Group (HAG), the III’s Scientific Office discussed concern over the European Union
16 requiring manufacturers and suppliers of PMDI to include a statement on their safety sheets that
17 dermal contact leads to respiratory injury. April 22, 1997 III memorandum regarding EU Risk
18 Phrases, Exh. 58, BASF-032543-032553.

19 1099. The III’s representative at the European Union hearings, Dr. Hoffman, from
20 BASF’s German parent, indicated that the III member companies were having difficulty
21 convincing the European regulators to accept the industry line that the animal studies had limited
22 “relevance for humans or ‘risk for humans.’” *Id.*, Exh. 58 at BASF-032551. That argument
23 directly contradicted the substantial risk information that defendants had obtained and/or
24 developed.

25 1100. Within one month of that April 22, 1997 letter, the III updated the progress of a
26 “harmonization” project in which the III would support ICI and Rhone-Poulenc (manufacturers
27 of isocyanates) “in the preparation of risk assessments for MDI and TDI for the European Union,
28

1 and to harmonize them with exercises in other regions.” III Project Status Forms,
2 Environmental, May 1997, Exh. 59, BASF-038173-038187 at 038178.

3 1101. The European III member companies shared the American III member
4 companies’ concerns about the U.S. regulatory environment. In June 1997, the European
5 MedTox Sub-Committee reviewed the “US regulatory scene.” Minutes of the June 24-25, 1997
6 European Med-Tox Sub-Committee meeting, Exh. 60, BASF-044025-044032 at 044027, Item
7 3(b)(1). In particular, the III member companies discussed an OSHA initiative in which “dermal
8 exposure, particularly to MDI, [was] seen as a problem.” *Id.*, Exh. 60 at BASF-044027, Item
9 3(b)(1).

10 1102. Further, in September 1997, the III member companies created the “Product
11 Safety Advisory Group (PSAG)” to “harmoniz[e] Product Stewardship approaches globally” by
12 collecting, reviewing, and *approving* “local literature.” Minutes of the September 3-4, 1997
13 meeting of the III Scientific Committee, Exh. 61, BASF-033513-033527 at 033517, Item 7.1
14 (emphasis added).

15 1103. In June 1998, a few months before BASF revised its skin contact disclosure,
16 BASF, Bayer, Dow, and Huntsman discussed the regulatory scrutiny they were receiving from
17 OSHA and NIOSH. Handwritten notes on a draft agenda for the June 15-16, 1998 “III AM-
18 MTX Sub Committee Meeting” show conclusively that the American III member companies
19 knew that the “dermal [route] risk [was] on NIOSH/OSHA radar screen as area they missed” and
20 that NIOSH and OSHA were concerned that dermal exposure to isocyanates “produces
21 [occupational] asthma.” Draft Agenda for June 15-16 1998 III American Med-Tox Sub-
22 Committee meeting, with handwritten notes, Exh. 62, BASF-032525-032531 at 032531; Jan. 15,
23 2008 BASF-Parod Depo at 210-212, Exh. 52.

24 1104. BASF (Dr. G. Ott), Bayer (Dr. R. Shiotsuka), Dow (Dr. T. Landry), and
25 Huntsman (Dr. A T Jolly and Dr. J P Lyon) each had representatives at this June 15-16, 1998
26 American Med-Tox Sub-Committee meeting. Exh. 62 at BASF-032525.

1 1105. Shortly after the III member companies re-energized their “harmonization” efforts
 2 in conjunction with concerns about increased regulatory scrutiny of the dermal induction route in
 3 both Europe and the United States, both BASF and Dow revised the skin contact disclosures in
 4 their MSDSs to harmonize with those of Bayer and Huntsman. By November 1999, Bayer,
 5 Dow, and Huntsman’s PMDI MSDSs each had an “animal-study-only” skin contact disclosure,
 6 and BASF’s PMDI MSDSs did not disclose the dermal induction hazard at all.

7 1106. The III member companies had established an “Issues Coordinating Committee”
 8 in part to “assure consistent global messages.” Issue Coordinating Committee, May 1999 slides,
 9 BASF-028641-028659 at 028642 (handwritten notes) and 028649, Exh. 63. In May 1999, the
 10 committee assessed the success of the III member companies’ efforts to “prevent EH&S
 11 [Environmental, Health, and Safety] issues from causing de-selection of [PMDI product] in the
 12 next 5-10 years.” *Id.*, Exh. 63 at BASF-028658. The committee concluded that, “if [the] III
 13 [harmonization] effort continues,” the industry’s effort to prevent the realities of the
 14 “asthma/sensitization” from causing end-user de-selection would be “successful.” *Id.*

15 1107. Thus, BASF, Bayer, Dow, and Huntsman, individually and in conspiracy, have
 16 used their MDI, PMDI, and TDI MSDSs and product labels to publicly conceal the existence of
 17 substantial risk information they have obtained or developed about the induction of human
 18 respiratory sensitization or isocyanate asthma from either skin contact with or low-level
 19 inhalation of MDI, PMDI, and/or TDI. They concealed the substantial risk information both to
 20 avoid or deflect anticipated regulatory scrutiny and to maintain their substantial isocyanate
 21 profits by avoiding customer “de-selection” of their products.

22 **D. Each defendant demonstrated its intention to conceal the SRI when it publicly**
 23 **disputed the potential for dermal- or low-level-induction of respiratory sensitization**
 24 **or asthma, in direct contradiction of the extensive substantial risk information it**
 25 **possessed.**

26 1108. In March 1984, each defendant, through the III, submitted information about MDI
 27 and PMDI to the EPA, but omitted any reference to the dermal-induction health effect. The III
 28 first discussed the serious pulmonary health effects associated with inhalation exposures:

1 The main risk to health of man is via inhalation. . . . In man, chemically-induced
 2 bronchitis and bronchopneumonia and conjunctivitis may occur after exposure to
 3 high concentrations. . . . Besides the effects due to the specific irritant action of
 4 the isocyanate, sensitization leading to bronchial asthma has been observed in
 5 some workers. . . .

6 *Initial Submission: Letter from International Isocyanate Institute to U.S. EPA submitting*
 7 *information on Monomeric and Polymeric MDI, Submitted March 14, 1984, EPA Document ID:*
 8 *FYI-OTS-0794-1027, EPA00609-00626 at 00621, Exh. 1. After documenting these serious*
 9 *pulmonary health effects associated with inhalation exposures, the III limited the health effects*
 10 *associated with dermal contact to "irritancy": "Dermal and eye contact is of concern with*
 11 *regard to irritancy." Id.*

12 1109. As alleged thoroughly above, in March 1984 both Bayer and Dow possessed
 13 substantial risk information about the dermal-induction health effect. By omitting this
 14 information from their 1984 submission to the EPA about MDI and PMDI, Bayer and Dow
 15 represented to the EPA that they neither possessed nor were aware of substantial risk information
 16 about the dermal-induction health effect. By making such a false representation to the EPA,
 17 Bayer and Dow each demonstrated its intent to conceal the substantial risk information.

18 1110. In October 1993, the defendants publicly disputed the possibility that low-level
 19 inhalation could cause respiratory sensitization. For example, in October 1993 the defendants,
 20 through the Diisocyanates Panel of the CMA (now the ACC), submitted comments to the EPA
 21 regarding its risk management process for diisocyanates. The defendants told the EPA that the
 22 proposition that "pulmonary function decrement and sensitization can occur at very low
 23 concentrations" was "not supported by available data." *Comments of the Chemical*
 24 *Manufacturers Association Diisocyanate Panel on the RMI Briefing Document for*
 25 *Diisocyanates*, October 12, 1993, at BAY010037, Exh. 4. Each defendant or its predecessor-in-
 26 interest was a member of the CMA's Diisocyanates Panel, which submitted these comments. *Id.*
 27 at BAY010041, n.1, Exh. 4.
 28

1 1111. As alleged thoroughly above, in October 1993 each defendant possessed
2 substantial risk information about the low-level-inhalation health effect. Yet BASF, Bayer,
3 Dow, and Huntsman each affirmatively represented to the EPA that the low-level-inhalation
4 health effect was “not supported by available data.” By making that affirmative representation,
5 BASF, Bayer, Dow, and Huntsman represented to the EPA that they neither possessed nor were
6 aware of substantial risk information about the low-level-inhalation health effect. By making
7 such a false representation to the EPA, BASF, Bayer, Dow, and Huntsman each demonstrated its
8 intent to conceal the substantial risk information.

9 1112. In May 2002, each defendant publicly detailed its position on the dermal-
10 induction health effect, but omitted the substantial risk information it possessed and instead
11 contended that the scant publicly-available information that suggests that the possibility for
12 isocyanate skin contact to cause respiratory sensitization is anecdotal, inconclusive, and
13 unreliable. In a May 2002 III paper entitled “Respiratory sensitization: the role of dermal
14 contact with MDI and TDI,” each defendant and other III member companies discussed the
15 animal and human data relevant to the potential link between skin contact with MDI and
16 respiratory sensitization. Exh. 2, at CHARM 012422 – 012446. The defendants neither
17 published nor otherwise discussed in that paper any of the substantial risk information they
18 possessed. Moreover, each defendant concluded the May 2002 paper by contending that the link
19 between respiratory sensitization and MDI skin contact was not well-established and that the
20 “available” human data was insufficient to establish the link: “The available data do not provide
21 sufficient evidence for a clear correlation between skin exposure and occupational asthma.” *Id.*
22 at CHARM 12442, Exh. 2. Each defendant was a co-author of that 2002 III paper. *Id.* at
23 CHARM 12425, Exh. 2.

24 1113. As alleged thoroughly above, in May 2002 each defendant possessed substantial
25 risk information about the dermal-induction health effect. By omitting this information from
26 their 2002 paper about the dermal induction health effect, BASF, Bayer, Dow, and Huntsman
27 each represented that they neither possessed nor were aware of substantial risk information about
28

1 the dermal-induction health effect. By making such a false representation, BASF, Bayer, Dow,
2 and Huntsman each demonstrated its intent to conceal the substantial risk information.

3 1114. Indeed, the defendants prepared this paper, and used it successfully, to persuade
4 the ACGIH not to place a “skin notation” on its TLVs for isocyanates. November 2, 2001
5 Minutes of American Chemistry Council Diisocyanates Panel Meeting, Bice/Dow 82384-82390
6 at 82385, Exh. 71; March 18, 2002 e-mail regarding “dermal paper,” BASF-003379-003394 at
7 3382 (“The aim is to have this finalized and available before the TDI TLV review ion [sic] 21
8 April.”), Exh. 72; Dow-Spence Depo at 531-538, Exh. 70.

9 1115. A “skin notation” on isocyanate TLVs (the ACGIH’s recommended exposure
10 limits) would have highlighted the hazard of skin exposure. Fearing the negative effect such a
11 notation would have on their isocyanate business, the defendants falsely represented to the
12 ACGIH that they neither possessed nor were aware of substantial risk information about the
13 dermal-induction health effect. By making such a false representation, especially in the context
14 of the ACGIH’s consideration of a skin notation that would have provided needed hazard
15 information to those who might be exposed to isocyanate products,. BASF, Bayer, Dow, and
16 Huntsman each demonstrated its intent to conceal the dermal-induction health effect substantial
17 risk information.

18 1116. Through the Diisocyanates Panel of the ACC, the defendants have recently
19 disputed the potential for dermal induction of respiratory sensitization directly to the EPA. In
20 their February 26, 2013 comments to the EPA’s proposed MDI Action Plan, each defendant
21 disputed the EPA’s statement in the MDI Action Plan that “[b]oth inhalation and dermal
22 exposures to diisocyanates are thought to contribute to the development of isocyanate asthma”
23 (*id.* at 9, Exh. 3). In commenting on that statement, each defendant represented to the EPA that
24 “the role that dermal contact with diisocyanates plays in the development of occupational asthma
25 remains unresolved for humans.” *Id.* at 10, Exh. 3. That statement directly contradicts the 1992
26 Human Cases SRI, which defendants knowingly failed to report to the EPA and are continuing to
27 conceal.

1 1117. As alleged thoroughly above, in February 2013 each defendant possessed
2 substantial risk information about the dermal-induction health effect. By omitting this
3 information from their 2013 comments to the EPA's MDI Action Plan, BASF, Bayer, Dow, and
4 Huntsman each represented to the EPA that they neither possessed nor were aware of substantial
5 risk information about the dermal-induction health effect. By making such a false representation
6 to the EPA, BASF, Bayer, Dow, and Huntsman each demonstrated its intent to conceal the
7 substantial risk information.

8 1118. Through the Diisocyanates Panel of the ACC, each defendant recently disputed
9 the potential for low-level inhalation exposures to cause respiratory sensitization. In their
10 February 26, 2013 comments to the EPA's proposed MDI Action Plan, each defendant disputed
11 the EPA's statement in the MDI Action Plan that "[b]oth inhalation and dermal exposures to
12 diisocyanates are thought to contribute to the development of isocyanate asthma" (Feb. 26, 2013
13 ACC Comments to MDI Action Plan at 9, Exh. 3). In commenting on that statement, each
14 defendant represented to the EPA: "The ability of diisocyanates to induce respiratory
15 sensitization in some individuals, and asthma in some cases, is a known potential adverse health
16 effect in humans *after exposure to concentrations above workplace exposure limits.*" *Id.* at 10
17 (emphasis added), Exh. 3.

18 1119. As alleged thoroughly above, in February 2013 each defendant possessed
19 substantial risk information about the low-level-inhalation health effect. By omitting this
20 information from their 2013 comments to the EPA's MDI Action Plan, BASF, Bayer, Dow, and
21 Huntsman each represented to the EPA that they neither possessed nor were aware of substantial
22 risk information about the low-level-inhalation health effect. By making such a false
23 representation to the EPA, BASF, Bayer, Dow, and Huntsman each demonstrated its intent to
24 conceal the substantial risk information.

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E. Each defendant demonstrated its intention to conceal the SRI when it refused to report the SRI after a TSCA compliance expert identified some of their reporting violations.

1120. Beginning in 2000 and continuing through September 2010, KBT&F prosecuted numerous plaintiffs' product liability, fraud, and conspiracy claims against many different companies, including defendants BASF, Bayer, and Dow, in the consolidated actions *Bice, et al. v. Micon, Inc., et al.*, Circuit Court of Tuscaloosa County, Alabama, Civil Action File Nos. CV-07-325, 07-326, and 07-327 ("*Bice*").

1121. Beginning in 2006 and continuing through May 2013, KBT&F prosecuted numerous plaintiffs' product liability, fraud, and conspiracy claims against many different companies, including defendants BASF, Bayer, Dow, and Huntsman, in *Richard D. Abbott, et al., v. Earth Support Services d/b/a Micon, Inc., et al.*, Superior Court of Wyoming County, West Virginia; Civil Action No. 08-C-138 ("*Abbott*").

1122. Between 2005 and 2009, *Bice* defendants BASF, Bayer, and Dow produced documents that revealed their receipt and development of substantial risk information. The *Bice* plaintiffs sought to use this evidence to help prove their product liability and fraud claims, but they did not pursue separate TSCA or FCA claims.

1123. In prosecuting the *Bice* claims, KBT&F worked closely with Joel Charm, who provided expert consultation and testimony regarding, among other things, the inadequacy of the *Bice* defendants' hazard warnings in their isocyanate Material Safety Data Sheets (MSDSs) and product labels.

1124. Mr. Charm also possessed extensive experience and expertise in TSCA Section 8(e) compliance. Among other things, after Congress enacted TSCA, Mr. Charm served as chairman of the TSCA Regulation Advisory Committee Recording and Reporting Task Group formed by the CMA to work with the EPA to develop guidance for compliance with Section 8(e).

1125. During his May 17, 2010 deposition, Mr. Charm testified that certain of the documents that these defendants produced, and that he had reviewed in connection with his

1 expert work on the case, referred to substantial risk information that TSCA required BASF,
2 Bayer, and Dow, as well as other entities who had obtained the information, to report
3 immediately to the EPA. Mr. Charm provided further testimony about some of BASF, Bayer,
4 and Dow's Section 8(e) reporting obligations and violations in his July 1, 2010 deposition.

5 1126. None of these documents or any testimony about them was filed by any party on
6 the public record until months after March 23, 2010, the effective date of the 2010 amendments
7 to the FCA, which removed state court proceedings from the FCA's public disclosure bar
8 provision. 31 U.S.C. § 3730(e)(4)(A). Where previously a disclosure in *any* "criminal, civil, or
9 administrative hearing" could operate as a bar, Congress specified in the 2010 amendments that
10 the bar now arose only from disclosures "in a *Federal* criminal, civil, or administrative hearing
11 *in which the Government or its agent is a party.*" 31 U.S.C. § 3730(e)(4)(A) (emphasis added).
12 Thus, to the extent that any of the public *Bice* filings disclosed the basis for this FCA claim, they
13 were filed after the 2010 amendments and do not constitute a "public disclosure" that could
14 possibly bar the claims stated in this complaint.

15 1127. Although Huntsman was not a party to the *Bice* case, Huntsman was a co-
16 defendant with BASF, Bayer, and Dow in the similar *Abbott* case. KBT&F believes that BASF,
17 Bayer, or Dow (or all together) notified Huntsman of Mr. Charm's testimony, and discussed its
18 implications with Huntsman.

19 1128. In or shortly after May 17, 2010, BASF, Bayer, and Dow, and probably
20 Huntsman, learned that Joel Charm, an individual with extensive experience with and expertise
21 in TSCA Section 8(e) compliance, believed and had testified under oath, based on his review of
22 the evidence, that the dermal-induction and low-level-inhalation health effects information
23 referenced in certain documents was substantial risk information that TSCA required be reported
24 to the EPA immediately. BASF, Bayer, and Dow, and probably Huntsman, each knew that it
25 had obtained or developed that very information, as well as other similar information.

26 1129. By refusing to report any of this information to the EPA under these
27 circumstances, regardless of their arguments against its reportability, BASF, Bayer, Dow, and
28

Huntsman each demonstrated its intent to conceal the information. At a minimum, BASF, Bayer, Dow, and Huntsman each demonstrated a reckless disregard of the reportability of the information.

**VI. THE STATUTES OF LIMITATIONS APPLICABLE TO EACH
DEFENDANT'S UNDERLYING FCA OBLIGATIONS HAVE NOT
EXPIRED AND DO NOT BAR THE FCA CLAIMS**

A. The statute of limitations applicable to the FCA obligation associated with each defendant's TSCA reporting violations has not expired and does not bar the FCA claims that are based on those obligations.

1. A violation of TSCA's Section 8(e) reporting is a continuing violation, and the claim to enforce a penalty for its violation does not accrue until the reporting obligation is fulfilled.

1130. Federal law provides the following statute of limitations for certain penalty enforcement actions:

Except as otherwise provided by Act of Congress, an action, suit or proceeding for the enforcement of any civil fine penalty, or forfeiture, pecuniary or otherwise, shall not be entertained unless commenced within five years from the date when the claim first accrued.

28 U.S.C. § 2462.

1131. Section 8(e) of TSCA provides:

Any person who manufactures, processes, or distributed in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment *shall immediately inform* the Administrator of such information *unless* such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e) (emphasis added).

1132. The requirement that the company "shall immediately inform" the EPA "unless" it has certain knowledge indicates that the reporting requirement is an ongoing obligation that continues until the company has either informed the EPA of the information or acquired actual knowledge that the EPA has been adequately informed of the information.

1 1133. TSCA makes it “unlawful for any person to . . . fail or refuse to . . . submit
2 reports, notices, or other information . . . as required by this chapter or a rule hereunder.” 28
3 U.S.C. § 2614(3)(B).

4 1134. TSCA’s civil penalty provision provides:

5 Any person who violates a provision of Section 2614 or 2689 of this title shall be
6 liable to the United States for a civil penalty in an amount not to exceed \$25,000
7 for each violation. Each day such a violation continues shall, for purposes of this
8 section, constitute a separate violation of section 2614 or 2689 of this title.

9 15 U.S.C. § 2615(a)(1).

10 1135. TSCA’s civil penalty provision affirms that TSCA reporting violations are
11 continuing violations (“[e]ach day such a violation continues”), and provides that the penalty
12 imposed for the continuing violation will increase each day the violation continues.

13 1136. A claim for a continuing reporting violation, or for the enforcement of a penalty
14 for that continuing violation, accrues only when the violator fulfills the reporting obligation.

15 1137. TSCA imposed an obligation on BASF to report each adverse effect, with respect
16 to each chemical, for each of the following separate items of substantial risk information that it
17 obtained or developed:

- 18 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 19 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- 20 c. 1989 German Mine SRI (two adverse effects, two chemicals);
- 21 d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- 22 e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- 23 f. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- 24 g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- 25 and
- 26 h. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

1 1138. BASF failed to fulfill each of these separate reporting obligations, and each such
 2 failure is a separate reporting violation that continues until BASF fulfills that reporting
 3 obligation.

4 1139. Because BASF has not fulfilled any of these reporting obligations, the separate
 5 claims to enforce the increasing civil penalty for each separate reporting obligation have not yet
 6 accrued, and the statute of limitations has therefore not yet begun to run.

7 1140. TSCA imposed an obligation on Bayer report each adverse effect, with respect to
 8 each chemical, for each of the following separate items of substantial risk information that it
 9 obtained or developed:

- 10 a. Bayer's 1979 Skin Contact SRI (one adverse effect, two chemicals);
- 11 b. 1982 Japanese Skin Contact SRI (one adverse effect, three chemicals);
- 12 c. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 13 d. 1989 Human Cases SRI (two adverse effects, two chemicals);
- 14 e. 1989 German Mine SRI (two adverse effects, two chemicals);
- 15 f. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- 16 g. 1992 Human Cases SRI (one adverse effect, two chemicals);
- 17 h. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- 18 i. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- 19 and
- 20 j. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

21 1141. Bayer failed to fulfill each of these separate reporting obligations, and each such
 22 failure is a separate reporting violation that continues until Bayer fulfills that reporting
 23 obligation.

24 1142. Because Bayer has not fulfilled any of these reporting obligations, the separate
 25 claims to enforce the increasing civil penalty for each separate reporting obligation have not yet
 26 accrued, and the statute of limitations has therefore not yet begun to run.

1 1143. TSCA imposed an obligation on Dow to report each adverse effect, with respect
 2 to each chemical, for each of the following separate items of substantial risk information that it
 3 obtained or developed:

- 4 a. 1982 Japanese Skin Contact SRI (one adverse effect, one chemical – Dow
 5 was not manufacturing, distributing, or processing MDI or PMDI in
 6 1982);
- 7 b. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 8 c. 1989 Human Cases SRI (two adverse effects, two chemicals);
- 9 d. 1989 German Mine SRI (two adverse effects, two chemicals);
- 10 e. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- 11 f. 1992 Human Cases SRI (one adverse effect, two chemicals);
- 12 g. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- 13 h. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
 14 and
- 15 i. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

16 1144. Dow failed to fulfill each of these separate reporting obligations, and each such
 17 failure is a separate reporting violation that continues until Dow fulfills that reporting obligation.

18 1145. Because Dow has not fulfilled any of these reporting obligations, the separate
 19 claims to enforce the increasing civil penalty for each separate reporting obligation have not yet
 20 accrued, and the statute of limitations has therefore not yet begun to run.

21 1146. TSCA imposed an obligation on Huntsman to report each adverse effect, with
 22 respect to each chemical, for each of the following separate items of substantial risk information
 23 that it obtained or developed:

- 24 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 25 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- 26 c. 1989 German Mine SRI (two adverse effects, two chemicals);
- 27 d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);

- e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- h. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

1147. Huntsman failed to fulfill each of these separate reporting obligations, and each such failure is a separate reporting violation that continues until Huntsman fulfills that reporting obligation.

1148. Because Huntsman has not fulfilled any of these reporting obligations, the separate claims to enforce the increasing civil penalty for each separate reporting obligation have not yet accrued, and the statute of limitations has therefore not yet begun to run.

2. Each defendant's concealment of its reporting violations tolled the statute of limitations.

1149. As thoroughly alleged in Section V above, BASF, Bayer, Dow, and Huntsman, individually and in conspiracy, have actively and knowingly concealed both the existence of and their failure to report to the EPA about the extensive quantity of substantial risk information they have obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI. Each defendant, individually and in conspiracy with the other defendants, has:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain

1 causal relationship between isocyanate skin contact and respiratory
2 response;

- 3 c. “Harmonized” or “standardized” the hazard and/or health effects
4 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
5 precautionary labels with the disclosures of the other defendants, so as to
6 conceal the existence of the substantial risk information about human
7 health effects; and
8 d. Publicly disputed the potential for dermal- or low-level-induction of
9 respiratory sensitization or asthma, in direct contradiction of the extensive
10 substantial risk information it is concealing.

11 1150. Further, as thoroughly alleged in Section V above, BASF, Bayer, and Dow,
12 individually and in conspiracy, have each concealed both the existence of the substantial risk
13 information and their failure to report it by refusing to report the substantial risk information to
14 the EPA, even after one of the *Bice* plaintiffs’ experts, who had extensive experience and
15 expertise in TSCA Section 8(e) reporting compliance, provided deposition and affidavit
16 testimony in and after May 2010 that identified some of the defendants’ Section 8(e) reporting
17 violations identified in this complaint. Although Huntsman was not a party to the *Bice* case,
18 Huntsman was a co-defendant with BASF, Bayer, and Dow in a related case filed in West
19 Virginia state court. KBT&F believes that BASF, Bayer, and Dow notified Huntsman of the
20 *Bice* case testimony, and discussed its implications with Huntsman.

21 1151. While each defendant was concealing its substantial risk information and its
22 reporting violations, the EPA was diligently seeking substantial risk information from each
23 defendant.

24 1152. In March 1978, after working with the regulated community for more than one
25 year through a task group established by CMA, the EPA issued guidance for compliance with
26 Section 8(e)’s reporting requirement. “Toxic Substances Control Act, Statement of
27 Interpretation and Enforcement Policy; Notification of Substantial Risk,” 43 Fed. Reg. 11110,
28

1 March 16, 1978 (“1978 Policy Statement”). As alleged thoroughly above, the EPA’s 1978
 2 Policy Statement provided detailed guidance for companies to determine whether TSCA required
 3 them to report specific items of information they obtained or developed. Therefore, the 1978
 4 Policy Statement shows the EPA’s diligence in seeking each defendant’s compliance with
 5 TSCA’s Section 8(e) requirement to report substantial risk information.

6 1153. On February 1, 1991, the EPA announced the Compliance Audit Program (CAP).
 7 The program essentially operated as an amnesty for prior TSCA Section 8(e) reporting
 8 violations. Registration and Agreement for TSCA Section 8(e) Compliance Audit Program, 56
 9 Fed. Reg. 4128 (February 1, 1991) (“CAP Agreement”), Exh. 26.

10 1154. The EPA instituted CAP based on its observation that regulated companies had
 11 been failing to report information that the EPA viewed as reportable under Section 8(e). CAP
 12 Agreement, Exh. 26, 56 Fed. Reg. at 4128, Unit I, Background.

13 1155. Thus, “to achieve the Agency’s goal of obtaining any outstanding section 8(e)
 14 data, EPA has developed this one-time voluntary compliance program designed to strongly
 15 encourage companies to voluntarily audit their files for studies reportable under section 8(e).”
 16 *Id.*, Exh. 26 at 4129. The EPA’s development, announcement, and implementation of CAP
 17 therefore shows the EPA’s diligence in seeking each defendant’s compliance with TSCA’s
 18 Section 8(e) requirement to report substantial risk information.

19 1156. In June 1991, in connection with CAP, the EPA issued the “TSCA Section 8(e)
 20 Reporting Guide” (the “1991 Reporting Guide”), which can be found on the EPA’s website at
 21 <http://www.epa.gov/oppt/tsca8e/pubs/1991guidance.pdf> (last visited May 7, 2015). The EPA’s
 22 1991 Reporting Guide reaffirmed and expanded on the 1978 Policy Statement, and provided
 23 detailed guidance for companies to determine whether TSCA required them to report specific
 24 items of information they obtained or developed. The EPA’s development, announcement, and
 25 implementation of the TSCA Section 8(e) Reporting Guide therefore shows the EPA’s diligence
 26 in seeking each defendant’s compliance with TSCA’s Section 8(e) requirement to report
 27 substantial risk information.

1 1157. In July 1993, the EPA proposed clarifications and amendments to its 1978 Policy
2 Statement, in “TSCA Section 8(e); Notice of Clarification and Solicitation of Public Comment,”
3 58 Fed. Reg. 37735, July 13, 1993 (“1993 Proposed Policy Clarification”). The EPA issued
4 these clarifications and proposed amendments after considering “questions raised by companies
5 considering participating in the Section 8(e) CAP.” *Id.*, 58 Fed. Reg. at 37736. The EPA’s 1993
6 Proposed Policy Clarification provided detailed guidance for companies to determine whether
7 TSCA required them to report specific items of information they obtained or developed. The
8 EPA’s development and announcement of the 1993 Proposed Policy Clarification therefore
9 shows the EPA’s diligence in seeking each defendant’s compliance with TSCA’s Section 8(e)
10 requirement to report substantial risk information.

11 1158. On May 15, 1996, EPA terminated CAP, “reached final settlements with CAP
12 participants, announced those settlements on October 15, 1996, and collected payment for
13 stipulated penalties.” 2003 TSCA Guidance Revisions, 68 Fed. Reg. at 33131, Unit II.D. The
14 EPA’s five-year pursuit of CAP shows the EPA’s diligence in seeking each defendant’s
15 compliance with TSCA’s Section 8(e) requirement to report substantial risk information.

16 1159. On April 2, 1996, the EPA announced the Integrated Risk Information System
17 (IRIS) Pilot Program. “Integrated Risk Information System (IRIS); Announcement of Pilot
18 Program; Request for Information,” 61 Fed. Reg. 14570 (April 2, 1996) (IRIS Pilot Program
19 Announcement). EPA explained that IRIS is an EPA database that contained “Agency
20 consensus scientific consensus positions on potential adverse human health effects that may
21 result from chronic (or lifetime) exposure to environmental contaminants.” *Id.*, 61 Fed. Reg. at
22 14570. The database contained “chemical-specific summaries of qualitative and quantitative
23 health information in support of the first two steps of the risk assessment process, i.e., hazard
24 identification and dose-response evaluation.” *Id.*

25 1160. To improve the IRIS database, the EPA initiated this Pilot Program for eleven
26 “Pilot chemical substances,” one of which was MDI. *Id.* at 14571.

1 1161. In the Pilot Program, the EPA sought from the public information about the Pilot
2 chemical substances:

3 While the Agency conducts a thorough literature search for each chemical
4 substance, *there may be other articles or unpublished studies we are not aware of.*
5 The Agency would greatly appreciate receiving scientific information from the
6 public during the information gathering stage of the Pilot. Interested persons
7 should provide scientific comments, analyses, studies, and other pertinent
8 scientific information. *The most useful documents for EPA are unpublished
9 studies or other primary technical sources that we may not otherwise obtain
10 through open literature searches.*

11 *Id.*, at 14571 (emphasis added).

12 1162. The EPA's IRIS Pilot Program shows the EPA's diligence in seeking
13 "unpublished studies we [EPA] are not aware of," specifically regarding MDI.

14 1163. In June 2003, the EPA formally revised certain parts of the 1978 Policy Statement
15 in a document entitled "TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification
16 and Reporting Guidance," 68 Fed. Reg. 33129, June 3, 2003 ("2003 TSCA Guidance
17 Revisions"). The EPA's 2003 TSCA Guidance Revisions provided detailed guidance for
18 companies to determine whether TSCA required them to report specific items of information
19 they obtained or developed. The EPA's development and announcement of the 2003 TSCA
20 Guidance Revisions therefore shows the EPA's diligence in seeking each defendant's
21 compliance with TSCA's Section 8(e) requirement to report substantial risk information.

22 1164. In April 2011, the EPA expressed its heightened interest in MDI and related
23 chemicals by issuing an "MDI Action Plan," in which it proposed increased scrutiny of MDI to
24 address its concerns about the chemical, and in particular "the potential health effects that may
25 result from exposures to the consumer or self-employed worker." MDI Action Plan at 1. The
26 EPA stated that "[r]egulatory proceedings indicated by the Action Plan will include appropriate
27 opportunities for public and stakeholder input, including through notice and comment
28 rulemaking processes." *Id.*

1165. The EPA's development, initiation, and implementation of the MDI Action Plan shows the EPA's diligence in seeking to obtain information about the potential health effects of exposure to MDI and related chemicals.

1166. In April 2011, the EPA expressed its heightened interest in TDI and related chemicals by issuing a "TDI Action Plan," in which it proposed increased scrutiny of MDI to address its concerns about the chemical, and in particular "the potential health effects that may result from exposures to the consumer or self-employed worker." *Toluene Diisocyanate (TDI) and Related Compounds Action Plan [RIN 2070-ZA14]*, U.S. Environmental Protection Agency, April 2011 at 1 (TDI Action Plan). The EPA stated that "[r]egulatory proceedings indicated by the Action Plan will include appropriate opportunities for public and stakeholder input, including through notice and comment rulemaking processes." *Id.*

1167. The EPA's development, initiation, and implementation of the TDI Action Plan shows the EPA's diligence in seeking to obtain information about the potential health effects of exposure to TDI and related chemicals.

B. The statute of limitations applicable to the FCA obligation associated with each defendant's separate breaches of their CAP Agreements with EPA has not expired and does not bar the FCA claims that are based on those obligations.

1168. Federal law provides a six-year statute of limitations for breach of contract actions brought by the United States:

Subject to the provisions of section 2416 of this title, and except as otherwise provided by Congress, every action for money damages brought by the United States or an officer or agency thereof which is founded upon any contract express or implied in law or fact, shall be barred unless the complaint is filed within six years after the right of action accrues. . . .

28 U.S.C. § 2415(a).

1169. Under federal law, however, the United States government's reasonable lack of knowledge about the claim tolls the statute of limitations:

For purposes of computing the limitations periods established in section 2415, there shall be excluded all periods during which . . . (c) facts material to the right of action are not known and reasonably could not be known by an official of the United States charged with the responsibility to act in the circumstances.

1 28 U.S.C. § 2416(c).

2
3 1170. As thoroughly alleged in Section V above, BASF, Bayer, Dow, and Huntsman,
4 individually and in conspiracy, have actively and knowingly concealed from the EPA their
5 separate breaches of the CAP Agreement, including particularly their failure to provide to the
6 EPA previously-unreported substantial risk information they had obtained about the induction of
7 human respiratory sensitization and asthma by either skin contact with or low-level inhalation of
8 TDI, MDI, and/or PMDI. After they breached the CAP Agreement, BASF, Bayer, Dow, and
9 Huntsman, individually and in conspiracy with the other defendants, has:

- 10 a. Refused to disclose to the EPA its breach of the CAP Agreement, or
11 provide to the EPA the substantial risk information it was contractually
12 required to provide under the CAP Agreement, even as it continued to
13 obtain and/or develop separate and additional substantial risk information
14 that corroborated the previously-obtained or –developed substantial risk
15 information, and even as internal III communications reminded it of that
16 previously-obtained or –developed substantial risk information;
- 17 b. Refused to disclose to the EPA its breach of the CAP Agreement, or
18 provide to the EPA the substantial risk information it was contractually
19 required to provide under the CAP Agreement, even as it reported the
20 results of animal studies that it claimed showed a less certain causal
21 relationship between isocyanate skin contact and respiratory response;
- 22 c. “Harmonized” or “standardized” the hazard and/or health effects
23 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
24 precautionary labels with the disclosures of the other defendants, so as to
25 conceal the existence of the substantial risk information about human
26 health effects; and

1 d. Publicly disputed the potential for dermal- or low-level-induction of
2 respiratory sensitization or asthma, in direct contradiction of the extensive
3 substantial risk information it is concealing.

4 1171. Further, as thoroughly alleged in Section V above, BASF, Bayer, and Dow,
5 individually and in conspiracy, have each concealed both the existence of the substantial risk
6 information and their failure to report it by refusing to report the substantial risk information to
7 the EPA, even after one of the *Bice* plaintiffs' experts, who had extensive experience and
8 expertise in TSCA Section 8(e) reporting compliance, provided deposition and affidavit
9 testimony in and after May 2010 that identified some of the defendants' Section 8(e) reporting
10 violations identified in this complaint. Although Huntsman was not a party to the *Bice* case,
11 Huntsman was a co-defendant with BASF, Bayer, and Dow in a related case filed in West
12 Virginia state court. KBT&F believes that BASF, Bayer, and Dow notified Huntsman of the
13 *Bice* case testimony, and discussed its implications with Huntsman.

14 1172. During and after the Compliance Audit Program, and through the date of this
15 complaint, BASF actively concealed from the EPA its possession of the substantial risk
16 information that it had agreed in the CAP Agreement to provide to the EPA. During that time,
17 therefore, the EPA did not know, and could not reasonably have known, that BASF had breached
18 the CAP Agreement or that it possessed the substantial risk information. Thus, the statute of
19 limitations on the EPA's breach of contract claim against BASF has not yet begun to run.

20 1173. During and after the Compliance Audit Program, and through the date of this
21 complaint, Bayer actively concealed from the EPA its possession of the substantial risk
22 information that it had agreed in the CAP Agreement to provide to the EPA. During that time,
23 therefore, the EPA did not know, and could not reasonably have known, that Bayer had breached
24 the CAP Agreement or that it possessed the substantial risk information. Thus, the statute of
25 limitations on the EPA's breach of contract claim against Bayer has not yet begun to run.

26 1174. During and after the Compliance Audit Program, and through the date of this
27 complaint, Dow actively concealed from the EPA its possession of the substantial risk
28

1 information that it had agreed in the CAP Agreement to provide to the EPA. During that time,
 2 therefore, the EPA did not know, and could not reasonably have known, that Dow had breached
 3 the CAP Agreement or that it possessed the substantial risk information. Thus, the statute of
 4 limitations on the EPA's breach of contract claim against Dow has not yet begun to run.

5 1175. During and after the Compliance Audit Program, and through the date of this
 6 complaint, Huntsman actively concealed from the EPA its possession of the substantial risk
 7 information that it had agreed in the CAP Agreement to provide to the EPA. During that time,
 8 therefore, the EPA did not know, and could not reasonably have known, that Huntsman had
 9 breached the CAP Agreement or that it possessed the substantial risk information. Thus, the
 10 statute of limitations on the EPA's breach of contract claim against Huntsman has not yet begun
 11 to run.

12 1176. As alleged thoroughly above, the EPA's damages under the CAP Agreement's
 13 damages provision include the full civil penalties for the substantial risk information "not
 14 submitted under the TSCA Section 8(e) Compliance Audit Program," calculated under the TSCA
 15 Enforcement Response Policy as of the date the "appropriate enforcement action" that EPA
 16 initiates after it has "determine[d] later" that the participating company breached the agreement.
 17 CAP Agreement, Exh. 26 at 56 Fed. Reg. 4129, Unit II.A.5. By agreeing to this damages
 18 provision, BASF, Bayer, Dow, and Huntsman each waived any statute of limitations defenses
 19 that might otherwise apply to EPA's underlying TSCA enforcement action claims as applied to
 20 the substantial risk information "not submitted under the TSCA Section 8(e) Compliance Audit
 21 Program."

22 VII. EACH DEFENDANT VIOLATED THE FALSE CLAIMS ACT

23 A. Each defendant knowingly concealed or knowingly and improperly avoided obligations to pay money to the United States Government.

24
 25 1177. As amended effective May 20, 2009, the FCA prohibits "knowingly conceal[ing]
 26 or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money
 27 or property to the Government." 31 U.S.C. § 3729(a)(1)(G). A claim for a violation of this
 28

1 provision is commonly called a “reverse false claim,” because it involves the improper
 2 withholding of money or property from the government, as opposed to the more common FCA
 3 claim, which involves the improper obtaining of money or property from the government.

4 1178. Before the 2009 amendments, the comparable reverse false claims provision
 5 imposed liability on a person who “knowingly makes, uses, or causes to be made or used, a false
 6 record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or
 7 property to the Government.” Superseded language of 31 U.S.C. 3729(a)(7)(2008).

8 1179. Thus, prior to May 20, 2009, the defendant’s communication of a “false record or
 9 statement” was a required element of a reverse false claim. The 2009 amendments created
 10 liability for a defendant’s knowing concealment or knowing and improper avoidance of an
 11 obligation, even if the defendant did not submit a false record or statement in connection with the
 12 concealment or avoidance. Therefore, on May 20, 2009, each defendant began to violate the
 13 FCA when it “knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] [its]
 14 obligation[s] to pay or transmit money or property to the Government.” 31 U.S.C. §
 15 3729(a)(1)(G).

16 1180. KBT&F brings this action within six years of the date of each defendant’s first
 17 violation of the FCA, and the action is therefore timely. 31 U.S.C. § 3731(b)(1).

18 1181. As amended effective May 20, 2009, the FCA defines the type of “obligation”
 19 whose concealment or avoidance violates the FCA: “[T]he term ‘obligation’ means an
 20 established duty, whether or not fixed, arising from an express or implied contractual, grantor-
 21 grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or
 22 regulation, or from the retention of any overpayment.” 31 U.S.C. § 3729(b)(3).

23 1182. Each defendant’s obligations to pay money to the United States Government
 24 arose in two contexts. First, each defendant’s obligations arose “from statute or regulation,”
 25 specifically the continuing duty that TSCA imposes on each defendant to pay civil penalties for
 26 its failure to report substantial risk information as required by Section 8(e). Second, each
 27 defendant’s obligations arose from the “express . . . contractual . . . relationship” of the CAP
 28

1 Agreement, which imposed on each participating defendant a contractual duty to pay damages
2 for its breach of the contractual duty to audit its files and report previously-unreported substantial
3 risk information.

4 **1. Each defendant knowingly concealed or knowingly and improperly avoided**
5 **or decreased its statutory and regulatory obligations to pay money to the**
6 **United States Government.**

7 1183. Since the enactment of TSCA, each defendant has had, and continues to have, “an
8 established duty” to pay civil penalties for its failure to comply with TSCA’s Section 8(e)
9 reporting requirements. This duty is one “arising from . . . statute or regulation.” This duty is,
10 therefore, an FCA “obligation,” “whether or not fixed.” 31 U.S.C. § 3729(b)(3).

11 1184. Therefore, when each defendant “knowingly conceal[ed] or knowingly and
12 improperly avoid[ed] or decrease[d]” that obligation, it violated the FCA, as amended effective
13 May 20, 2009. 31 U.S.C. § 3729(a)(1)(G).

14 1185. Prior to the FCA’s 2009 amendments, courts uniformly prohibited reverse false
15 claims for unassessed fines or penalties, reasoning that unassessed fines and penalties are not
16 “obligations” but rather are mere contingent or potential claims.

17 1186. Because the pre-2009 statute did not define “obligation,” federal courts created
18 their own definition of the term, and eventually many Circuits adopted a narrow definition
19 similar to the Sixth Circuit’s:

20 To recover under the False Claims Act, . . . the United States must demonstrate
21 that it was owed a specific, legal obligation at the time that the alleged false
22 record or statement was made, used, or caused to be made or used. The obligation
23 cannot be merely a potential liability: instead, in order to be subject to the
24 penalties of the False Claims Act, a defendant must have a present duty to pay
25 money or property that was created by a statute, regulation, contract, judgment, or
26 acknowledgment of the indebtedness. The duty, in other words, must have been
27 an obligation in the nature of those that gave rise to actions of debt at common
28 law for money or things owed The deliberate use of the certain, indicative,
past tense suggests that Congress intended the reverse false claims provision to
apply only to existing legal duties to pay or deliver property.

26 *Am. Textile Mfrs. Inst., Inc. v. The Ltd., Inc.*, 190 F.3d 729, 735 (6th Cir. 1999) (“ATMI”),
27 quoting *United States v. Q Internat’l Courier, Inc.*, 131 F.3d 770, 773 (8th Cir 1997).

1187. Based on this narrow definition, the *ATMI* court dismissed a reverse false claim for false statements made by importers to avoid payment of customs duties, ruling that “[c]ontingent obligations—those that will arise only after the exercise of discretion by government actors—are not contemplated by the statute. *ATMI*, 190 F.3d at 738. The court explained that “as opposed to quasi-contractual obligations created by statute or regulation (such as the imposition of a standard mailing rate), contingent obligations (such as the imposition of a civil penalty for an antitrust violation) attach only after the exercise of administrative or prosecutorial discretion, and often after a selection from a range of penalties. *Id.*

1188. In its 2009 amendments to the FCA, Congress expressly rejected the *ATMI* court’s ruling, and inserted a much broader definition of “obligation” into the amended statute, to correct the *ATMI* court’s narrow definition that led to the rejected ruling. Congress defined “obligation” to make clear both that the duty on which the obligation is based need not be a “fixed” duty, and that this unfixed duty could arise from various non-contractual circumstances, including “from statute or regulation”:

the term “obligation” means an established duty, *whether or not fixed*, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, *from statute or regulation*, or from the retention of any overpayment.

31 U.S.C. 3729(b)(3)(emphasis added).

1189. The legislative history of the amendments confirms that Congress intended to correct those court opinions (including *ATMI*, which the Senate Committee expressly criticized at p. 14, fn.10 of its Report) in which courts had incorrectly applied a narrow construction of the “obligations” described in the FCA:

Further, this legislation addresses current confusion among courts that have developed conflicting definitions of the term “obligation” in Section 3729(a)(7). The term “obligation” is now defined under new Section 3729(b)(3) and includes fixed and contingent duties owed to the Government—including fixed liquidated obligations such as judgments, and fixed, unliquidated obligations such as tariffs on imported goods. It is also noteworthy to restate that while *the new definition of “obligation” expressly includes contingent, non-fixed obligations*, the Committee supports the position of the Department of Justice that current section 3729(a)(7) “speaks of an ‘obligation,’ not a ‘fixed obligation.’ By including contingent

obligations such as, “implied contractual, quasi-contractual, grantor-grantee, licensor-licensee, fee-based, or similar relationship,” this new section reflects the Committee’s view, held since the passage of the 1986 Amendments, that *an “obligation” arises across the spectrum of possibilities from the fixed amount debt obligation where all particulars are defined to the instance where there is a relationship between the Government and a person that “results in a duty to pay the Government money, whether or not the amount owed is yet fixed.”*

S. REP. NO. 111-10, 111th Cong., 1st Sess. at 14 (“SEN. REP. NO. 111-10”) (footnotes omitted) (emphasis added).

1190. While Congress emphasized (in the last sentence of the legislative history quoted above) that it defined “obligation” to encompass duties (to pay even unfixed amounts) that arose from a “relationship between the Government and a person,” Congress also recognized that the new statutory definition expanded the reach of the FCA so that such “relationships” would include “statutory relationships” that arise from statutory duties:

S. 386 also includes the term “statutory” to the definition of “obligation.” This term was included to ensure that duties created by a statutory authority that may not be an express or implied contract or other relation are included *as these statutory relationships confer a duty upon the recipient of Government funds* regardless of the existence of a contract.

SEN. REP. NO. 111019 at 15 (emphasis added).

1191. This legislative history indicates that Congress intended that a statutory duty would create a “statutory relationship” upon which an FCA claim can be based. Having clarified that “an ‘obligation’ arises . . . where there is a *relationship* between the Government and a person that ‘results in a duty to pay the Government money, whether or not the amount owed is yet fixed’” (*id.* at 14, emphasis added), Congress emphasized that such a “relationship” includes a “statutory relationship” (*id.* at 15). Later in the legislative process, Congress also added duties arising from a “regulation” to the definition of “obligation,” thereby including “regulatory” relationships within the class of relationships that confer a duty. 31 U.S.C. § 3729(b)(3).

1192. The legislative history, and the plain language of the amendments themselves, indicate that the FCA term “obligation” now encompasses unassessed and unfixed fines and penalties.

1 1193. Thus, each defendant has an FCA “obligation,” because their statutory or
2 regulatory relationship “result[ed] in a duty to pay the Government money, whether or not the
3 amount owed is yet fixed.” SEN. REP. NO. 111-10 at 14.

4 1194. Each defendant’s statutory or regulatory relationship with the EPA arises in part
5 from the United States Government’s provision to each defendants of a privilege or benefit (the
6 legal ability to sell or distribute isocyanates) that is dependent, in part, on the defendant’s
7 compliance with its TSCA obligations.

8 1195. Congress stated as its policy structure for TSCA that the EPA should have the
9 authority to regulate chemicals that present an unreasonable risk of injury, and that chemical
10 manufacturers and processors should be responsible for developing data about those risks. 15
11 U.S.C. § 2601(b)(1), (b)(2), and (c). To accomplish that purpose, Congress provided the EPA
12 with broad authority to regulate the manufacture and sale of chemicals so as to prevent
13 unreasonable risks, and required chemical manufacturers to inform the EPA about the risks of
14 their chemicals.

15 1196. Specifically, Congress authorized the EPA to prohibit, limit, or restrict the
16 production or sale of any chemical that the EPA reasonably concludes “will present an
17 unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2605(a). In other words,
18 each defendant’s ability to manufacture or sale a particular chemical is a privilege or benefit that
19 the EPA can withdraw, limit, or restrict.

20 1197. To ensure that the EPA has sufficient risk information to inform its regulation of
21 this privilege to manufacture or sell chemicals, Congress required regulated companies to inform
22 the EPA of any substantial risk information they receive (*id.* at § 2607(e)), and even granted the
23 EPA the authority to require chemical companies to develop risk information about their
24 chemicals, should the EPA find that the existing data is insufficient reasonably to determine
25 those risks (*id.* at § 2603).

26 1198. The EPA itself has emphasized that the timely reporting of substantial risk
27 information is indispensable to the EPA’s ability to identify and assess a chemical’s health risk:
28

1 In general, EPA considers Section 8(e) of TSCA to be a critically important
 2 information gathering tool that serves as an “early warning” mechanism for
 3 keeping the Agency and others apprised of new-found serious chemical hazards
 and/or exposures; Section 8(e) data are extremely valuable input for the hazard
 identification and risk assessment activities within and outside the EPA.

4 1991 TSCA Guidance at 1.

5 1199. Each defendant has a statutory and regulatory “relationship” with the United
 6 States Government, through the EPA, in which the government provides each defendant with the
 7 privilege to manufacture and sell chemicals that do not present an unreasonable risk of harm, in
 8 exchange for which each defendant must inform the EPA of information that reasonably supports
 9 the conclusion that its chemical presents a substantial risk of injury to health or the environment.
 10 Each defendant’s Section 8(e) substantial risk reporting plays a central and vital role in this
 11 relationship, a fact that Congress emphasized by imposing on the non-compliant companies the
 12 obligation to pay large monetary penalties, which accumulate on a daily basis, for any violations.

13 1200. Each defendant’s obligation to pay the civil penalties arising from its multiple
 14 failures to fulfill its Section 8(e) reporting obligations constitute multiple “obligations” as
 15 defined in 31 U.S.C. § 3729(b)(3), as amended effective May 20, 2009.

16 1201. Therefore, on May 20, 2009, each defendant began to violate the FCA when it
 17 “knowingly conceal[ed] or knowingly and improperly avoid[ed] or decreas[ed] [its]
 18 obligation[s] to pay or transmit money or property to the Government.” 31 U.S.C. §
 19 3729(a)(1)(G) (emphasis added).

20 1202. KBT&F brings this action within six years of the date of each defendant’s first
 21 violation of the FCA, and the action is therefore timely. 31 U.S.C. § 3731(b)(1).

22 1203. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of
 23 specific intent to defraud.” 31 U.S.C. § 3729(b)((1)(B). Rather, those terms “mean that a
 24 person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the
 25 information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at §
 26 3729(b)(1)(A)(ii) and (iii).

- a. **BASF knowingly concealed or knowingly and improperly avoided or decreased its statutory and regulatory obligations to pay money to the United States Government.**

1204. On May 20, 2009, BASF was liable to the EPA for civil penalties that totaled \$4,760,900,000 for its multiple, continuing violations of its TSCA Section 8(e) reporting obligations, as specified in the following chart:

TSCA Civil Penalties through 5/20/2009 -- BASF								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1988 Mine-workers SRI			2,983 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
1989 Human Cases SRI			2,863 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1989 German Mine SRI				2,601 days	1,763 days	128 days		0
	Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	

TSCA Civil Penalties through 5/20/2009 -- BASF									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1989 Nakata Papers SRI				2,601 days	1,763 days	128 days	0		
5	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
6	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days	0		
8	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
9	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days	0		
10	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
11	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
12	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
13	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
14	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
15									
1993 Especial Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days	0		
16	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
17	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
18	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
19	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
20	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
21									
2003 Isocyanate Asthma SRI			0 days	381 days	1,763 days	128 days	0		
22	Dermal – MDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
23	Dermal – PMDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
24									
TOTAL							4,760,900,000		

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1 1205. As alleged thoroughly in Section V above, prior to May 20, 2009, BASF,
 2 individually and in conspiracy with the other defendants, had been actively and knowingly
 3 concealing from the EPA both the existence of and its failure to report to the EPA about the
 4 extensive quantity of substantial risk information its had obtained about the induction of human
 5 respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI,
 6 MDI, and/or PMDI.

7 1206. By this conduct, BASF had been actively and knowingly concealing its multiple
 8 obligations to pay money to the United States Government.

9 1207. By this conduct, BASF had also been knowingly and improperly avoiding or
 10 decreasing its multiple obligations to pay money to the United States Government.

11 1208. Prior to May 20, 2009, BASF, individually and in conspiracy with the other
 12 defendants, had:

- 13 a. Refused to report the substantial risk information to the EPA, even as it
 14 continued to obtain and/or develop separate and additional substantial risk
 15 information that corroborated the previously-obtained or –developed
 16 substantial risk information, and even as internal III communications
 17 reminded it of that previously-obtained or –developed substantial risk
 18 information;
- 19 b. Refused to report the substantial risk information to the EPA, even as it
 20 reported the results of animal studies that it claimed showed a less certain
 21 causal relationship between isocyanate skin contact and respiratory
 22 response;
- 23 c. “Harmonized” or “standardized” the hazard and/or health effects
 24 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
 25 precautionary labels with the disclosures of the other defendants, so as to
 26 conceal the existence of the substantial risk information about human
 27 health effects; and

1 d. Publicly disputed the potential for dermal- or low-level-induction of
2 respiratory sensitization or asthma, in direct contradiction of the extensive
3 substantial risk information it was concealing.

4 1209. On May 20, 2009, BASF continued actively and knowingly to conceal from the
5 EPA its reporting failure and the existence of the extensive quantity of substantial risk
6 information it had obtained, as alleged thoroughly in Section V above.

7 1210. By this conduct, BASF continued actively and knowingly to conceal its multiple
8 obligations to pay money to the United States Government.

9 1211. By this conduct, BASF also continued knowingly and improperly to avoid or
10 decrease its multiple obligations to pay money to the United States Government.

11 1212. At a minimum, BASF “act[ed] in reckless disregard of the truth” of its multiple
12 obligations to pay money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

13 1213. After May 20, 2009, and continuing through the filing of this complaint, BASF
14 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
15 and the existence of the extensive quantity of substantial risk information its had obtained, as
16 alleged thoroughly in Section V above.

17 1214. Among the other concealment activities thoroughly alleged in Section V above, in
18 and after May 2010, BASF concealed both the existence of the substantial risk information and
19 their failure to report it by refusing to report the substantial risk information to the EPA, even
20 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
21 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
22 2010 that identified some of the defendants’ Section 8(e) reporting violations identified in this
23 complaint.

24 1215. By this and other conduct, BASF thus continued actively and knowingly to
25 conceal its multiple obligations to pay money to the United States Government.

26 1216. By this and other conduct, BASF thus continued knowingly and improperly to
27 avoid or decrease its multiple obligations to pay money to the United States Government.
28

1217. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of its multiple obligations to pay money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

1218. Each day after May 20, 2009 through the filing of this complaint, BASF became liable to the EPA for the additional daily penalty amounts by which TSCA’s civil penalties for each of BASF’s reporting violations increased. Specifically, BASF became liable for an additional \$975,000 each day (26 separate violations at \$37,500 per violation). And each day after May 20, 2009 through the filing of this complaint, BASF continued actively and knowingly to conceal from the EPA its continuing reporting failures and the existence of the extensive quantity of substantial risk information its had obtained, as alleged thoroughly in Section V above.

1219. Each day after May 20, 2009 through the filing of this complaint, BASF has thus actively and knowingly concealed these additional, multiple obligations to pay money to the United States Government, and has therefore committed multiple FCA violations on each such day.

1220. Each day after May 20, 2009 through the filing of this complaint, BASF has thus knowingly and improperly avoided or decreased these additional, multiple obligations to pay money to the United States Government, and has therefore committed multiple FCA violations on each such day.

1221. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of these additional, multiple obligations to pay money to the United States Government., and has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

b. **Bayer knowingly concealed or knowingly and improperly avoided or decreased its statutory and regulatory obligations to pay money to the United States Government.**

1222. On May 20, 2009, Bayer was liable to the EPA for civil penalties that totaled \$6,128,025,000 for its multiple, continuing violations of its TSCA Section 8(e) reporting obligations, as specified in the following chart:

TSCA Civil Penalties through 5/20/2009 -- Bayer								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL	
2								
3			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
Bayer's 1979 Skin Contact SRI5			6,218 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	1/22/80	155,450,000	71,527,500	57,297,500	4,800,000	289,075,000	
6	Dermal - PMDI	1/22/80	155,450,000	71,527,500	57,297,500	4,800,000	289,075,000	
1987 Japanese Skin Contact SRI9			5,378 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	5/11/82	134,450,000	71,527,500	57,297,500	4,800,000	268,075,000	
	Dermal – PMDI	5/11/82	134,450,000	71,527,500	57,297,500	4,800,000	268,075,000	
10	Dermal - TDI	5/11/82	134,450,000	71,527,500	57,297,500	4,800,000	268,075,000	
1988 Mine- workers SRI			2,983 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
1989 Human Cases SRI			2,802 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	
	Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	
	LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	
	LLI – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	
1989 German Mine SRI			2,802 days	2,601 days	1,763 days	128 days		0
	Dermal - MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	
	Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	
	LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	
	LLI - PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000	

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TSCA Civil Penalties through 5/20/2009 -- Bayer									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1989 Nakata Papers SRI			2,802 days	2,601 days	1,763 days	128 days	0		
5	Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
6	Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days	0		
8	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
9	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days	0		
11	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
12	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
13	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
14	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
1993 Special Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days	0		
16	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
18	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
19	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
20	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
2003 Isocyanate Asthma SRI			0 days	381 days	1,763 days	128 days	0		
22	Dermal – MDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
23	Dermal – PMDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
24									
TOTAL							6,128,025,000		

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1 1223. As alleged thoroughly in Section V above, prior to May 20, 2009, Bayer,
2 individually and in conspiracy with the other defendants, had been actively and knowingly
3 concealing from the EPA both the existence of and its failure to report to the EPA about the
4 extensive quantity of substantial risk information its had obtained about the induction of human
5 respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI,
6 MDI, and/or PMDI.

7 1224. By this conduct, Bayer had been actively and knowingly concealing its multiple
8 obligations to pay money to the United States Government.

9 1225. By this conduct, Bayer had also been knowingly and improperly avoiding or
10 decreasing its multiple obligations to pay money to the United States Government.

11 1226. Prior to May 20, 2009, Bayer, individually and in conspiracy with the other
12 defendants, had:

- 13 a. Refused to report the substantial risk information to the EPA, even as it
14 continued to obtain and/or develop separate and additional substantial risk
15 information that corroborated the previously-obtained or –developed
16 substantial risk information, and even as internal III communications
17 reminded it of that previously-obtained or –developed substantial risk
18 information;
- 19 b. Refused to report the substantial risk information to the EPA, even as it
20 reported the results of animal studies that it claimed showed a less certain
21 causal relationship between isocyanate skin contact and respiratory
22 response;
- 23 c. “Harmonized” or “standardized” the hazard and/or health effects
24 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
25 precautionary labels with the disclosures of the other defendants, so as to
26 conceal the existence of the substantial risk information about human
27 health effects; and
28

1 d. Publicly disputed the potential for dermal- or low-level-induction of
2 respiratory sensitization or asthma, in direct contradiction of the extensive
3 substantial risk information it was concealing.

4 1227. On May 20, 2009, Bayer continued actively and knowingly to conceal from the
5 EPA its reporting failure and the existence of the extensive quantity of substantial risk
6 information it had obtained, as alleged thoroughly in Section V above.

7 1228. By this conduct, Bayer continued actively and knowingly to conceal its multiple
8 obligations to pay money to the United States Government.

9 1229. By this conduct, Bayer also continued knowingly and improperly to avoid or
10 decrease its multiple obligations to pay money to the United States Government.

11 1230. At a minimum, Bayer "act[ed] in reckless disregard of the truth" of its multiple
12 obligations to pay money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

13 1231. After May 20, 2009, and continuing through the filing of this complaint, Bayer
14 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
15 and the existence of the extensive quantity of substantial risk information its had obtained, as
16 alleged thoroughly in Section V above.

17 1232. Among the other concealment activities thoroughly alleged in Section V above, in
18 and after May 2010, Bayer concealed both the existence of the substantial risk information and
19 their failure to report it by refusing to report the substantial risk information to the EPA, even
20 after one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA
21 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
22 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
23 complaint.

24 1233. By this and other conduct, Bayer thus continued actively and knowingly to
25 conceal its multiple obligations to pay money to the United States Government.

26 1234. By this and other conduct, Bayer thus continued knowingly and improperly to
27 avoid or decrease its multiple obligations to pay money to the United States Government.
28

1 1235. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
2 its multiple obligations to pay money to the United States Government. 31 U.S.C. §
3 3729(b)(1)(A)(iii).

4 1236. Each day after May 20, 2009 through the filing of this complaint, Bayer became
5 liable to the EPA for the additional daily penalty amounts by which TSCA’s civil penalties for
6 each of Bayer’s reporting violations increased. Specifically, Bayer became liable for an
7 additional \$1,162,500 each day (31 separate violations at \$37,500 per violation). And each day
8 after May 20, 2009 through the filing of this complaint, Bayer continued actively and knowingly
9 to conceal from the EPA its continuing reporting failures and the existence of the extensive
10 quantity of substantial risk information its had obtained, as alleged thoroughly in Section V
11 above.

12 1237. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
13 actively and knowingly concealed these additional, multiple obligations to pay money to the
14 United States Government, and has therefore committed multiple FCA violations on each such
15 day.

16 1238. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
17 knowingly and improperly avoided or decreased these additional, multiple obligations to pay
18 money to the United States Government, and has therefore committed multiple FCA violations
19 on each such day.

20 1239. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
21 these additional, multiple obligations to pay money to the United States Government., and has
22 therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

23 c. **Dow knowingly concealed or knowingly and improperly avoided or**
24 **decreased its statutory and regulatory obligations to pay money to the**
25 **United States Government.**

26 1240. On May 20, 2009, Dow was liable to the EPA for civil penalties that totaled
27 \$5,035,175,000 for its multiple, continuing violations of its TSCA Section 8(e) reporting
28 obligations, as specified in the following chart:

TSCA Civil Penalties through 5/20/2009 -- Dow									
SRI		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/2009	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1982				5,378 days	2,601 days	1,763 days	128 days		0
Japanese Skin Contact SRI		Dermal - TDI	5/11/82	134,450,000	71,527,500	57,297,500	4,800,000	268,075,000	
1988				3,045 days	2,601 days	1,763 days	128 days		0
Mine- workers SRI		Dermal – MDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
		Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
		LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
		LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
1989				2,863 days	2,601 days	1,763 days	128 days		0
Human Cases SRI		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1989					2,601 days	1,763 days	128 days		0
German Mine SRI		Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1989					2,601 days	1,763 days	128 days		0
Nakata Papers SRI		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	

TSCA Civil Penalties through 5/20/2009 -- Dow									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/2009	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days			0
5	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
6	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days			0
8	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
9	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
10	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
11	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
1993 Special Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days			0
13	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
14	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
15	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
16	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
2003 Isocyanate Asthma SRI			0 days	381 days	1,763 days	128 days			0
19	Dermal – MDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
20	Dermal – PMDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
TOTAL							5,035,175,000		

1241. As alleged thoroughly in Section V above, prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human

1 respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI,
2 MDI, and/or PMDI.

3 1242. By this conduct, Dow had been actively and knowingly concealing its multiple
4 obligations to pay money to the United States Government.

5 1243. By this conduct, Dow had also been knowingly and improperly avoiding or
6 decreasing its multiple obligations to pay money to the United States Government.

7 1244. Prior to May 20, 2009, Dow, individually and in conspiracy with the other
8 defendants, had:

- 9 a. Refused to report the substantial risk information to the EPA, even as it
10 continued to obtain and/or develop separate and additional substantial risk
11 information that corroborated the previously-obtained or –developed
12 substantial risk information, and even as internal III communications
13 reminded it of that previously-obtained or –developed substantial risk
14 information;
- 15 b. Refused to report the substantial risk information to the EPA, even as it
16 reported the results of animal studies that it claimed showed a less certain
17 causal relationship between isocyanate skin contact and respiratory
18 response;
- 19 c. “Harmonized” or “standardized” the hazard and/or health effects
20 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
21 precautionary labels with the disclosures of the other defendants, so as to
22 conceal the existence of the substantial risk information about human
23 health effects; and
- 24 d. Publicly disputed the potential for dermal- or low-level-induction of
25 respiratory sensitization or asthma, in direct contradiction of the extensive
26 substantial risk information it was concealing.

1 1245. On May 20, 2009, Dow continued actively and knowingly to conceal from the
2 EPA its reporting failure and the existence of the extensive quantity of substantial risk
3 information it had obtained, as alleged thoroughly in Section V above.

4 1246. By this conduct, Dow continued actively and knowingly to conceal its multiple
5 obligations to pay money to the United States Government.

6 1247. By this conduct, Dow also continued knowingly and improperly to avoid or
7 decrease its multiple obligations to pay money to the United States Government.

8 1248. At a minimum, Dow “act[ed] in reckless disregard of the truth” of its multiple
9 obligations to pay money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

10 1249. After May 20, 2009, and continuing through the filing of this complaint, Dow has
11 continued actively and knowingly to conceal from the EPA its continuing reporting failures and
12 the existence of the extensive quantity of substantial risk information its had obtained, as alleged
13 thoroughly in Section V above.

14 1250. Among the other concealment activities thoroughly alleged in Section V above, in
15 and after May 2010, Dow concealed both the existence of the substantial risk information and
16 their failure to report it by refusing to report the substantial risk information to the EPA, even
17 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
18 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
19 2010 that identified some of the defendants’ Section 8(e) reporting violations identified in this
20 complaint.

21 1251. By this and other conduct, Dow thus continued actively and knowingly to conceal
22 its multiple obligations to pay money to the United States Government.

23 1252. By this and other conduct, Dow thus continued knowingly and improperly to
24 avoid or decrease its multiple obligations to pay money to the United States Government.

25 1253. At a minimum, Dow has continued to “act[] in reckless disregard of the truth” of
26 its multiple obligations to pay money to the United States Government. 31 U.S.C. §
27 3729(b)(1)(A)(iii).
28

1 1254. Each day after May 20, 2009 through the filing of this complaint, Dow became
2 liable to the EPA for the additional daily penalty amounts by which TSCA's civil penalties for
3 each of Dow's reporting violations increased. Specifically, Dow became liable for an additional
4 \$1,012,500 each day (27 separate violations at \$37,500 per violation). And each day after May
5 20, 2009 through the filing of this complaint, Dow continued actively and knowingly to conceal
6 from the EPA its continuing reporting failures and the existence of the extensive quantity of
7 substantial risk information its had obtained, as alleged thoroughly in Section V above.

8 1255. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
9 actively and knowingly concealed these additional, multiple obligations to pay money to the
10 United States Government, and has therefore committed multiple FCA violations on each such
11 day.

12 1256. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
13 knowingly and improperly avoided or decreased these additional, multiple obligations to pay
14 money to the United States Government, and has therefore committed multiple FCA violations
15 on each such day.

16 1257. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
17 these additional, multiple obligations to pay money to the United States Government., and has
18 therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

19 d. **Huntsman knowingly concealed or knowingly and improperly**
20 **avoided or decreased its statutory and regulatory obligations to pay**
money to the United States Government.

21 1258. On May 20, 2009, Huntsman was liable to the EPA for civil penalties that totaled
22 \$4,767,100,000 for its multiple, continuing violations of its TSCA Section 8(e) reporting
23 obligations, as specified in the following chart:
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TSCA Civil Penalties through 5/20/2009 -- Huntsman									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1988 Mine-workers SRI			3,045 days	2,601 days	1,763 days	128 days			0
5	Dermal – MDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000		
6	Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000		
7	LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000		
8	LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000		
1989 Human Cases SRI			2,863 days	2,601 days	1,763 days	128 days			0
10	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
11	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
12	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
13	LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
14									
1989 German Mine SRI				2,601 days	1,763 days	128 days			0
15	Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
16	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
17	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
18	LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
19									
1989 Nakata Papers SRI				2,601 days	1,763 days	128 days			0
20	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
21	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000		
22									
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days			0
23	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
24	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
25									
26									
27									

TSCA Civil Penalties through 5/20/2009 -- Huntsman									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days			0
	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
6	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
7	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
8	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
1993 Special Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days			0
	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000		
2003 Isocyanate Asthma SRI			0 days	381 days	1,763 days	128 days			0
	Dermal – MDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
	Dermal – PMDI	2/28/03	0	10,477,500	57,297,500	4,800,000	72,575,000		
TOTAL							4,767,100,000		

1259. As alleged thoroughly in Section V above, prior to May 20, 2009, Huntsman, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1 1260. By this conduct, Huntsman had been actively and knowingly concealing its
2 multiple obligations to pay money to the United States Government.

3 1261. By this conduct, Huntsman had also been knowingly and improperly avoiding or
4 decreasing its multiple obligations to pay money to the United States Government.

5 1262. Prior to May 20, 2009, Huntsman, individually and in conspiracy with the other
6 defendants, had:

- 7 a. Refused to report the substantial risk information to the EPA, even as it
8 continued to obtain and/or develop separate and additional substantial risk
9 information that corroborated the previously-obtained or –developed
10 substantial risk information, and even as internal III communications
11 reminded it of that previously-obtained or –developed substantial risk
12 information;
- 13 b. Refused to report the substantial risk information to the EPA, even as it
14 reported the results of animal studies that it claimed showed a less certain
15 causal relationship between isocyanate skin contact and respiratory
16 response;
- 17 c. “Harmonized” or “standardized” the hazard and/or health effects
18 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
19 precautionary labels with the disclosures of the other defendants, so as to
20 conceal the existence of the substantial risk information about human
21 health effects; and
- 22 d. Publicly disputed the potential for dermal- or low-level-induction of
23 respiratory sensitization or asthma, in direct contradiction of the extensive
24 substantial risk information it was concealing.

25 1263. On May 20, 2009, Huntsman continued actively and knowingly to conceal from
26 the EPA its reporting failure and the existence of the extensive quantity of substantial risk
27 information it had obtained, as alleged thoroughly in Section V above.

1 1264. By this conduct, Huntsman continued actively and knowingly to conceal its
2 multiple obligations to pay money to the United States Government.

3 1265. By this conduct, Huntsman also continued knowingly and improperly to avoid or
4 decrease its multiple obligations to pay money to the United States Government.

5 1266. At a minimum, Huntsman “act[ed] in reckless disregard of the truth” of its
6 multiple obligations to pay money to the United States Government. 31 U.S.C. §
7 3729(b)(1)(A)(iii).

8 1267. After May 20, 2009, and continuing through the filing of this complaint,
9 Huntsman has continued actively and knowingly to conceal from the EPA its continuing
10 reporting failures and the existence of the extensive quantity of substantial risk information its
11 had obtained, as alleged thoroughly in Section V above.

12 1268. Among the other concealment activities thoroughly alleged in Section V above, in
13 and after May 2010, Huntsman concealed both the existence of the substantial risk information
14 and their failure to report it by refusing to report the substantial risk information to the EPA,
15 even after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in
16 TSCA Section 8(e) reporting compliance, provided deposition and affidavit testimony in and
17 after May 2010 that identified some of the defendants’ Section 8(e) reporting violations
18 identified in this complaint. Although Huntsman was not a party to the *Bice* case, Huntsman was
19 a co-defendant with BASF, Bayer, and Dow in a related case filed in West Virginia state court.
20 KBT&F believes that BASF, Bayer, and Dow notified Huntsman of the *Bice* case testimony, and
21 discussed its implications with Huntsman.

22 1269. By this and other conduct, Huntsman thus continued actively and knowingly to
23 conceal its multiple obligations to pay money to the United States Government.

24 1270. By this and other conduct, Huntsman thus continued knowingly and improperly to
25 avoid or decrease its multiple obligations to pay money to the United States Government.
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1 1271. At a minimum, Huntsman has continued to “act[] in reckless disregard of the
2 truth” of its multiple obligations to pay money to the United States Government. 31 U.S.C. §
3 3729(b)(1)(A)(iii).

4 1272. Each day after May 20, 2009 through the filing of this complaint, Huntsman
5 became liable to the EPA for the additional daily penalty amounts by which TSCA’s civil
6 penalties for each of Huntsman’s reporting violations increased. Specifically, Huntsman became
7 liable for an additional \$975,000 each day (26 separate violations at \$37,500 per violation). And
8 each day after May 20, 2009 through the filing of this complaint, Huntsman continued actively
9 and knowingly to conceal from the EPA its continuing reporting failures and the existence of the
10 extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
11 Section V above.

12 1273. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
13 thus actively and knowingly concealed these additional, multiple obligations to pay money to the
14 United States Government, and has therefore committed multiple FCA violations on each such
15 day.

16 1274. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
17 thus knowingly and improperly avoided or decreased these additional, multiple obligations to
18 pay money to the United States Government, and has therefore committed multiple FCA
19 violations on each such day.

20 1275. At a minimum, Huntsman has continued to “act[] in reckless disregard of the
21 truth” of these additional, multiple obligations to pay money to the United States Government.,
22 and has therefore committed multiple FCA violations on each day. 31 U.S.C. §
23 3729(b)(1)(A)(iii).

24 **2. Each defendant knowingly concealed or knowingly and improperly avoided**
25 **or decreased its contractual obligations to transmit money to the United**
26 **States Government.**

27 1276. As alleged thoroughly above, each defendant participated in the EPA’s
28 Compliance Audit Program, and was therefore bound by the CAP Agreement, which the EPA

1 required each participating company to sign, and which is published in the Federal Register.
2 CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129-4131.

3 1277. By virtue of its participation in CAP, BASF entered a contract with the EPA in
4 the form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
5 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

6 1278. By virtue of its participation in CAP, Bayer entered a contract with the EPA in the
7 form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
8 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

9 1279. By virtue of its participation in CAP, Dow entered a contract with the EPA in the
10 form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
11 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

12 1280. By virtue of its participation in CAP, Huntsman entered a contract with the EPA
13 in the form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by
14 CAP Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

15 1281. In their respective contracts with the EPA, each defendant agreed and had a
16 contractual duty to audit its substantial risk reporting compliance and to submit all previously
17 unsubmitted substantial risk information, in return for which the EPA agreed to reduce
18 significantly the reporting penalties for each submitted report, and to cap the total reporting
19 penalties for all previously unsubmitted information at \$1 million. CAP Agreement, Exh. 26, 56
20 Fed. Reg. at 4129-4130, Section II.B.1 – II.B.3.

21 1282. In their respective contracts with the EPA, each defendant agreed and had a
22 contractual duty to certify its completion of the audit program at the program's conclusion. CAP
23 Agreement, Exh. 26, 56 Fed. Reg. at 4130, Section II.B.4.

24 1283. In their respective contracts with the EPA, each defendant agreed that its failure to
25 comply with its contractual obligations would authorize the EPA to impose full penalties for any
26 substantial risk information it had submitted under CAP and received a reduced or "capped"
27 amnesty penalty. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4130, Section II.D.4.

1 1284. The EPA was unable to locate the Consent Agreement or Consent Order that
 2 summarized the results of the program with respect to BASF, Bayer, Dow, or Huntsman.
 3 Although the EPA's TSCA Section 8(e) Final Summary Chart (Exh. 29) establishes that each
 4 defendant submitted substantial risk information under CAP for which they each received
 5 reduced or "amnesty" penalties, KBT&F is not currently able to calculate the differential
 6 between the full penalties that would have been due for those submissions absent the amnesty
 7 reduction.

8 1285. In their respective contracts with the EPA, each defendant agreed that its failure to
 9 comply with its contractual obligations would authorize the EPA to pursue full penalties for the
 10 company's failure to submit substantial risk information that it should have submitted under the

11 CAP Agreement:

12 EPA reserves its rights under TSCA Section 16 to take appropriate enforcement
 13 action if EPA determines later that Regulatee was required to submit under TSCA
 14 section 8(e) a study or report determined by the Regulatee to be not reportable and
 15 therefore not submitted under the TSCA Section 8(e) Compliance Audit Program.
 In such event, the terms of the EPA TSCA Sections 8, 12, and 13 Enforcement
 Response Policy will apply to such proceeding.

16 CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.

17 1286. Under this contractual damages provision, BASF, Bayer, Dow, and Huntsman
 18 each agreed that the civil penalties for the substantial risk information "not submitted under the
 19 TSCA Section 8(e) Compliance Audit Program" would be calculated under the TSCA
 20 Enforcement Response Policy as of and through the date the EPA takes "appropriate
 21 enforcement action" after it has "determine[d] later" that the participating company breached the
 22 agreement."

23 1287. As alleged thoroughly above, the terms of the EPA's TSCA Enforcement
 24 Response Policy require each participating defendant to pay the maximum daily penalty for each
 25 reporting violation.

26 1288. Thus, by participating in CAP under the terms of the CAP Agreement, BASF,
 27 Bayer, Dow, and Huntsman each agreed and has a contractual duty to pay these damages.

1 1289. Shortly after it instituted CAP, the EPA amended the contract to extend through
 2 February 28, 1992 the deadline for participating companies to submit substantial risk
 3 information, and also inserted a provision that allowed for additional extensions to be assessed
 4 on a case-by-case basis. CAP Modification 1, Exh. 27, 56 Fed. Reg. at 19514.

5 1290. In response to questions about EPA's guidance about the reportability of
 6 information concerning environmental distribution and contamination, the EPA announced on
 7 June 20, 1991 that it would provide more specific guidance about the reportability of such
 8 information. CAP Modification 2, Exh. 28, 56 Fed. Reg. at 28459, Unit 3.D. The EPA issued
 9 that guidance on July 13, 1993. 1993 Proposed Policy Clarification, 58 Fed. Reg. 37735. The
 10 CAP reporting deadline appears to have been extended as the EPA issued this guidance and
 11 analyzed the comments received about the revised guidance. 2003 TSCA Guidance Revisions,
 12 68 Fed. Reg. 33129, June 3, 2003. After terminating CAP on May 15, 1996, the EPA "reached
 13 final settlements with CAP participants, announced those settlements on October 15, 1996, and
 14 collected payment for stipulated penalties." *Id.*, 68 Fed. Reg. at 33131, Unit II.D.

15 1291. Thus, BASF, Bayer, Dow, and Huntsman had a duty under the CAP Agreement to
 16 audit their files for unreported substantial risk information and to submit such information to the
 17 EPA by May 15, 1996.

- 18 a. **BASF knowingly concealed or knowingly and improperly avoided or**
 19 **decreased its contractual obligations to transmit money to the United**
 20 **States Government.**

21 1292. BASF violated its contractual CAP Agreement duty to submit the following
 22 unreported substantial risk information to the EPA by May 15, 1996:

- 23 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
 24 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
 25 c. 1989 German Mine SRI (two adverse effects, two chemicals);
 26 d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
 27 e. 1992 Human Cases SRI (one adverse effect, two chemicals);
 28 f. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and

g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

1293. Under the CAP Agreement's damages provision, the EPA's damages for BASF's violation include the civil penalties for the substantial risk information "not submitted under the TSCA Section 8(e) Compliance Audit Program" as calculated under the TSCA Enforcement Response Policy as of and through the date the EPA takes "appropriate enforcement action" after it has "determine[d] later" that the participating company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.

1294. On May 20, 2009, the civil penalties for the substantial risk information that BASF was obligated but failed to provide to the EPA under the CAP Agreement totaled \$4,615,750,000, as specified in the following chart:

Damages for Breach of CAP Agreement through 5/20/2009 -- BASF								
	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1988 Mine- workers SRI			2,983 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
1989 Human Cases SRI			2,863 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	

Damages for Breach of CAP Agreement through 5/20/2009 -- BASF								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1989 German Mine SRI				2,601 days	1,763 days	128 days		0
5	Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
6	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
7	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
8	LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1989 Nakata Papers SRI				2,601 days	1,763 days	128 days		0
	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000	
	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000	
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
1993 Special Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
	LLI - PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
TOTAL							4,615,750,000	

1295. On May 20, 2009, BASF had a contractual duty to pay these amounts to the EPA as contractual damages for BASF's multiple breaches of the CAP Agreement.

1296. As alleged thoroughly in Section V above, prior to May 20, 2009, BASF, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1297. By this conduct, BASF had been actively and knowingly concealing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1298. By this conduct, BASF had also been knowingly and improperly avoiding or decreasing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1299. Prior to May 20, 2009, BASF, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;

- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1300. On May 20, 2009, BASF continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1301. By this conduct, BASF continued actively and knowingly to conceal its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1302. By this conduct, BASF also continued knowingly and improperly to avoid or decrease its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1303. At a minimum, BASF “act[ed] in reckless disregard of the truth” of its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

1304. After May 20, 2009, and continuing through the filing of this complaint, BASF has continued actively and knowingly to conceal from the EPA its continuing reporting failures and the existence of the extensive quantity of substantial risk information its had obtained, as alleged thoroughly in Section V above.

1305. Among the other concealment activities thoroughly alleged in Section V above, in and after May 2010, BASF concealed both the existence of the substantial risk information and its failure to report it by refusing to report the substantial risk information to the EPA, even after

1 one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA Section
2 8(e) reporting compliance, provided deposition and affidavit testimony in and after May 2010
3 that identified some of the defendants' Section 8(e) reporting violations identified in this
4 complaint.

5 1306. By this and other conduct, BASF thus continued actively and knowingly to
6 conceal its multiple breaches of the CAP Agreement and its consequent multiple obligations to
7 pay money as contractual breach damages to the United States Government.

8 1307. By this and other conduct, BASF thus continued knowingly and improperly to
9 avoid or decrease its multiple breaches of the CAP Agreement and its consequent multiple
10 obligations to pay money as contractual breach damages to the United States Government.

11 1308. At a minimum, BASF has continued to "act[] in reckless disregard of the truth" of
12 its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay
13 money as contractual breach damages to the United States Government. 31 U.S.C. §
14 3729(b)(1)(A)(iii).

15 1309. Each day after May 20, 2009 through the filing of this complaint, BASF became
16 liable to the EPA for the additional daily penalty amounts for the substantial risk information that
17 BASF was obligated but failed to provide to the EPA under the CAP Agreement. Specifically,
18 BASF became liable for an additional \$900,000 each day (24 separate violations at \$37,500 per
19 violation). Each day after May 20, 2009, BASF had a contractual duty to pay these amounts to
20 the EPA as contractual damages for BASF's multiple breaches of the CAP Agreement. And
21 each day after May 20, 2009 through the filing of this complaint, BASF continued actively and
22 knowingly to conceal from the EPA its continuing reporting failures and the existence of the
23 extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
24 Section V above.

25 1310. Each day after May 20, 2009 through the filing of this complaint, BASF has thus
26 actively and knowingly concealed these additional, multiple breaches of the CAP Agreement and
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its consequent multiple obligations to pay money as contractual breach damages to the United States Government, and has therefore committed multiple FCA violations on each such day.

1311. Each day after May 20, 2009 through the filing of this complaint, BASF has thus knowingly and improperly avoided or decreased these additional, multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government, and has therefore committed multiple FCA violations on each such day.

1312. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of these additional, multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government, and has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

b. **Bayer knowingly concealed or knowingly and improperly avoided or decreased its contractual obligations to transmit money to the United States Government.**

1313. Bayer violated its contractual CAP Agreement duty to submit the following unreported substantial risk information to the EPA by May 15, 1996:

- a. Bayer’s 1979 Skin Contact SRI (one adverse effect, two chemicals);
- b. 1982 Japanese Skin Contact SRI (one adverse effect, three chemicals);
- c. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- d. 1989 Human Cases SRI (two adverse effects, two chemicals);
- e. 1989 German Mine SRI (two adverse effects, two chemicals);
- f. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- g. 1992 Human Cases SRI (one adverse effect, two chemicals);
- h. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
- i. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

1314. Under the CAP Agreement’s damages provision, the EPA’s damages for Bayer’s violation include the civil penalties for the substantial risk information “not submitted under the TSCA Section 8(e) Compliance Audit Program” as calculated under the TSCA Enforcement

Response Policy as of and through the date the EPA takes “appropriate enforcement action” after it has “determine[d] later” that the participating company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.

1315. On May 20, 2009, the civil penalties for the substantial risk information that Bayer was obligated but failed to provide to the EPA under the CAP Agreement totaled \$5,982,875,000, as specified in the following chart:

Damages for Breach of CAP Agreement through 5/20/2009 -- Bayer								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
Bayer's 1979 Skin Contact SRI			6,218 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	1/22/80	155,450,000	71,527,500	57,297,500	4,800,000	289,075,000	
	Dermal - PMDI	1/22/80	155,450,000	71,527,500	57,297,500	4,800,000	289,075,000	
Japanese Skin Contact SRI			5,378 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	5/11/82	134,450,000	71,527,500	57,297,500	4,800,000	268,075,000	
	Dermal – PMDI	5/11/82	134,450,000	71,527,500	57,297,500	4,800,000	268,075,000	
	Dermal - TDI	5/11/82	134,450,000	71,527,500	57,297,500	4,800,000	268,075,000	
1988 Mine-workers SRI			2,983 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	Dermal – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – MDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	
	LLI – PMDI	11/30/88	74,575,000	71,527,500	57,297,500	4,800,000	208,200,000	

Damages for Breach of CAP Agreement through 5/20/2009 -- Bayer									
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL		
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day			
1989 Human Cases SRI			2,802 days	2,601 days	1,763 days	128 days			0
5	Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
6	Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
7	LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
8	LLI – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
1989 German Mine SRI			2,802 days	2,601 days	1,763 days	128 days			0
	Dermal - MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
	Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
	LLI – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
	LLI - PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
1989 Nakata Papers SRI			2,802 days	2,601 days	1,763 days	128 days			0
	Dermal – MDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
	Dermal – PMDI	5/30/89	70,050,000	71,527,500	57,297,500	4,800,000	203,675,000		
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days			0
19	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
20	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000		
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days			0
22	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
23	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
24	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
25	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000		
26									
27									

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Damages for Breach of CAP Agreement through 5/20/2009 -- Bayer								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/09	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1993 Especially Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days		0
	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
TOTAL							5,982,875,000	

1316. On May 20, 2009, Bayer had a contractual duty to pay these amounts to the EPA as contractual damages for Bayer's multiple breaches of the CAP Agreement.

1317. As alleged thoroughly in Section V above, prior to May 20, 2009, Bayer, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1318. By this conduct, Bayer had been actively and knowingly concealing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1319. By this conduct, Bayer had also been knowingly and improperly avoiding or decreasing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1320. Prior to May 20, 2009, Bayer, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1321. On May 20, 2009, Bayer continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1322. By this conduct, Bayer continued actively and knowingly to conceal its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1323. By this conduct, Bayer also continued knowingly and improperly to avoid or decrease its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1 1324. At a minimum, Bayer “act[ed] in reckless disregard of the truth” of its multiple
2 breaches of the CAP Agreement and its consequent multiple obligations to pay money as
3 contractual breach damages to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

4 1325. After May 20, 2009, and continuing through the filing of this complaint, Bayer
5 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
6 and the existence of the extensive quantity of substantial risk information its had obtained, as
7 alleged thoroughly in Section V above.

8 1326. Among the other concealment activities thoroughly alleged in Section V above, in
9 and after May 2010, Bayer concealed both the existence of the substantial risk information and
10 its failure to report it by refusing to report the substantial risk information to the EPA, even after
11 one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA Section
12 8(e) reporting compliance, provided deposition and affidavit testimony in and after May 2010
13 that identified some of the defendants’ Section 8(e) reporting violations identified in this
14 complaint.

15 1327. By this and other conduct, Bayer thus continued actively and knowingly to
16 conceal its multiple breaches of the CAP Agreement and its consequent multiple obligations to
17 pay money as contractual breach damages to the United States Government.

18 1328. By this and other conduct, Bayer thus continued knowingly and improperly to
19 avoid or decrease its multiple breaches of the CAP Agreement and its consequent multiple
20 obligations to pay money as contractual breach damages to the United States Government.

21 1329. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
22 its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay
23 money as contractual breach damages to the United States Government. 31 U.S.C. §
24 3729(b)(1)(A)(iii).

25 1330. Each day after May 20, 2009 through the filing of this complaint, Bayer became
26 liable to the EPA for the additional daily penalty amounts for the substantial risk information that
27 Bayer was obligated but failed to provide to the EPA under the CAP Agreement. Specifically,
28

1 Bayer became liable for an additional \$1,087,500 each day (29 separate violations at \$37,500 per
2 violation). Each day after May 20, 2009, Bayer had a contractual duty to pay these amounts to
3 the EPA as contractual damages for Bayer's multiple breaches of the CAP Agreement. And each
4 day after May 20, 2009 through the filing of this complaint, Bayer continued actively and
5 knowingly to conceal from the EPA its continuing reporting failures and the existence of the
6 extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
7 Section V above.

8 1331. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
9 actively and knowingly concealed these additional, multiple breaches of the CAP Agreement and
10 its consequent multiple obligations to pay money as contractual breach damages to the United
11 States Government, and has therefore committed multiple FCA violations on each such day.

12 1332. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
13 knowingly and improperly avoided or decreased these additional, multiple breaches of the CAP
14 Agreement and its consequent multiple obligations to pay money as contractual breach damages
15 to the United States Government, and has therefore committed multiple FCA violations on each
16 such day.

17 1333. At a minimum, Bayer has continued to "act[] in reckless disregard of the truth" of
18 these additional, multiple breaches of the CAP Agreement and its consequent multiple
19 obligations to pay money as contractual breach damages to the United States Government, and
20 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

21 c. **Dow knowingly concealed or knowingly and improperly avoided or**
22 **decreased its contractual obligations to transmit money to the United**
23 **States Government.**

24 1334. Dow violated its contractual CAP Agreement duty to submit the following
unreported substantial risk information to the EPA by May 15, 1996:

- 25 a. 1982 Japanese Skin Contact SRI (one adverse effect, one chemical);
- 26 b. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 27 c. 1989 Human Cases SRI (two adverse effects, two chemicals);

- d. 1989 German Mine SRI (two adverse effects, two chemicals);
- e. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- f. 1992 Human Cases SRI (one adverse effect, two chemicals);
- g. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
- h. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

1335. Under the CAP Agreement's damages provision, the EPA's damages for Dow's violation include the civil penalties for the substantial risk information "not submitted under the TSCA Section 8(e) Compliance Audit Program" as calculated under the TSCA Enforcement Response Policy as of and through the date the EPA takes "appropriate enforcement action" after it has "determine[d] later" that the participating company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.

1336. On May 20, 2009, the civil penalties for the substantial risk information that Dow was obligated but failed to provide to the EPA under the CAP Agreement totaled \$4,890,025,000, as specified in the following chart:

Damages for Breach of CAP Agreement through 5/20/2009 -- Dow

	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/2009	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1988 Japanese Skin Contact SRI	Dermal - TDI	5/11/82	5,378 days 134,450,000	2,601 days 71,527,500	1,763 days 57,297,500	128 days 4,800,000	268,075,000	0
1988 Mine-workers SRI	Dermal – MDI	9/29/88	3,045 days 76,125,000	2,601 days 71,527,500	1,763 days 57,297,500	128 days 4,800,000	209,750,000	0
	Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
	LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
	LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	

Damages for Breach of CAP Agreement through 5/20/2009 -- Dow								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/2009	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1989 Human Cases SRI			2,863 days	2,601 days	1,763 days	128 days		0
5	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
6	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
7	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
8	LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1989 German Mine SRI				2,601 days	1,763 days	128 days		0
10	Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
11	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
12	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
13	LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1989 Nakata Dampers SRI				2,601 days	1,763 days	128 days		0
15	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
16	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
1993 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days		0
18	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000	
19	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000	
1993 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days		0
21	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
22	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
23	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
24	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
25								
26								
27								

Damages for Breach of CAP Agreement through 5/20/2009 -- Dow								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/2009	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1994 Especially Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days		0
6	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
7	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
8	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
9	LLI – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
TOTAL							4,890,025,000	

1337. On May 20, 2009, Dow had a contractual duty to pay these amounts to the EPA as contractual damages for Dow's multiple breaches of the CAP Agreement.

1338. As alleged thoroughly in Section V above, prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1339. By this conduct, Dow had been actively and knowingly concealing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1340. By this conduct, Dow had also been knowingly and improperly avoiding or decreasing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1341. Prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1342. On May 20, 2009, Dow continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1343. By this conduct, Dow continued actively and knowingly to conceal its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1344. By this conduct, Dow also continued knowingly and improperly to avoid or decrease its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1 1345. At a minimum, Dow “act[ed] in reckless disregard of the truth” of its multiple
2 breaches of the CAP Agreement and its consequent multiple obligations to pay money as
3 contractual breach damages to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

4 1346. After May 20, 2009, and continuing through the filing of this complaint, Dow has
5 continued actively and knowingly to conceal from the EPA its continuing reporting failures and
6 the existence of the extensive quantity of substantial risk information its had obtained, as alleged
7 thoroughly in Section V above.

8 1347. Among the other concealment activities thoroughly alleged in Section V above, in
9 and after May 2010, Dow concealed both the existence of the substantial risk information and its
10 failure to report it by refusing to report the substantial risk information to the EPA, even after
11 one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA Section
12 8(e) reporting compliance, provided deposition and affidavit testimony in and after May 2010
13 that identified some of the defendants’ Section 8(e) reporting violations identified in this
14 complaint.

15 1348. By this and other conduct, Dow thus continued actively and knowingly to conceal
16 its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay
17 money as contractual breach damages to the United States Government.

18 1349. By this and other conduct, Dow thus continued knowingly and improperly to
19 avoid or decrease its multiple breaches of the CAP Agreement and its consequent multiple
20 obligations to pay money as contractual breach damages to the United States Government.

21 1350. At a minimum, Dow has continued to “act[] in reckless disregard of the truth” of
22 its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay
23 money as contractual breach damages to the United States Government. 31 U.S.C. §
24 3729(b)(1)(A)(iii).

25 1351. Each day after May 20, 2009 through the filing of this complaint, Dow became
26 liable to the EPA for the additional daily penalty amounts for the substantial risk information that
27 Dow was obligated but failed to provide to the EPA under the CAP Agreement. Specifically,
28

1 Dow became liable for an additional \$937,500 each day (25 separate violations at \$37,500 per
2 violation). Each day after May 20, 2009, Dow had a contractual duty to pay these amounts to the
3 EPA as contractual damages for Dow's multiple breaches of the CAP Agreement. And each day
4 after May 20, 2009 through the filing of this complaint, Dow continued actively and knowingly
5 to conceal from the EPA its continuing reporting failures and the existence of the extensive
6 quantity of substantial risk information its had obtained, as alleged thoroughly in Section V
7 above.

8 1352. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
9 actively and knowingly concealed these additional, multiple breaches of the CAP Agreement and
10 its consequent multiple obligations to pay money as contractual breach damages to the United
11 States Government, and has therefore committed multiple FCA violations on each such day.

12 1353. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
13 knowingly and improperly avoided or decreased these additional, multiple breaches of the CAP
14 Agreement and its consequent multiple obligations to pay money as contractual breach damages
15 to the United States Government, and has therefore committed multiple FCA violations on each
16 such day.

17 1354. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
18 these additional, multiple breaches of the CAP Agreement and its consequent multiple
19 obligations to pay money as contractual breach damages to the United States Government, and
20 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

21 d. **Huntsman knowingly concealed or knowingly and improperly**
22 **avoided or decreased its contractual obligations to transmit money to**
23 **the United States Government.**

24 1355. Huntsman violated its contractual CAP Agreement duty to submit the following
25 unreported substantial risk information to the EPA by May 15, 1996:

- 26 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 27 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- 28 c. 1989 German Mine SRI (two adverse effects, two chemicals);

- d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

1356. Under the CAP Agreement's damages provision, the EPA's damages for Huntsman's violation include the civil penalties for the substantial risk information "not submitted under the TSCA Section 8(e) Compliance Audit Program" as calculated under the TSCA Enforcement Response Policy as of and through the date the EPA takes "appropriate enforcement action" after it has "determine[d] later" that the participating company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.

1357. On May 20, 2009, the civil penalties for the substantial risk information that Huntsman was obligated but failed to provide to the EPA under the CAP Agreement totaled \$4,621,950,000, as specified in the following chart:

Damages for Breach of CAP Agreement through 5/20/2009 -- Huntsman									
		Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/2009	TOTAL	
				\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1988 Mine-workers SRI				3,045 days	2,601 days	1,763 days	128 days		0
		Dermal – MDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
		Dermal – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
		LLI – MDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
		LLI – PMDI	9/29/88	76,125,000	71,527,500	57,297,500	4,800,000	209,750,000	
1989 Human Cases SRI				2,863 days	2,601 days	1,763 days	128 days		0
		Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
		LLI – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	

Damages for Breach of CAP Agreement through 5/20/2009 -- Huntsman								
SRI	Effect/ Chemical	Report Due	Through 1/30/97	1/31/97 – 3/15/04	3/16/04 – 1/12/09	1/12/09 – 5/20/2009	TOTAL	
			\$25k/day	\$27.5k/day	\$32.5k/day	\$37.5k/day		
1989 German Mine SRI				2,601 days	1,763 days	128 days		0
5	Dermal - MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
6	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
7	LLI – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
8	LLI - PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
9								
1989 Nakata Paper SRI				2,601 days	1,763 days	128 days		0
10	Dermal – MDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
11	Dermal – PMDI	3/30/89	71,575,000	71,527,500	57,297,500	4,800,000	205,200,000	
12								
1992 Human Cases SRI			1,760 days	2,601 days	1,763 days	128 days		0
13	Dermal – MDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000	
14	Dermal – PMDI	4/6/92	44,000,000	71,527,500	57,297,500	4,800,000	177,625,000	
15								
1992 Specific Scenario SRI			1,701 days	2,601 days	1,763 days	128 days		0
16	Dermal – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
17	Dermal – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
18	LLI – MDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
19	LLI – PMDI	6/4/92	42,525,000	71,527,500	57,297,500	4,800,000	176,150,000	
20								
1993 Español Work Situation SRI			1,366 days	2,601 days	1,763 days	128 days		0
21	Dermal – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
22	Dermal – PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
23	LLI – MDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
24	LLI - PMDI	5/5/93	34,150,000	71,527,500	57,297,500	4,800,000	167,775,000	
25								
26								
TOTAL							4,621,950,000	

28

1358. On May 20, 2009, Huntsman had a contractual duty to pay these amounts to the EPA as contractual damages for Huntsman's multiple breaches of the CAP Agreement.

1359. As alleged thoroughly in Section V above, prior to May 20, 2009, Huntsman, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1360. By this conduct, Huntsman had been actively and knowingly concealing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1361. By this conduct, Huntsman had also been knowingly and improperly avoiding or decreasing its multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money as contractual breach damages to the United States Government.

1362. Prior to May 20, 2009, Huntsman, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;

- 1 c. “Harmonized” or “standardized” the hazard and/or health effects
 2 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
 3 precautionary labels with the disclosures of the other defendants, so as to
 4 conceal the existence of the substantial risk information about human
 5 health effects; and
 6 d. Publicly disputed the potential for dermal- or low-level-induction of
 7 respiratory sensitization or asthma, in direct contradiction of the extensive
 8 substantial risk information it was concealing.

9 1363. On May 20, 2009, Huntsman continued actively and knowingly to conceal from
 10 the EPA its reporting failure and the existence of the extensive quantity of substantial risk
 11 information it had obtained, as alleged thoroughly in Section V above.

12 1364. By this conduct, Huntsman continued actively and knowingly to conceal its
 13 multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money
 14 as contractual breach damages to the United States Government.

15 1365. By this conduct, Huntsman also continued knowingly and improperly to avoid or
 16 decrease its multiple breaches of the CAP Agreement and its consequent multiple obligations to
 17 pay money as contractual breach damages to the United States Government.

18 1366. At a minimum, Huntsman “act[ed] in reckless disregard of the truth” of its
 19 multiple breaches of the CAP Agreement and its consequent multiple obligations to pay money
 20 as contractual breach damages to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

21 1367. After May 20, 2009, and continuing through the filing of this complaint,
 22 Huntsman has continued actively and knowingly to conceal from the EPA its continuing
 23 reporting failures and the existence of the extensive quantity of substantial risk information its
 24 had obtained, as alleged thoroughly in Section V above.

25 1368. Among the other concealment activities thoroughly alleged in Section V above, in
 26 and after May 2010, Huntsman concealed both the existence of the substantial risk information
 27 and its failure to report it by refusing to report the substantial risk information to the EPA, even
 28

1 after one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA
2 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
3 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
4 complaint.

5 1369. By this and other conduct, Huntsman thus continued actively and knowingly to
6 conceal its multiple breaches of the CAP Agreement and its consequent multiple obligations to
7 pay money as contractual breach damages to the United States Government.

8 1370. By this and other conduct, Huntsman thus continued knowingly and improperly to
9 avoid or decrease its multiple breaches of the CAP Agreement and its consequent multiple
10 obligations to pay money as contractual breach damages to the United States Government.

11 1371. At a minimum, Huntsman has continued to "act[] in reckless disregard of the
12 truth" of its multiple breaches of the CAP Agreement and its consequent multiple obligations to
13 pay money as contractual breach damages to the United States Government. 31 U.S.C. §
14 3729(b)(1)(A)(iii).

15 1372. Each day after May 20, 2009 through the filing of this complaint, Huntsman
16 became liable to the EPA for the additional daily penalty amounts for the substantial risk
17 information that Huntsman was obligated but failed to provide to the EPA under the CAP
18 Agreement. Specifically, Huntsman became liable for an additional \$900,000 each day (24
19 separate violations at \$37,500 per violation). Each day after May 20, 2009, Huntsman had a
20 contractual duty to pay these amounts to the EPA as contractual damages for Huntsman's
21 multiple breaches of the CAP Agreement. And each day after May 20, 2009 through the filing
22 of this complaint, Huntsman continued actively and knowingly to conceal from the EPA its
23 continuing reporting failures and the existence of the extensive quantity of substantial risk
24 information its had obtained, as alleged thoroughly in Section V above.

25 1373. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
26 thus actively and knowingly concealed these additional, multiple breaches of the CAP
27 Agreement and its consequent multiple obligations to pay money as contractual breach damages
28

1 to the United States Government, and has therefore committed multiple FCA violations on each
2 such day.

3 1374. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
4 thus knowingly and improperly avoided or decreased these additional, multiple breaches of the
5 CAP Agreement and its consequent multiple obligations to pay money as contractual breach
6 damages to the United States Government, and has therefore committed multiple FCA violations
7 on each such day.

8 1375. At a minimum, Huntsman has continued to “act[] in reckless disregard of the
9 truth” of these additional, multiple breaches of the CAP Agreement and its consequent multiple
10 obligations to pay money as contractual breach damages to the United States Government, and
11 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

12 **B. Each defendant knowingly concealed or knowingly and improperly avoided or**
13 **decreased obligations to transfer *property* to the United States Government.**

14 1376. The FCA prohibits the knowing concealment or knowing and improper avoidance
15 of “an obligation to pay or transmit money *or property* to the Government.” 31 U.S.C. §
16 3729(a)(1)(G) (emphasis added).

17 1377. Each defendant’s obligations to transmit property to the United States
18 Government arose in two contexts. First, each defendant’s obligations arose “from statute or
19 regulation,” specifically the continuing duty that TSCA imposes on each defendant to report
20 substantial risk information. Second, each defendant’s obligations arose from the “express . . .
21 contractual . . . relationship” of the CAP Agreement, which imposed a contractual duty to audit
22 their files and report previously-unreported substantial risk information.

23 **1. Each defendant knowingly concealed or knowingly and improperly avoided**
24 **or decreased its *statutory and regulatory obligations* to transfer *property* to the**
25 **United States Government.**

26 1378. The FCA prohibits the knowing concealment or knowing and improper avoidance
27 of “an obligation to pay or transmit money *or property* to the Government.” 31 U.S.C. §
28 3729(a)(1)(G) (emphasis added).

1 1379. With certain exemptions, TSCA imposed a duty on each defendant that obtained
2 or developed substantial risk information immediately to report that substantial risk information
3 to the EPA. 15 U.S.C. § 2607(e).

4 1380. Thus, under TSCA each defendant has had, and continues to have, “an established
5 duty” immediately to report substantial risk information to the EPA. This duty is one “arising
6 from . . . statute or regulation.” This duty is, therefore, an FCA “obligation.” 31 U.S.C. §
7 3729(b)(3).

8 1381. Therefore, when each defendant “knowingly conceal[ed] or knowingly and
9 improperly avoid[ed] or decrease[d]” that obligation, it violated the FCA, as amended effective
10 May 20, 2009. 31 U.S.C. § 3729(a)(1)(G).

11 1382. That substantial risk information constitutes “property” that TSCA obligated each
12 defendant to “transmit . . . to the Government.” 31 U.S.C. § 3729(a)(1)(G).

13 1383. As alleged thoroughly above, each defendant acquired or compiled this
14 substantial risk information in the course and conduct of its isocyanate business.

15 1384. As alleged thoroughly above, each defendant has treated the information as its
16 property by, among other things, handling it as information to which it (along with its
17 conspirators) has the exclusive right and benefit. Indeed, each defendant has actively concealed
18 the substantial risk information over decades, and has implicitly and explicitly denied its
19 existence in its products’ health effects disclosures, in scientific papers, and in submissions and
20 comments to the EPA.

21 1385. Each defendant knew or should have known that the United States Government
22 views substantial risk information as extremely valuable property.

23 1386. Congress stated as its policy structure for TSCA that the EPA should have the
24 authority to regulate chemicals that present an unreasonable risk of injury, and that chemical
25 manufacturers and processors should be responsible for developing data about those risks. 15
26 U.S.C. § 2601(b)(1), (b)(2), and (c). To accomplish that purpose, Congress provided the EPA
27 with broad authority to regulate the manufacture and sale of chemicals so as to prevent
28

1 unreasonable risks, and required chemical manufacturers to inform the EPA about the risks of
2 their chemicals.

3 1387. Specifically, Congress authorized the EPA to prohibit, limit, or restrict the
4 production or sale of any chemical that the EPA reasonably concludes “will present an
5 unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2605(a). In other words,
6 each defendant’s ability to manufacture or sale a particular chemical is a privilege or benefit that
7 the EPA can withdraw, limit, or restrict.

8 1388. To ensure that the EPA has sufficient risk information to inform its regulation of
9 this privilege to manufacture or sell chemicals, Congress required regulated companies to inform
10 the EPA of any substantial risk information they receive (*id.* at § 2607(e)), and even granted the
11 EPA the authority to require chemical companies to develop risk information about their
12 chemicals, should the EPA find that the existing data is insufficient reasonably to determine
13 those risks (*id.* at § 2603).

14 1389. Each defendant’s legal ability to sell or distribute isocyanates is therefore
15 dependent, in part, on the defendant’s timely provision of substantial risk information, which
16 demonstrates that the substantial risk information is valuable property.

17 1390. To strongly encourage regulated companies to submit substantial risk information,
18 Congress required “immediate” reporting and penalized non-compliance with significant
19 monetary penalties that increase by tens of thousands of dollars on a daily basis. These
20 provisions demonstrate that Congress views the substantial risk information as valuable property.

21 1391. The EPA itself has emphasized that the timely reporting of substantial risk
22 information is indispensable to the EPA’s ability to identify and assess a chemical’s health risk:

23 In general, EPA considers Section 8(e) of TSCA to be a critically important
24 information gathering tool that serves as an “early warning” mechanism for
25 keeping the Agency and others apprised of new-found serious chemical hazards
and/or exposures; Section 8(e) data are extremely valuable input for the hazard
identification and risk assessment activities within and outside the EPA.

26 1991 TSCA Guidance at 1.
27
28

1392. The EPA indicates that “incomplete and inaccurate information will have far-reaching effects on the Agency’s risk assessment, regulatory priority setting, and regulation development process.” TSCA Enforcement Response Policy at 18.

1393. On February 1, 1991, the EPA announced the Compliance Audit Program (CAP). The program essentially operated as an amnesty for prior TSCA Section 8(e) reporting violations. Registration and Agreement for TSCA Section 8(e) Compliance Audit Program, 56 Fed. Reg. 4128 (February 1, 1991) (“CAP Agreement”), Exh. 26.

1394. The EPA instituted CAP based on its observation that regulated companies had been failing to report information that the EPA viewed as reportable under Section 8(e). CAP Agreement, Exh. 26, 56 Fed. Reg. at 4128, Unit I, Background.

1395. In announcing the program, the EPA stated:
Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals. EPA has the responsibility under TSCA to perform needed risk assessments on chemicals. Section 8(e) is a very important part of TSCA’s section 8 information reporting and recordkeeping provisions that enable EPA to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).

Id., CAP Agreement, Exh. 26, 56 Fed Reg. at 4128, Unit I, Background (emphasis added).

1396. Thus, “to achieve the Agency’s goal of obtaining any outstanding section 8(e) data, EPA has developed this one-time voluntary compliance program designed to strongly encourage companies to voluntarily audit their files for studies reportable under section 8(e).” *Id.* at 4129.

1397. The EPA’s development and implementation of CAP demonstrate that it viewed substantial risk information as extremely valuable property, and was willing significantly to reduce non-compliance penalties to obtain that property.

1398. Thus, the United States Government treats the substantial risk information as extremely valuable property that regulated companies must develop and report in return for the

1 privilege of selling potentially dangerous chemicals. Similarly, the statutory and regulatory
 2 framework requires regulated companies to view the information as valuable property that they
 3 must timely report to the government (and may be required by the government to develop) in
 4 exchange for the privilege of selling their products.

- 5 a. **BASF knowingly concealed or knowingly and improperly avoided or**
 6 **decreased its statutory and regulatory obligations to transfer property**
 7 **to the United States Government.**

8 1399. On May 20, 2009, BASF was and had been obligated to provide the EPA with the
 9 following substantial risk information:

- 10 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
 11 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
 12 c. 1989 German Mine SRI (two adverse effects, two chemicals);
 13 d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
 14 e. 1992 Human Cases SRI (one adverse effect, two chemicals);
 15 f. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
 16 g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
 17 and
 18 h. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

19 1400. As alleged thoroughly in Section V above, prior to May 20, 2009, BASF,
 20 individually and in conspiracy with the other defendants, had been actively and knowingly
 21 concealing from the EPA both the existence of and its failure to report to the EPA about the
 22 extensive quantity of substantial risk information its had obtained about the induction of human
 23 respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI,
 24 MDI, and/or PMDI.

25 1401. By this conduct, BASF had been actively and knowingly concealing its multiple
 26 obligations to transmit property to the United States Government.

27 1402. By this conduct, BASF had also been knowingly and improperly avoiding or
 28 decreasing its multiple obligations to transmit property to the United States Government.

1 1403. Prior to May 20, 2009, BASF, individually and in conspiracy with the other
2 defendants, had:

- 3 a. Refused to report the substantial risk information to the EPA, even as it
4 continued to obtain and/or develop separate and additional substantial risk
5 information that corroborated the previously-obtained or –developed
6 substantial risk information, and even as internal III communications
7 reminded it of that previously-obtained or –developed substantial risk
8 information;
- 9 b. Refused to report the substantial risk information to the EPA, even as it
10 reported the results of animal studies that it claimed showed a less certain
11 causal relationship between isocyanate skin contact and respiratory
12 response;
- 13 c. “Harmonized” or “standardized” the hazard and/or health effects
14 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
15 precautionary labels with the disclosures of the other defendants, so as to
16 conceal the existence of the substantial risk information about human
17 health effects; and
- 18 d. Publicly disputed the potential for dermal- or low-level-induction of
19 respiratory sensitization or asthma, in direct contradiction of the extensive
20 substantial risk information it was concealing.

21 1404. On May 20, 2009, BASF continued actively and knowingly to conceal from the
22 EPA its reporting failure and the existence of the extensive quantity of substantial risk
23 information it had obtained, as alleged thoroughly in Section V above.

24 1405. By this conduct, BASF continued actively and knowingly to conceal its multiple
25 obligations to transmit property to the United States Government.

26 1406. By this conduct, BASF also continued knowingly and improperly to avoid or
27 decrease its multiple obligations to transmit property to the United States Government.

1 1407. At a minimum, BASF “act[ed] in reckless disregard of the truth” of its multiple
2 obligations to transmit property to the United States Government. 31 U.S.C. §
3 3729(b)(1)(A)(iii).

4 1408. On May 20, 2009, the value of the property that BASF was obligated to but failed
5 to transmit to the United States equaled at least the amount of the civil penalties that BASF was
6 liable to pay for its prior failures to report the substantial risk information. Indeed, BASF viewed
7 the property as more valuable than those penalties, because it risked the payment of those
8 penalties to avoid providing the substantial risk information to the EPA.

9 1409. BASF profited from the sale of its isocyanate products during the time it
10 concealed and failed to report this substantial risk information. As alleged thoroughly above,
11 BASF concealed the information to avoid customer de-selection of its isocyanate products, and
12 to avoid or deflect regulatory scrutiny that might have restricted or eliminated its ability to sell its
13 isocyanate products. BASF’s decision to risk the penalty in order to gain profits from the sale of
14 its isocyanate products indicates that it viewed the substantial risk information as equal to or very
15 close to the value of its net profits during the period of its non-compliance.

16 1410. Thus, the value of BASF’s substantial risk information as of May 20, 2009
17 equaled at least the amount of BASF’s TSCA Section 8(e) civil penalties or equaled some or all
18 of BASF’s net profits from isocyanate sales during the period of its non-compliance.

19 1411. After May 20, 2009, and continuing through the filing of this complaint, BASF
20 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
21 and the existence of the extensive quantity of substantial risk information its had obtained, as
22 alleged thoroughly in Section V above.

23 1412. Among the other concealment activities thoroughly alleged in Section V above, in
24 and after May 2010, BASF concealed both the existence of the substantial risk information and
25 their failure to report it by refusing to report the substantial risk information to the EPA, even
26 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
27 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
28

1 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
2 complaint.

3 1413. By this and other conduct, BASF thus continued actively and knowingly to
4 conceal its multiple obligations to transmit property to the United States Government.

5 1414. By this and other conduct, BASF thus continued knowingly and improperly to
6 avoid or decrease its multiple obligations to transmit property to the United States Government.

7 1415. At a minimum, BASF has continued to "act[] in reckless disregard of the truth" of
8 its multiple obligations to transmit property to the United States Government. 31 U.S.C. §
9 3729(b)(1)(A)(iii).

10 1416. Each day after May 20, 2009 through the filing of this complaint, TSCA required
11 BASF to transmit property by reporting the substantial risk information, and by its non-
12 compliance BASF became liable to the EPA for the additional daily penalty amounts by which
13 TSCA's civil penalties for each of BASF's reporting violations increased. And each day after
14 May 20, 2009 through the filing of this complaint, BASF continued actively and knowingly to
15 conceal from the EPA its continuing reporting failures and the existence of the extensive quantity
16 of substantial risk information its had obtained, as alleged thoroughly in Section V above.

17 1417. Each day after May 20, 2009 through the filing of this complaint, BASF has thus
18 actively and knowingly concealed these additional, multiple obligations to transmit property to
19 the United States Government, and has therefore committed multiple FCA violations on each
20 such day.

21 1418. Each day after May 20, 2009 through the filing of this complaint, BASF has thus
22 knowingly and improperly avoided or decreased these additional, multiple obligations to transmit
23 property to the United States Government, and has therefore committed multiple FCA violations
24 on each such day.

25 1419. At a minimum, BASF has continued to "act[] in reckless disregard of the truth" of
26 these additional, multiple obligations to transmit property to the United States Government., and
27 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

- b. **Bayer knowingly concealed or knowingly and improperly avoided or decreased its statutory and regulatory obligations to transfer property to the United States Government.**

1420. On May 20, 2009, Bayer was and had been obligated to provide the EPA with the following substantial risk information:

- a. Bayer's 1979 Skin Contact SRI (one adverse effect, two chemicals);
- b. 1982 Japanese Skin Contact SRI (one adverse effect, three chemicals);
- c. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- d. 1989 Human Cases SRI (two adverse effects, two chemicals);
- e. 1989 German Mine SRI (two adverse effects, two chemicals);
- f. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- g. 1992 Human Cases SRI (one adverse effect, two chemicals);
- h. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- i. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- j. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

1421. As alleged thoroughly in Section V above, prior to May 20, 2009, Bayer, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1422. By this conduct, Bayer had been actively and knowingly concealing its multiple obligations to transmit property to the United States Government.

1423. By this conduct, Bayer had also been knowingly and improperly avoiding or decreasing its multiple obligations to transmit property to the United States Government.

1424. Prior to May 20, 2009, Bayer, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1425. On May 20, 2009, Bayer continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1426. By this conduct, Bayer continued actively and knowingly to conceal its multiple obligations to transmit property to the United States Government.

1427. By this conduct, Bayer also continued knowingly and improperly to avoid or decrease its multiple obligations to transmit property to the United States Government.

1 1428. At a minimum, Bayer “act[ed] in reckless disregard of the truth” of its multiple
2 obligations to transmit property to the United States Government. 31 U.S.C. §
3 3729(b)(1)(A)(iii).

4 1429. On May 20, 2009, the value of the property that Bayer was obligated to but failed
5 to transmit to the United States equaled at least the amount of the civil penalties that Bayer was
6 liable to pay for its prior failures to report the substantial risk information. Indeed, Bayer viewed
7 the property as more valuable than those penalties, because it risked the payment of those
8 penalties to avoid providing the substantial risk information to the EPA.

9 1430. Bayer profited from the sale of its isocyanate products during the time it
10 concealed and failed to report this substantial risk information. As alleged thoroughly above,
11 Bayer concealed the information to avoid customer de-selection of its isocyanate products, and to
12 avoid or deflect regulatory scrutiny that might have restricted or eliminated its ability to sell its
13 isocyanate products. Bayer’s decision to risk the penalty in order to gain profits from the sale of
14 its isocyanate products indicates that it viewed the substantial risk information as equal to or very
15 close to the value of its net profits during the period of its non-compliance.

16 1431. Thus, the value of Bayer’s substantial risk information as of May 20, 2009
17 equaled at least the amount of Bayer’s TSCA Section 8(e) civil penalties or equaled some or all
18 of Bayer’s net profits from isocyanate sales during the period of its non-compliance.

19 1432. After May 20, 2009, and continuing through the filing of this complaint, Bayer
20 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
21 and the existence of the extensive quantity of substantial risk information its had obtained, as
22 alleged thoroughly in Section V above.

23 1433. Among the other concealment activities thoroughly alleged in Section V above, in
24 and after May 2010, Bayer concealed both the existence of the substantial risk information and
25 their failure to report it by refusing to report the substantial risk information to the EPA, even
26 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
27 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
28

1 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
2 complaint.

3 1434. By this and other conduct, Bayer thus continued actively and knowingly to
4 conceal its multiple obligations to transmit property to the United States Government.

5 1435. By this and other conduct, Bayer thus continued knowingly and improperly to
6 avoid or decrease its multiple obligations to transmit property to the United States Government.

7 1436. At a minimum, Bayer has continued to "act[] in reckless disregard of the truth" of
8 its multiple obligations to transmit property to the United States Government. 31 U.S.C. §
9 3729(b)(1)(A)(iii).

10 1437. Each day after May 20, 2009 through the filing of this complaint, TSCA required
11 Bayer to transmit property by reporting the substantial risk information, and by its non-
12 compliance Bayer became liable to the EPA for the additional daily penalty amounts by which
13 TSCA's civil penalties for each of Bayer's reporting violations increased. And each day after
14 May 20, 2009 through the filing of this complaint, Bayer continued actively and knowingly to
15 conceal from the EPA its continuing reporting failures and the existence of the extensive quantity
16 of substantial risk information its had obtained, as alleged thoroughly in Section V above.

17 1438. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
18 actively and knowingly concealed these additional, multiple obligations to transmit property to
19 the United States Government, and has therefore committed multiple FCA violations on each
20 such day.

21 1439. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
22 knowingly and improperly avoided or decreased these additional, multiple obligations to transmit
23 property to the United States Government, and has therefore committed multiple FCA violations
24 on each such day.

25 1440. At a minimum, Bayer has continued to "act[] in reckless disregard of the truth" of
26 these additional, multiple obligations to transmit property to the United States Government., and
27 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).
28

- c. Dow knowingly concealed or knowingly and improperly avoided or decreased its statutory and regulatory obligations to transfer property to the United States Government.

1441. On May 20, 2009, Dow was and had been obligated to provide the EPA with the following substantial risk information:

- a. 1982 Japanese Skin Contact SRI (one adverse effect, one chemical);
- b. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- c. 1989 Human Cases SRI (two adverse effects, two chemicals);
- d. 1989 German Mine SRI (two adverse effects, two chemicals);
- e. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- f. 1992 Human Cases SRI (one adverse effect, two chemicals);
- g. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- h. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- i. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

1442. As alleged thoroughly in Section V above, prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1443. By this conduct, Dow had been actively and knowingly concealing its multiple obligations to transmit property to the United States Government.

1444. By this conduct, Dow had also been knowingly and improperly avoiding or decreasing its multiple obligations to transmit property to the United States Government.

1445. Prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1446. On May 20, 2009, Dow continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1447. By this conduct, Dow continued actively and knowingly to conceal its multiple obligations to transmit property to the United States Government.

1448. By this conduct, Dow also continued knowingly and improperly to avoid or decrease its multiple obligations to transmit property to the United States Government.

1 1449. At a minimum, Dow “act[ed] in reckless disregard of the truth” of its multiple
2 obligations to transmit property to the United States Government. 31 U.S.C. §
3 3729(b)(1)(A)(iii).

4 1450. On May 20, 2009, the value of the property that Dow was obligated to but failed
5 to transmit to the United States equaled at least the amount of the civil penalties that Dow was
6 liable to pay for its prior failures to report the substantial risk information. Indeed, Dow viewed
7 the property as more valuable than those penalties, because it risked the payment of those
8 penalties to avoid providing the substantial risk information to the EPA.

9 1451. Dow profited from the sale of its isocyanate products during the time it concealed
10 and failed to report this substantial risk information. As alleged thoroughly above, Dow
11 concealed the information to avoid customer de-selection of its isocyanate products, and to avoid
12 or deflect regulatory scrutiny that might have restricted or eliminated its ability to sell its
13 isocyanate products. Dow’s decision to risk the penalty in order to gain profits from the sale of
14 its isocyanate products indicates that it viewed the substantial risk information as equal to or very
15 close to the value of its net profits during the period of its non-compliance.

16 1452. Thus, the value of Dow’s substantial risk information as of May 20, 2009 equaled
17 at least the amount of Dow’s TSCA Section 8(e) civil penalties or equaled some or all of Dow’s
18 net profits from isocyanate sales during the period of its non-compliance.

19 1453. After May 20, 2009, and continuing through the filing of this complaint, Dow has
20 continued actively and knowingly to conceal from the EPA its continuing reporting failures and
21 the existence of the extensive quantity of substantial risk information its had obtained, as alleged
22 thoroughly in Section V above.

23 1454. Among the other concealment activities thoroughly alleged in Section V above, in
24 and after May 2010, Dow concealed both the existence of the substantial risk information and
25 their failure to report it by refusing to report the substantial risk information to the EPA, even
26 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
27 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
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1 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
2 complaint.

3 1455. By this and other conduct, Dow thus continued actively and knowingly to conceal
4 its multiple obligations to transmit property to the United States Government.

5 1456. By this and other conduct, Dow thus continued knowingly and improperly to
6 avoid or decrease its multiple obligations to transmit property to the United States Government.

7 1457. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
8 its multiple obligations to transmit property to the United States Government. 31 U.S.C. §
9 3729(b)(1)(A)(iii).

10 1458. Each day after May 20, 2009 through the filing of this complaint, TSCA required
11 Dow to transmit property by reporting the substantial risk information, and by its non-
12 compliance Dow became liable to the EPA for the additional daily penalty amounts by which
13 TSCA's civil penalties for each of Dow's reporting violations increased. And each day after
14 May 20, 2009 through the filing of this complaint, Dow continued actively and knowingly to
15 conceal from the EPA its continuing reporting failures and the existence of the extensive quantity
16 of substantial risk information its had obtained, as alleged thoroughly in Section V above.

17 1459. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
18 actively and knowingly concealed these additional, multiple obligations to transmit property to
19 the United States Government, and has therefore committed multiple FCA violations on each
20 such day.

21 1460. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
22 knowingly and improperly avoided or decreased these additional, multiple obligations to transmit
23 property to the United States Government, and has therefore committed multiple FCA violations
24 on each such day.

25 1461. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
26 these additional, multiple obligations to transmit property to the United States Government., and
27 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

d. Huntsman knowingly concealed or knowingly and improperly avoided or decreased its statutory and regulatory obligations to transfer property to the United States Government.

1462. On May 20, 2009, Huntsman was and had been obligated to provide the EPA with the following substantial risk information:

- a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- b. 1989 Human Cases SRI (two adverse effects, two chemicals);
- c. 1989 German Mine SRI (two adverse effects, two chemicals);
- d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals);
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals);
- and
- h. 2003 Isocyanate Asthma SRI (one adverse effect, two chemicals).

1463. As alleged thoroughly in Section V above, prior to May 20, 2009, Huntsman, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1464. By this conduct, Huntsman had been actively and knowingly concealing its multiple obligations to transmit property to the United States Government.

1465. By this conduct, Huntsman had also been knowingly and improperly avoiding or decreasing its multiple obligations to transmit property to the United States Government.

1466. Prior to May 20, 2009, Huntsman, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk

1 information that corroborated the previously-obtained or –developed
2 substantial risk information, and even as internal III communications
3 reminded it of that previously-obtained or –developed substantial risk
4 information;

- 5 b. Refused to report the substantial risk information to the EPA, even as it
6 reported the results of animal studies that it claimed showed a less certain
7 causal relationship between isocyanate skin contact and respiratory
8 response;
- 9 c. “Harmonized” or “standardized” the hazard and/or health effects
10 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
11 precautionary labels with the disclosures of the other defendants, so as to
12 conceal the existence of the substantial risk information about human
13 health effects; and
- 14 d. Publicly disputed the potential for dermal- or low-level-induction of
15 respiratory sensitization or asthma, in direct contradiction of the extensive
16 substantial risk information it was concealing.

17 1467. On May 20, 2009, Huntsman continued actively and knowingly to conceal from
18 the EPA its reporting failure and the existence of the extensive quantity of substantial risk
19 information it had obtained, as alleged thoroughly in Section V above.

20 1468. By this conduct, Huntsman continued actively and knowingly to conceal its
21 multiple obligations to transmit property to the United States Government.

22 1469. By this conduct, Huntsman also continued knowingly and improperly to avoid or
23 decrease its multiple obligations to transmit property to the United States Government.

24 1470. At a minimum, Huntsman “act[ed] in reckless disregard of the truth” of its
25 multiple obligations to transmit property to the United States Government. 31 U.S.C. §
26 3729(b)(1)(A)(iii).

1 1471. On May 20, 2009, the value of the property that Huntsman was obligated to but
2 failed to transmit to the United States equaled at least the amount of the civil penalties that
3 Huntsman was liable to pay for its prior failures to report the substantial risk information.
4 Indeed, Huntsman viewed the property as more valuable than those penalties, because it risked
5 the payment of those penalties to avoid providing the substantial risk information to the EPA.

6 1472. Huntsman profited from the sale of its isocyanate products during the time it
7 concealed and failed to report this substantial risk information. As alleged thoroughly above,
8 Huntsman concealed the information to avoid customer de-selection of its isocyanate products,
9 and to avoid or deflect regulatory scrutiny that might have restricted or eliminated its ability to
10 sell its isocyanate products. Huntsman's decision to risk the penalty in order to gain profits from
11 the sale of its isocyanate products indicates that it viewed the substantial risk information as
12 equal to or very close to the value of its net profits during the period of its non-compliance.

13 1473. Thus, the value of Huntsman's substantial risk information as of May 20, 2009
14 equaled at least the amount of Huntsman's TSCA Section 8(e) civil penalties or equaled some or
15 all of Huntsman's net profits from isocyanate sales during the period of its non-compliance.

16 1474. After May 20, 2009, and continuing through the filing of this complaint,
17 Huntsman has continued actively and knowingly to conceal from the EPA its continuing
18 reporting failures and the existence of the extensive quantity of substantial risk information its
19 had obtained, as alleged thoroughly in Section V above.

20 1475. Among the other concealment activities thoroughly alleged in Section V above, in
21 and after May 2010, Huntsman concealed both the existence of the substantial risk information
22 and their failure to report it by refusing to report the substantial risk information to the EPA,
23 even after one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in
24 TSCA Section 8(e) reporting compliance, provided deposition and affidavit testimony in and
25 after May 2010 that identified some of the defendants' Section 8(e) reporting violations
26 identified in this complaint. Although Huntsman was not a party to the *Bice* case, Huntsman was
27 a co-defendant with BASF, Bayer, and Dow in a related case filed in West Virginia state court.
28

1 KBT&F believes that BASF, Bayer, and Dow notified Huntsman of the *Bice* case testimony, and
2 discussed its implications with Huntsman.

3 1476. By this and other conduct, Huntsman thus continued actively and knowingly to
4 conceal its multiple obligations to transmit property to the United States Government.

5 1477. By this and other conduct, Huntsman thus continued knowingly and improperly to
6 avoid or decrease its multiple obligations to transmit property to the United States Government.

7 1478. At a minimum, Huntsman has continued to “act[] in reckless disregard of the
8 truth” of its multiple obligations to transmit property to the United States Government. 31
9 U.S.C. § 3729(b)(1)(A)(iii).

10 1479. Each day after May 20, 2009 through the filing of this complaint, TSCA required
11 Huntsman to transmit property by reporting the substantial risk information, and by its non-
12 compliance Huntsman became liable to the EPA for the additional daily penalty amounts by
13 which TSCA’s civil penalties for each of Huntsman’s reporting violations increased. And each
14 day after May 20, 2009 through the filing of this complaint, Huntsman continued actively and
15 knowingly to conceal from the EPA its continuing reporting failures and the existence of the
16 extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
17 Section V above.

18 1480. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
19 thus actively and knowingly concealed these additional, multiple obligations to transmit property
20 to the United States Government, and has therefore committed multiple FCA violations on each
21 such day.

22 1481. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
23 thus knowingly and improperly avoided or decreased these additional, multiple obligations to
24 transmit property to the United States Government, and has therefore committed multiple FCA
25 violations on each such day.

26 1482. At a minimum, Huntsman has continued to “act[] in reckless disregard of the
27 truth” of these additional, multiple obligations to transmit property to the United States
28

1 Government., and has therefore committed multiple FCA violations on each day. 31 U.S.C. §
2 3729(b)(1)(A)(iii).

3 2. **Each defendant knowingly concealed or knowingly and improperly avoided**
4 **or decreased its contractual obligations to transfer property to the United**
5 **States Government.**

6 1483. As alleged thoroughly above, each defendant participated in the EPA's
7 Compliance Audit Program, and were therefore bound by the CAP Agreement, which the EPA
8 required each participating company to sign, and which is published in the Federal Register.
9 CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129-4131.

10 1484. By virtue of its participation in CAP, BASF entered a contract with the EPA in
11 the form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
12 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

13 1485. By virtue of its participation in CAP, Bayer entered a contract with the EPA in the
14 form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
15 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

16 1486. By virtue of its participation in CAP, Dow entered a contract with the EPA in the
17 form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by CAP
18 Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

19 1487. By virtue of its participation in CAP, Huntsman entered a contract with the EPA
20 in the form and substance set out in the CAP Agreement, attached as Exh. 26, as modified by
21 CAP Modification 1 (Exh. 27) and CAP Modification 2 (Exh. 28).

22 1488. In their respective contracts with the EPA, each defendant agreed and had a
23 contractual duty to audit its substantial risk reporting compliance and to submit all previously
24 unsubmitted substantial risk information, in return for which the EPA agreed to reduce
25 significantly the reporting penalties for each submitted report, and to cap the total reporting
26 penalties for all previously unsubmitted information at \$1 million. CAP Agreement, Exh. 26, 56
27 Fed. Reg. at 4129-4130, Section II.B.1 – II.B.3.

1 1489. In their respective contracts with the EPA, each defendant agreed and had a
 2 contractual duty to certify its completion of the audit program at the program's conclusion. CAP
 3 Agreement, Exh. 26, 56 Fed. Reg. at 4130, Section II.B.4.

4 1490. As alleged thoroughly above, the substantial risk information that TSCA required
 5 each defendant to report constitutes "property" that TSCA obligated each defendant to "transmit
 6 . . . to the Government." 31 U.S.C. § 3729(a)(1)(G).

7 1491. That substantial risk information also constitutes "property" that the CAP
 8 Agreement obligated each defendant to "transmit . . . to the Government." 31 U.S.C. §
 9 3729(a)(1)(G).

10 1492. As alleged thoroughly above, the EPA noted the significant value of the
 11 substantial risk information in the CAP Agreement: "Up-to-date information on hazard and
 12 exposure is vital in supporting EPA efforts to protect human health and the environment from
 13 risks from toxic chemicals." CAP Agreement, Exh. 26, 56 Fed. Reg. at 4128, Unit I.3. The EPA
 14 instituted CAP to achieve the Agency's goal of obtaining any outstanding section 8(e) data
 15 [substantial risk information]." *Id.* at 4129, Unit I.3. And the heart of the CAP Agreement
 16 concerned each participating company's submission of the substantial risk information in
 17 exchange for the EPA's "amnesty"-level penalties. *Id.* at 4129-4130, Units II.B and C. The
 18 substantial risk information that BASF, Bayer, Dow, and Huntsman failed to provide was the
 19 contractual property that the EPA contracted to obtain.

- 20 a. **BASF knowingly concealed or knowingly and improperly avoided or**
 21 **decreased its contractual obligations to transfer property to the United**
States Government.

22 1493. BASF violated its contractual CAP-Agreement duty to submit the following
 23 unreported substantial risk information to the EPA by May 15, 1996:

- 24 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
 25 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
 26 c. 1989 German Mine SRI (two adverse effects, two chemicals);
 27 d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
 28

- e. 1992 Human Cases SRI (one adverse effect, two chemicals);
- f. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
- g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

1494. On May 20, 2009, BASF was and had been obligated to provide the EPA with the substantial risk information, specified above, that it had failed to provide to the EPA as required by the CAP Agreement.

1495. As alleged thoroughly in Section V above, prior to May 20, 2009, BASF, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1496. By this conduct, BASF had been actively and knowingly concealing its multiple breaches of its CAP-Agreement duty to transmit property to the United States Government.

1497. By this conduct, BASF had also been knowingly and improperly avoiding or decreasing its multiple breaches of its CAP-Agreement duty to transmit property to the United States Government.

1498. Prior to May 20, 2009, BASF, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain

1 causal relationship between isocyanate skin contact and respiratory
2 response;

3 c. “Harmonized” or “standardized” the hazard and/or health effects
4 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
5 precautionary labels with the disclosures of the other defendants, so as to
6 conceal the existence of the substantial risk information about human
7 health effects; and

8 d. Publicly disputed the potential for dermal- or low-level-induction of
9 respiratory sensitization or asthma, in direct contradiction of the extensive
10 substantial risk information it was concealing.

11 1499. On May 20, 2009, BASF continued actively and knowingly to conceal from the
12 EPA its reporting failures and the existence of the extensive quantity of substantial risk
13 information it had obtained, as alleged thoroughly in Section V above.

14 1500. By this conduct, BASF continued actively and knowingly to conceal its multiple
15 breaches of its CAP-Agreement duty to transmit property to the United States Government.

16 1501. By this conduct, BASF also continued knowingly and improperly to avoid or
17 decrease its multiple breaches of its CAP-Agreement duty to transmit property to the United
18 States Government.

19 1502. At a minimum, BASF “act[ed] in reckless disregard of the truth” of its multiple
20 breaches of its CAP-Agreement duty to transmit property to the United States Government. 31
21 U.S.C. § 3729(b)(1)(A)(iii).

22 1503. On May 20, 2009, the value of the property that BASF was obligated but had
23 failed to transmit to the United States under the CAP Agreement equaled at least the amount of
24 the contractual damages for breach. Those damages included the civil penalties for the
25 substantial risk information “not submitted under the TSCA Section 8(e) Compliance Audit
26 Program” as calculated under the TSCA Enforcement Response Policy as of and through the date
27 the EPA takes “appropriate enforcement action” after it has “determine[d] later” that the
28

1 participating company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129,
2 Unit II.A.5. Indeed, BASF viewed the property as more valuable than those damages, because it
3 risked the payment of those damages to avoid providing the substantial risk information to the
4 EPA.

5 1504. BASF profited from the sale of its isocyanate products during the time it
6 concealed and failed to report this substantial risk information. As alleged thoroughly above,
7 BASF concealed the information to avoid customer de-selection of its isocyanate products, and
8 to avoid or deflect regulatory scrutiny that might have restricted or eliminated its ability to sell its
9 isocyanate products. BASF's decision to breach the CAP Agreement and risk contractual
10 damages in order to gain profits from the sale of its isocyanate products indicates that it viewed
11 the substantial risk information as equal to or very close to the value of its net profits during the
12 period of its non-compliance.

13 1505. Thus, the value, as of May 20, 2009, of the substantial risk information that BASF
14 was obligated but had failed to provide to the EPA under the CAP Agreement equaled at least
15 the amount of BASF's TSCA Section 8(e) civil penalties or equaled some or all of BASF's net
16 profits from isocyanate sales during the period of its non-compliance.

17 1506. After May 20, 2009, and continuing through the filing of this complaint, BASF
18 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
19 and the existence of the extensive quantity of substantial risk information its had obtained, as
20 alleged thoroughly in Section V above.

21 1507. Among the other concealment activities thoroughly alleged in Section V above, in
22 and after May 2010, BASF concealed both the existence of the substantial risk information and
23 its failure to report it by refusing to report the substantial risk information to the EPA, even after
24 one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA Section
25 8(e) reporting compliance, provided deposition and affidavit testimony in and after May 2010
26 that identified some of the defendants' Section 8(e) reporting violations identified in this
27 complaint.

1 1508. By this and other conduct, BASF thus continued actively and knowingly to
2 conceal its multiple breaches of its CAP-Agreement duty to transmit property to the United
3 States Government.

4 1509. By this and other conduct, BASF thus continued knowingly and improperly to
5 avoid or decrease its multiple breaches of its CAP-Agreement duty to transmit property to the
6 United States Government.

7 1510. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of
8 its multiple breaches of its CAP-Agreement duty to transmit property to the United States
9 Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

10 1511. Each day after May 20, 2009 through the filing of this complaint, TSCA required
11 BASF to report the substantial risk information that it had failed to provide to the EPA as
12 required by the CAP Agreement. Each day after May 20, 2009, BASF had a contractual duty to
13 provide the substantial risk information to the EPA. And each day after May 20, 2009 through
14 the filing of this complaint, BASF continued actively and knowingly to conceal from the EPA its
15 continuing reporting failures, its continuing contractual breaches, and the existence of the
16 extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
17 Section V above.

18 1512. Each day after May 20, 2009 through the filing of this complaint, BASF has thus
19 actively and knowingly concealed these additional, multiple breaches of its CAP-Agreement
20 duty to transmit property to the United States Government, and has therefore committed multiple
21 FCA violations on each such day.

22 1513. Each day after May 20, 2009 through the filing of this complaint, BASF has thus
23 knowingly and improperly avoided or decreased these additional, multiple breaches of its CAP-
24 Agreement duty to transmit property to the United States Government, and has therefore
25 committed multiple FCA violations on each such day.

26 1514. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of
27 these additional, multiple breaches of its CAP-Agreement duty to transmit property to the United
28

1 States Government., and has therefore committed multiple FCA violations on each day. 31

2 U.S.C. § 3729(b)(1)(A)(iii).

- 3 b. **Bayer knowingly concealed or knowingly and improperly avoided or**
 4 **decreased its contractual obligations to transfer property to the United**
 5 **States Government.**

6 1515. Bayer violated its contractual CAP-Agreement duty to submit the following
 7 unreported substantial risk information to the EPA by May 15, 1996:

- 8 a. Bayer's 1979 Skin Contact SRI (one adverse effect, two chemicals);
 9 b. 1982 Japanese Skin Contact SRI (one adverse effect, three chemicals);
 10 c. 1988 Mineworkers SRI (two adverse effects, two chemicals);
 11 d. 1989 Human Cases SRI (two adverse effects, two chemicals);
 12 e. 1989 German Mine SRI (two adverse effects, two chemicals);
 13 f. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
 14 g. 1992 Human Cases SRI (one adverse effect, two chemicals);
 15 h. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
 16 i. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

17 1516. On May 20, 2009, Bayer was and had been obligated to provide the EPA with the
 18 substantial risk information, specified above, that it had failed to provide to the EPA as required
 19 by the CAP Agreement.

20 1517. As alleged thoroughly in Section V above, prior to May 20, 2009, Bayer,
 21 individually and in conspiracy with the other defendants, had been actively and knowingly
 22 concealing from the EPA both the existence of and its failure to report to the EPA about the
 23 extensive quantity of substantial risk information its had obtained about the induction of human
 24 respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI,
 25 MDI, and/or PMDI.

26 1518. By this conduct, Bayer had been actively and knowingly concealing its multiple
 27 breaches of its CAP-Agreement duty to transmit property to the United States Government.
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1 1519. By this conduct, Bayer had also been knowingly and improperly avoiding or
2 decreasing its multiple breaches of its CAP-Agreement duty to transmit property to the United
3 States Government.

4 1520. Prior to May 20, 2009, Bayer, individually and in conspiracy with the other
5 defendants, had:

- 6 a. Refused to report the substantial risk information to the EPA, even as it
7 continued to obtain and/or develop separate and additional substantial risk
8 information that corroborated the previously-obtained or –developed
9 substantial risk information, and even as internal III communications
10 reminded it of that previously-obtained or –developed substantial risk
11 information;
- 12 b. Refused to report the substantial risk information to the EPA, even as it
13 reported the results of animal studies that it claimed showed a less certain
14 causal relationship between isocyanate skin contact and respiratory
15 response;
- 16 c. “Harmonized” or “standardized” the hazard and/or health effects
17 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
18 precautionary labels with the disclosures of the other defendants, so as to
19 conceal the existence of the substantial risk information about human
20 health effects; and
- 21 d. Publicly disputed the potential for dermal- or low-level-induction of
22 respiratory sensitization or asthma, in direct contradiction of the extensive
23 substantial risk information it was concealing.

24 1521. On May 20, 2009, Bayer continued actively and knowingly to conceal from the
25 EPA its reporting failures and the existence of the extensive quantity of substantial risk
26 information it had obtained, as alleged thoroughly in Section V above.

1 1522. By this conduct, Bayer continued actively and knowingly to conceal its multiple
2 breaches of its CAP-Agreement duty to transmit property to the United States Government.

3 1523. By this conduct, Bayer also continued knowingly and improperly to avoid or
4 decrease its multiple breaches of its CAP-Agreement duty to transmit property to the United
5 States Government.

6 1524. At a minimum, Bayer “act[ed] in reckless disregard of the truth” of its multiple
7 breaches of its CAP-Agreement duty to transmit property to the United States Government. 31
8 U.S.C. § 3729(b)(1)(A)(iii).

9 1525. On May 20, 2009, the value of the property that Bayer was obligated but had
10 failed to transmit to the United States under the CAP Agreement equaled at least the amount of
11 the contractual damages for breach. Those damages included the civil penalties for the
12 substantial risk information “not submitted under the TSCA Section 8(e) Compliance Audit
13 Program” as calculated under the TSCA Enforcement Response Policy as of and through the date
14 the EPA takes “appropriate enforcement action” after it has “determine[d] later” that the
15 participating company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129,
16 Unit II.A.5. Indeed, Bayer viewed the property as more valuable than those damages, because it
17 risked the payment of those damages to avoid providing the substantial risk information to the
18 EPA.

19 1526. Bayer profited from the sale of its isocyanate products during the time it
20 concealed and failed to report this substantial risk information. As alleged thoroughly above,
21 Bayer concealed the information to avoid customer de-selection of its isocyanate products, and to
22 avoid or deflect regulatory scrutiny that might have restricted or eliminated its ability to sell its
23 isocyanate products. Bayer’s decision to breach the CAP Agreement and risk contractual
24 damages in order to gain profits from the sale of its isocyanate products indicates that it viewed
25 the substantial risk information as equal to or very close to the value of its net profits during the
26 period of its non-compliance.

1 1527. Thus, the value, as of May 20, 2009, of the substantial risk information that Bayer
2 was obligated but had failed to provide to the EPA under the CAP Agreement equaled at least
3 the amount of Bayer's TSCA Section 8(e) civil penalties or equaled some or all of Bayer's net
4 profits from isocyanate sales during the period of its non-compliance.

5 1528. After May 20, 2009, and continuing through the filing of this complaint, Bayer
6 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
7 and the existence of the extensive quantity of substantial risk information its had obtained, as
8 alleged thoroughly in Section V above.

9 1529. Among the other concealment activities thoroughly alleged in Section V above, in
10 and after May 2010, Bayer concealed both the existence of the substantial risk information and
11 its failure to report it by refusing to report the substantial risk information to the EPA, even after
12 one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA Section
13 8(e) reporting compliance, provided deposition and affidavit testimony in and after May 2010
14 that identified some of the defendants' Section 8(e) reporting violations identified in this
15 complaint.

16 1530. By this and other conduct, Bayer thus continued actively and knowingly to
17 conceal its multiple breaches of its CAP-Agreement duty to transmit property to the United
18 States Government.

19 1531. By this and other conduct, Bayer thus continued knowingly and improperly to
20 avoid or decrease its multiple breaches of its CAP-Agreement duty to transmit property to the
21 United States Government.

22 1532. At a minimum, Bayer has continued to "act[] in reckless disregard of the truth" of
23 its multiple breaches of its CAP-Agreement duty to transmit property to the United States
24 Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

25 1533. Each day after May 20, 2009 through the filing of this complaint, TSCA required
26 Bayer to report the substantial risk information that it had failed to provide to the EPA as
27 required by the CAP Agreement. Each day after May 20, 2009, Bayer had a contractual duty to
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1 provide the substantial risk information to the EPA. And each day after May 20, 2009 through
2 the filing of this complaint, Bayer continued actively and knowingly to conceal from the EPA its
3 continuing reporting failures, its continuing contractual breaches, and the existence of the
4 extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
5 Section V above.

6 1534. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
7 actively and knowingly concealed these additional, multiple breaches of its CAP-Agreement
8 duty to transmit property to the United States Government, and has therefore committed multiple
9 FCA violations on each such day.

10 1535. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
11 knowingly and improperly avoided or decreased these additional, multiple breaches of its CAP-
12 Agreement duty to transmit property to the United States Government, and has therefore
13 committed multiple FCA violations on each such day.

14 1536. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
15 these additional, multiple breaches of its CAP-Agreement duty to transmit property to the United
16 States Government., and has therefore committed multiple FCA violations on each day. 31
17 U.S.C. § 3729(b)(1)(A)(iii).

18 c. **Dow knowingly concealed or knowingly and improperly avoided or**
19 **decreased its contractual obligations to transfer property to the United**
States Government.

20 1537. Dow violated its contractual CAP-Agreement duty to submit the following
21 unreported substantial risk information to the EPA by May 15, 1996:

- 22 a. 1982 Japanese Skin Contact SRI (one adverse effect, one chemical);
- 23 b. 1988 Mineworkers SRI (two adverse effects, two chemicals);
- 24 c. 1989 Human Cases SRI (two adverse effects, two chemicals);
- 25 d. 1989 German Mine SRI (two adverse effects, two chemicals);
- 26 e. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
- 27 f. 1992 Human Cases SRI (one adverse effect, two chemicals);

g. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and

h. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

1538. On May 20, 2009, Dow was and had been obligated to provide the EPA with the substantial risk information, specified above, that it had failed to provide to the EPA as required by the CAP Agreement.

1539. As alleged thoroughly in Section V above, prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had been actively and knowingly concealing from the EPA both the existence of and its failure to report to the EPA about the extensive quantity of substantial risk information its had obtained about the induction of human respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI, MDI, and/or PMDI.

1540. By this conduct, Dow had been actively and knowingly concealing its multiple breaches of its CAP-Agreement duty to transmit property to the United States Government.

1541. By this conduct, Dow had also been knowingly and improperly avoiding or decreasing its multiple breaches of its CAP-Agreement duty to transmit property to the United States Government.

1542. Prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain

1 causal relationship between isocyanate skin contact and respiratory
2 response;

- 3 c. “Harmonized” or “standardized” the hazard and/or health effects
4 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
5 precautionary labels with the disclosures of the other defendants, so as to
6 conceal the existence of the substantial risk information about human
7 health effects; and
8 d. Publicly disputed the potential for dermal- or low-level-induction of
9 respiratory sensitization or asthma, in direct contradiction of the extensive
10 substantial risk information it was concealing.

11 1543. On May 20, 2009, Dow continued actively and knowingly to conceal from the
12 EPA its reporting failures and the existence of the extensive quantity of substantial risk
13 information it had obtained, as alleged thoroughly in Section V above.

14 1544. By this conduct, Dow continued actively and knowingly to conceal its multiple
15 breaches of its CAP-Agreement duty to transmit property to the United States Government.

16 1545. By this conduct, Dow also continued knowingly and improperly to avoid or
17 decrease its multiple breaches of its CAP-Agreement duty to transmit property to the United
18 States Government.

19 1546. At a minimum, Dow “act[ed] in reckless disregard of the truth” of its multiple
20 breaches of its CAP-Agreement duty to transmit property to the United States Government. 31
21 U.S.C. § 3729(b)(1)(A)(iii).

22 1547. On May 20, 2009, the value of the property that Dow was obligated but had failed
23 to transmit to the United States under the CAP Agreement equaled at least the amount of the
24 contractual damages for breach. Those damages included the civil penalties for the substantial
25 risk information “not submitted under the TSCA Section 8(e) Compliance Audit Program” as
26 calculated under the TSCA Enforcement Response Policy as of and through the date the EPA
27 takes “appropriate enforcement action” after it has “determine[d] later” that the participating
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1 company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129, Unit II.A.5.
2 Indeed, Dow viewed the property as more valuable than those damages, because it risked the
3 payment of those damages to avoid providing the substantial risk information to the EPA.

4 1548. Dow profited from the sale of its isocyanate products during the time it concealed
5 and failed to report this substantial risk information. As alleged thoroughly above, Dow
6 concealed the information to avoid customer de-selection of its isocyanate products, and to avoid
7 or deflect regulatory scrutiny that might have restricted or eliminated its ability to sell its
8 isocyanate products. Dow's decision to breach the CAP Agreement and risk contractual
9 damages in order to gain profits from the sale of its isocyanate products indicates that it viewed
10 the substantial risk information as equal to or very close to the value of its net profits during the
11 period of its non-compliance.

12 1549. Thus, the value, as of May 20, 2009, of the substantial risk information that Dow
13 was obligated but had failed to provide to the EPA under the CAP Agreement equaled at least
14 the amount of Dow's TSCA Section 8(e) civil penalties or equaled some or all of Dow's net
15 profits from isocyanate sales during the period of its non-compliance.

16 1550. After May 20, 2009, and continuing through the filing of this complaint, Dow has
17 continued actively and knowingly to conceal from the EPA its continuing reporting failures and
18 the existence of the extensive quantity of substantial risk information its had obtained, as alleged
19 thoroughly in Section V above.

20 1551. Among the other concealment activities thoroughly alleged in Section V above, in
21 and after May 2010, Dow concealed both the existence of the substantial risk information and its
22 failure to report it by refusing to report the substantial risk information to the EPA, even after
23 one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA Section
24 8(e) reporting compliance, provided deposition and affidavit testimony in and after May 2010
25 that identified some of the defendants' Section 8(e) reporting violations identified in this
26 complaint.

1 1552. By this and other conduct, Dow thus continued actively and knowingly to conceal
2 its multiple breaches of its CAP-Agreement duty to transmit property to the United States
3 Government.

4 1553. By this and other conduct, Dow thus continued knowingly and improperly to
5 avoid or decrease its multiple breaches of its CAP-Agreement duty to transmit property to the
6 United States Government.

7 1554. At a minimum, Dow has continued to “act[] in reckless disregard of the truth” of
8 its multiple breaches of its CAP-Agreement duty to transmit property to the United States
9 Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

10 1555. Each day after May 20, 2009 through the filing of this complaint, TSCA required
11 Dow to report the substantial risk information that it had failed to provide to the EPA as required
12 by the CAP Agreement. Each day after May 20, 2009, Dow had a contractual duty to provide
13 the substantial risk information to the EPA. And each day after May 20, 2009 through the filing
14 of this complaint, Dow continued actively and knowingly to conceal from the EPA its continuing
15 reporting failures, its continuing contractual breaches, and the existence of the extensive quantity
16 of substantial risk information its had obtained, as alleged thoroughly in Section V above.

17 1556. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
18 actively and knowingly concealed these additional, multiple breaches of its CAP-Agreement
19 duty to transmit property to the United States Government, and has therefore committed multiple
20 FCA violations on each such day.

21 1557. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
22 knowingly and improperly avoided or decreased these additional, multiple breaches of its CAP-
23 Agreement duty to transmit property to the United States Government, and has therefore
24 committed multiple FCA violations on each such day.

25 1558. At a minimum, Dow has continued to “act[] in reckless disregard of the truth” of
26 these additional, multiple breaches of its CAP-Agreement duty to transmit property to the United
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1 States Government., and has therefore committed multiple FCA violations on each day. 31

2 U.S.C. § 3729(b)(1)(A)(iii).

- 3 d. **Huntsman knowingly concealed or knowingly and improperly**
 4 **avoided or decreased its contractual obligations to transfer property to**
 5 **the United States Government.**

6 1559. Huntsman violated its contractual CAP-Agreement duty to submit the following
 7 unreported substantial risk information to the EPA by May 15, 1996:

- 8 a. 1988 Mineworkers SRI (two adverse effects, two chemicals);
 9 b. 1989 Human Cases SRI (two adverse effects, two chemicals);
 10 c. 1989 German Mine SRI (two adverse effects, two chemicals);
 11 d. 1989 Nakata Papers SRI (one adverse effect, two chemicals);
 12 e. 1992 Human Cases SRI (one adverse effect, two chemicals);
 13 f. 1992 Specific Scenario SRI (two adverse effects, two chemicals); and
 14 g. 1993 Especial Work Situation SRI (two adverse effects, two chemicals).

15 1560. On May 20, 2009, Huntsman was and had been obligated to provide the EPA with
 16 the substantial risk information, specified above, that it had failed to provide to the EPA as
 17 required by the CAP Agreement.

18 1561. As alleged thoroughly in Section V above, prior to May 20, 2009, Huntsman,
 19 individually and in conspiracy with the other defendants, had been actively and knowingly
 20 concealing from the EPA both the existence of and its failure to report to the EPA about the
 21 extensive quantity of substantial risk information its had obtained about the induction of human
 22 respiratory sensitization and asthma by either skin contact with or low-level inhalation of TDI,
 23 MDI, and/or PMDI.

24 1562. By this conduct, Huntsman had been actively and knowingly concealing its
 25 multiple breaches of its CAP-Agreement duty to transmit property to the United States
 26 Government.
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1 1563. By this conduct, Huntsman had also been knowingly and improperly avoiding or
2 decreasing its multiple breaches of its CAP-Agreement duty to transmit property to the United
3 States Government.

4 1564. Prior to May 20, 2009, Huntsman, individually and in conspiracy with the other
5 defendants, had:

- 6 a. Refused to report the substantial risk information to the EPA, even as it
7 continued to obtain and/or develop separate and additional substantial risk
8 information that corroborated the previously-obtained or –developed
9 substantial risk information, and even as internal III communications
10 reminded it of that previously-obtained or –developed substantial risk
11 information;
- 12 b. Refused to report the substantial risk information to the EPA, even as it
13 reported the results of animal studies that it claimed showed a less certain
14 causal relationship between isocyanate skin contact and respiratory
15 response;
- 16 c. “Harmonized” or “standardized” the hazard and/or health effects
17 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
18 precautionary labels with the disclosures of the other defendants, so as to
19 conceal the existence of the substantial risk information about human
20 health effects; and
- 21 d. Publicly disputed the potential for dermal- or low-level-induction of
22 respiratory sensitization or asthma, in direct contradiction of the extensive
23 substantial risk information it was concealing.

24 1565. On May 20, 2009, Huntsman continued actively and knowingly to conceal from
25 the EPA its reporting failures and the existence of the extensive quantity of substantial risk
26 information it had obtained, as alleged thoroughly in Section V above.

1 1566. By this conduct, Huntsman continued actively and knowingly to conceal its
2 multiple breaches of its CAP-Agreement duty to transmit property to the United States
3 Government.

4 1567. By this conduct, Huntsman also continued knowingly and improperly to avoid or
5 decrease its multiple breaches of its CAP-Agreement duty to transmit property to the United
6 States Government.

7 1568. At a minimum, Huntsman “act[ed] in reckless disregard of the truth” of its
8 multiple breaches of its CAP-Agreement duty to transmit property to the United States
9 Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

10 1569. On May 20, 2009, the value of the property that Huntsman was obligated but had
11 failed to transmit to the United States under the CAP Agreement equaled at least the amount of
12 the contractual damages for breach. Those damages included the civil penalties for the
13 substantial risk information “not submitted under the TSCA Section 8(e) Compliance Audit
14 Program” as calculated under the TSCA Enforcement Response Policy as of and through the date
15 the EPA takes “appropriate enforcement action” after it has “determine[d] later” that the
16 participating company breached the agreement. CAP Agreement, Exh. 26, 56 Fed. Reg. at 4129,
17 Unit II.A.5. Indeed, Huntsman viewed the property as more valuable than those damages,
18 because it risked the payment of those damages to avoid providing the substantial risk
19 information to the EPA.

20 1570. Huntsman profited from the sale of its isocyanate products during the time it
21 concealed and failed to report this substantial risk information. As alleged thoroughly above,
22 Huntsman concealed the information to avoid customer de-selection of its isocyanate products,
23 and to avoid or deflect regulatory scrutiny that might have restricted or eliminated its ability to
24 sell its isocyanate products. Huntsman’s decision to breach the CAP Agreement and risk
25 contractual damages in order to gain profits from the sale of its isocyanate products indicates that
26 it viewed the substantial risk information as equal to or very close to the value of its net profits
27 during the period of its non-compliance.

1 1571. Thus, the value, as of May 20, 2009, of the substantial risk information that
2 Huntsman was obligated but had failed to provide to the EPA under the CAP Agreement equaled
3 at least the amount of Huntsman's TSCA Section 8(e) civil penalties or equaled some or all of
4 Huntsman's net profits from isocyanate sales during the period of its non-compliance.

5 1572. After May 20, 2009, and continuing through the filing of this complaint,
6 Huntsman has continued actively and knowingly to conceal from the EPA its continuing
7 reporting failures and the existence of the extensive quantity of substantial risk information its
8 had obtained, as alleged thoroughly in Section V above.

9 1573. Among the other concealment activities thoroughly alleged in Section V above, in
10 and after May 2010, Huntsman concealed both the existence of the substantial risk information
11 and its failure to report it by refusing to report the substantial risk information to the EPA, even
12 after one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA
13 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
14 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
15 complaint.

16 1574. By this and other conduct, Huntsman thus continued actively and knowingly to
17 conceal its multiple breaches of its CAP-Agreement duty to transmit property to the United
18 States Government.

19 1575. By this and other conduct, Huntsman thus continued knowingly and improperly to
20 avoid or decrease its multiple breaches of its CAP-Agreement duty to transmit property to the
21 United States Government.

22 1576. At a minimum, Huntsman has continued to "act[] in reckless disregard of the
23 truth" of its multiple breaches of its CAP-Agreement duty to transmit property to the United
24 States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

25 1577. Each day after May 20, 2009 through the filing of this complaint, TSCA required
26 Huntsman to report the substantial risk information that it had failed to provide to the EPA as
27 required by the CAP Agreement. Each day after May 20, 2009, Huntsman had a contractual
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1 duty to provide the substantial risk information to the EPA. And each day after May 20, 2009
 2 through the filing of this complaint, Huntsman continued actively and knowingly to conceal from
 3 the EPA its continuing reporting failures, its continuing contractual breaches, and the existence
 4 of the extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
 5 Section V above.

6 1578. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
 7 thus actively and knowingly concealed these additional, multiple breaches of its CAP-Agreement
 8 duty to transmit property to the United States Government, and has therefore committed multiple
 9 FCA violations on each such day.

10 1579. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
 11 thus knowingly and improperly avoided or decreased these additional, multiple breaches of its
 12 CAP-Agreement duty to transmit property to the United States Government, and has therefore
 13 committed multiple FCA violations on each such day.

14 1580. At a minimum, Huntsman has continued to “act[] in reckless disregard of the
 15 truth” of these additional, multiple breaches of its CAP-Agreement duty to transmit property to
 16 the United States Government., and has therefore committed multiple FCA violations on each
 17 day. 31 U.S.C. § 3729(b)(1)(A)(iii).

18 **C. Each defendant had possession, custody, or control of money or property to be used**
 19 **by the United States Government and knowingly delivered less than all of it.**

20 1581. As amended effective May 20, 2009, an entity violates the FCA when it “has
 21 possession custody, or control of property or money used, or to be used, by the Government and
 22 knowingly delivers, or causes to be delivered, less than all of that money or property.” 31 U.S.C.
 23 § 3729(a)(1)(D).

24 1582. Before the 2009 amendments, the comparable reverse false claims provision
 25 imposed liability on a person who “has possession, custody, or control of property or money
 26 used, or to be used, by the Government and, intending to defraud the Government or willfully to
 27 conceal the property, delivers, or causes to be delivered, less property than the amount *for which*
 28

1 *the person receives a certificate or receipt.*” Superseded language of 31 U.S.C. 3729(a)(4)(2008)
2 (emphasis added).

3 1583. Thus, prior to May 20, 2009, the defendant’s receipt of a “certificate or receipt”
4 for the money or property was a required element of the claim. The 2009 amendments created
5 liability for a defendant’s knowing delivery of less than all of the money or property to be used
6 by the government, regardless of whether the government provided a receipt or certificate for the
7 money or property. Therefore, on May 20, 2009, each defendant began to violate the FCA when
8 it “knowingly deliver[ed], or cause[d] to be delivered, less than all of that money or property.”
9 31 U.S.C. § 3729(a)(1)(D).

10 1584. KBT&F brings this action within six years of the date of each defendant’s first
11 violation of the FCA, and the action is therefore timely. 31 U.S.C. § 3731(b)(1).

12 **1. Each defendant had possession custody, or control of money to be used by the**
13 **United States Government and knowingly delivered less than all of it.**

14 **a. BASF possessed money and failed to deliver it to the United States**
15 **Government.**

16 1585. As alleged thoroughly above, on May 20, 2009, BASF had “possession, custody,
17 or control of . . . money . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That
18 money comprised the civil penalties that BASF was obligated to pay to the United States
19 Government under its statutory and regulatory TSCA duties and under its contractual CAP-
20 Agreement duties.

21 1586. The United States Government would have used this money that BASF was and
22 continues to be obligated to pay.

23 1587. As alleged thoroughly above, on May 20, 2009, BASF “deliver[ed], or cause[d] to
24 be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D).

25 1588. As alleged thoroughly above, on May 20, 2009. BASF “*knowingly* deliver[ed], or
26 cause[d] to be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D) (emphasis
27 added).
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1589. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)((1)(B). Rather, those terms “mean that a person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at § 3729(b)(1)(A)(ii) and (iii).

1590. Prior to May 20, 2009, BASF, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1 1591. On May 20, 2009, BASF continued actively and knowingly to conceal from the
2 EPA its reporting failure and the existence of the extensive quantity of substantial risk
3 information it had obtained, as alleged thoroughly in Section V above.

4 1592. By this conduct, BASF continued actively and knowingly to conceal its multiple
5 obligations to deliver money to the United States Government.

6 1593. At a minimum, BASF “act[ed] in reckless disregard of the truth” of its multiple
7 obligations to deliver money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

8 1594. After May 20, 2009, and continuing through the filing of this complaint, BASF
9 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
10 and the existence of the extensive quantity of substantial risk information its had obtained, as
11 alleged thoroughly in Section V above.

12 1595. Among the other concealment activities thoroughly alleged in Section V above, in
13 and after May 2010, BASF concealed both the existence of the substantial risk information and
14 their failure to report it by refusing to report the substantial risk information to the EPA, even
15 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
16 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
17 2010 that identified some of the defendants’ Section 8(e) reporting violations identified in this
18 complaint.

19 1596. By this and other conduct, BASF thus continued actively and knowingly to
20 conceal its multiple obligations to deliver money to the United States Government.

21 1597. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of
22 its multiple obligations to deliver money to the United States Government. 31 U.S.C. §
23 3729(b)(1)(A)(iii).

24 1598. Each day after May 20, 2009 through the filing of this complaint, BASF became
25 liable to the EPA for the additional daily penalty amounts by which TSCA’s civil penalties for
26 each of BASF’s reporting violations increased. And each day after May 20, 2009 through the
27 filing of this complaint, BASF continued actively and knowingly to conceal from the EPA its
28

1 continuing reporting failures and the existence of the extensive quantity of substantial risk
2 information its had obtained, as alleged thoroughly in Section V above.

3 1599. Each day after May 20, 2009 through the filing of this complaint, BASF has thus
4 actively and knowingly concealed these additional, multiple obligations to deliver money to the
5 United States Government, and has therefore committed multiple FCA violations on each such
6 day.

7 1600. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of
8 these additional, multiple obligations to deliver money to the United States Government., and has
9 therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

10 **b. Bayer possessed money and failed to deliver it to the United States**
11 **Government.**

12 1601. As alleged thoroughly above, on May 20, 2009, Bayer had “possession, custody,
13 or control of . . . money . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That
14 money comprised the civil penalties that Bayer was obligated to pay to the United States
15 Government under its statutory and regulatory TSCA duties and under its contractual CAP-
16 Agreement duties.

17 1602. The United States Government would have used this money that Bayer was and
18 continues to be obligated to pay.

19 1603. As alleged thoroughly above, on May 20, 2009, Bayer “deliver[ed], or cause[d] to
20 be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D).

21 1604. As alleged thoroughly above, on May 20, 2009. Bayer “*knowingly* deliver[ed], or
22 cause[d] to be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D) (emphasis
23 added).

24 1605. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of
25 specific intent to defraud.” 31 U.S.C. § 3729(b)((1)(B). Rather, those terms “mean that a
26 person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the
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1 information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at §
2 3729(b)(1)(A)(ii) and (iii).

3 1606. Prior to May 20, 2009, Bayer, individually and in conspiracy with the other
4 defendants, had:

- 5 a. Refused to report the substantial risk information to the EPA, even as it
6 continued to obtain and/or develop separate and additional substantial risk
7 information that corroborated the previously-obtained or –developed
8 substantial risk information, and even as internal III communications
9 reminded it of that previously-obtained or –developed substantial risk
10 information;
- 11 b. Refused to report the substantial risk information to the EPA, even as it
12 reported the results of animal studies that it claimed showed a less certain
13 causal relationship between isocyanate skin contact and respiratory
14 response;
- 15 c. “Harmonized” or “standardized” the hazard and/or health effects
16 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
17 precautionary labels with the disclosures of the other defendants, so as to
18 conceal the existence of the substantial risk information about human
19 health effects; and
- 20 d. Publicly disputed the potential for dermal- or low-level-induction of
21 respiratory sensitization or asthma, in direct contradiction of the extensive
22 substantial risk information it was concealing.

23 1607. On May 20, 2009, Bayer continued actively and knowingly to conceal from the
24 EPA its reporting failure and the existence of the extensive quantity of substantial risk
25 information it had obtained, as alleged thoroughly in Section V above.

26 1608. By this conduct, Bayer continued actively and knowingly to conceal its multiple
27 obligations to deliver money to the United States Government.

1 1609. At a minimum, Bayer “act[ed] in reckless disregard of the truth” of its multiple
2 obligations to deliver money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

3 1610. After May 20, 2009, and continuing through the filing of this complaint, Bayer
4 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
5 and the existence of the extensive quantity of substantial risk information its had obtained, as
6 alleged thoroughly in Section V above.

7 1611. Among the other concealment activities thoroughly alleged in Section V above, in
8 and after May 2010, Bayer concealed both the existence of the substantial risk information and
9 their failure to report it by refusing to report the substantial risk information to the EPA, even
10 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
11 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
12 2010 that identified some of the defendants’ Section 8(e) reporting violations identified in this
13 complaint.

14 1612. By this and other conduct, Bayer thus continued actively and knowingly to
15 conceal its multiple obligations to deliver money to the United States Government.

16 1613. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
17 its multiple obligations to deliver money to the United States Government. 31 U.S.C. §
18 3729(b)(1)(A)(iii).

19 1614. Each day after May 20, 2009 through the filing of this complaint, Bayer became
20 liable to the EPA for the additional daily penalty amounts by which TSCA’s civil penalties for
21 each of Bayer’s reporting violations increased. And each day after May 20, 2009 through the
22 filing of this complaint, Bayer continued actively and knowingly to conceal from the EPA its
23 continuing reporting failures and the existence of the extensive quantity of substantial risk
24 information its had obtained, as alleged thoroughly in Section V above.

25 1615. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
26 actively and knowingly concealed these additional, multiple obligations to deliver money to the
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1 United States Government, and has therefore committed multiple FCA violations on each such
2 day.

3 1616. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
4 these additional, multiple obligations to deliver money to the United States Government., and has
5 therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

6 c. **Dow possessed money and failed to deliver it to the United States**
7 **Government.**

8 1617. As alleged thoroughly above, on May 20, 2009, Dow had “possession, custody, or
9 control of . . . money . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That
10 money comprised the civil penalties that Dow was obligated to pay to the United States
11 Government under its statutory and regulatory TSCA duties and under its contractual CAP-
12 Agreement duties.

13 1618. The United States Government would have used this money that Dow was and
14 continues to be obligated to pay.

15 1619. As alleged thoroughly above, on May 20, 2009, Dow “deliver[ed], or cause[d] to
16 be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D).

17 1620. As alleged thoroughly above, on May 20, 2009. Dow “*knowingly* deliver[ed], or
18 cause[d] to be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D) (emphasis
19 added).

20 1621. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of
21 specific intent to defraud.” 31 U.S.C. § 3729(b)((1)(B). Rather, those terms “mean that a
22 person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the
23 information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at §
24 3729(b)(1)(A)(ii) and (iii).

25 1622. Prior to May 20, 2009, Dow, individually and in conspiracy with the other
26 defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1623. On May 20, 2009, Dow continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1624. By this conduct, Dow continued actively and knowingly to conceal its multiple obligations to deliver money to the United States Government.

1625. At a minimum, Dow “act[ed] in reckless disregard of the truth” of its multiple obligations to deliver money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

1626. After May 20, 2009, and continuing through the filing of this complaint, Dow has continued actively and knowingly to conceal from the EPA its continuing reporting failures and

1 the existence of the extensive quantity of substantial risk information its had obtained, as alleged
2 thoroughly in Section V above.

3 1627. Among the other concealment activities thoroughly alleged in Section V above, in
4 and after May 2010, Dow concealed both the existence of the substantial risk information and
5 their failure to report it by refusing to report the substantial risk information to the EPA, even
6 after one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA
7 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
8 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
9 complaint.

10 1628. By this and other conduct, Dow thus continued actively and knowingly to conceal
11 its multiple obligations to deliver money to the United States Government.

12 1629. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
13 its multiple obligations to deliver money to the United States Government. 31 U.S.C. §
14 3729(b)(1)(A)(iii).

15 1630. Each day after May 20, 2009 through the filing of this complaint, Dow became
16 liable to the EPA for the additional daily penalty amounts by which TSCA's civil penalties for
17 each of Dow's reporting violations increased. And each day after May 20, 2009 through the
18 filing of this complaint, Dow continued actively and knowingly to conceal from the EPA its
19 continuing reporting failures and the existence of the extensive quantity of substantial risk
20 information its had obtained, as alleged thoroughly in Section V above.

21 1631. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
22 actively and knowingly concealed these additional, multiple obligations to deliver money to the
23 United States Government, and has therefore committed multiple FCA violations on each such
24 day.

25 1632. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
26 these additional, multiple obligations to deliver money to the United States Government., and has
27 therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

d. **Huntsman possessed money and failed to deliver it to the United States Government.**

1633. As alleged thoroughly above, on May 20, 2009, Huntsman had “possession, custody, or control of . . . money . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That money comprised the civil penalties that Huntsman was obligated to pay to the United States Government under its statutory and regulatory TSCA duties and under its contractual CAP-Agreement duties.

1634. The United States Government would have used this money that Huntsman was and continues to be obligated to pay.

1635. As alleged thoroughly above, on May 20, 2009, Huntsman “deliver[ed], or cause[d] to be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D).

1636. As alleged thoroughly above, on May 20, 2009, Huntsman “*knowingly* deliver[ed], or cause[d] to be delivered, less than all of that money.” 31 U.S.C. § 3729(a)(1)(D) (emphasis added).

1637. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)((1)(B). Rather, those terms “mean that a person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at § 3729(b)(1)(A)(ii) and (iii).

1638. Prior to May 20, 2009, Huntsman, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;

- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1639. On May 20, 2009, Huntsman continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1640. By this conduct, Huntsman continued actively and knowingly to conceal its multiple obligations to deliver money to the United States Government.

1641. At a minimum, Huntsman “act[ed] in reckless disregard of the truth” of its multiple obligations to deliver money to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

1642. After May 20, 2009, and continuing through the filing of this complaint, Huntsman has continued actively and knowingly to conceal from the EPA its continuing reporting failures and the existence of the extensive quantity of substantial risk information its had obtained, as alleged thoroughly in Section V above.

1643. Among the other concealment activities thoroughly alleged in Section V above, in and after May 2010, Huntsman concealed both the existence of the substantial risk information and their failure to report it by refusing to report the substantial risk information to the EPA,

1 even after one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in
2 TSCA Section 8(e) reporting compliance, provided deposition and affidavit testimony in and
3 after May 2010 that identified some of the defendants' Section 8(e) reporting violations
4 identified in this complaint.

5 1644. By this and other conduct, Huntsman thus continued actively and knowingly to
6 conceal its multiple obligations to deliver money to the United States Government.

7 1645. At a minimum, Huntsman has continued to "act[] in reckless disregard of the
8 truth" of its multiple obligations to deliver money to the United States Government. 31 U.S.C. §
9 3729(b)(1)(A)(iii).

10 1646. Each day after May 20, 2009 through the filing of this complaint, Huntsman
11 became liable to the EPA for the additional daily penalty amounts by which TSCA's civil
12 penalties for each of Huntsman's reporting violations increased. And each day after May 20,
13 2009 through the filing of this complaint, Huntsman continued actively and knowingly to
14 conceal from the EPA its continuing reporting failures and the existence of the extensive quantity
15 of substantial risk information its had obtained, as alleged thoroughly in Section V above.

16 1647. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
17 thus actively and knowingly concealed these additional, multiple obligations to deliver money to
18 the United States Government, and has therefore committed multiple FCA violations on each
19 such day.

20 1648. At a minimum, Huntsman has continued to "act[] in reckless disregard of the
21 truth" of these additional, multiple obligations to deliver money to the United States
22 Government., and has therefore committed multiple FCA violations on each day. 31 U.S.C. §
23 3729(b)(1)(A)(iii).

2. **Each defendant had possession custody, or control of *property* to be used by the United States Government and knowingly delivered less than all of it.**

a. **BASF possessed property and failed to deliver it to the United States Government.**

1649. As alleged thoroughly above, on May 20, 2009, BASF had “possession, custody, or control of property . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That property comprised the substantial risk information that BASF was obligated to deliver to the United States Government under its statutory and regulatory TSCA duties and under its contractual CAP-Agreement duties.

1650. The United States Government would have used this property that BASF was and continues to be obligated to pay.

1651. The EPA indicates that “incomplete and inaccurate information will have far-reaching effects on the Agency’s risk assessment, regulatory priority setting, and regulation development process.” TSCA Enforcement Response Policy at 18.

1652. The EPA has also described the vital importance that substantial risk information has to the EPA’s risk assessment and public protection activities:

Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals. EPA has the responsibility under TSCA to perform needed risk assessments on chemicals. Section 8(e) is a very important part of TSCA’s section 8 information reporting and recordkeeping provisions that enable EPA to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).

Id., CAP Agreement, Exh. 26, 56 Fed Reg. at 4128, Unit I, Background (emphasis added).

1653. As alleged thoroughly above, on May 20, 2009, BASF “deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D).

1654. As alleged thoroughly above, on May 20, 2009. BASF “*knowingly* deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D) (emphasis added).

1 1655. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of
2 specific intent to defraud.” 31 U.S.C. § 3729(b)((1)(B). Rather, those terms “mean that a
3 person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the
4 information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at §
5 3729(b)(1)(A)(ii) and (iii).

6 1656. Prior to May 20, 2009, BASF, individually and in conspiracy with the other
7 defendants, had:

- 8 a. Refused to report the substantial risk information to the EPA, even as it
9 continued to obtain and/or develop separate and additional substantial risk
10 information that corroborated the previously-obtained or –developed
11 substantial risk information, and even as internal III communications
12 reminded it of that previously-obtained or –developed substantial risk
13 information;
- 14 b. Refused to report the substantial risk information to the EPA, even as it
15 reported the results of animal studies that it claimed showed a less certain
16 causal relationship between isocyanate skin contact and respiratory
17 response;
- 18 c. “Harmonized” or “standardized” the hazard and/or health effects
19 disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and
20 precautionary labels with the disclosures of the other defendants, so as to
21 conceal the existence of the substantial risk information about human
22 health effects; and
- 23 d. Publicly disputed the potential for dermal- or low-level-induction of
24 respiratory sensitization or asthma, in direct contradiction of the extensive
25 substantial risk information it was concealing.

1 1657. On May 20, 2009, BASF continued actively and knowingly to conceal from the
2 EPA its reporting failure and the existence of the extensive quantity of substantial risk
3 information it had obtained, as alleged thoroughly in Section V above.

4 1658. By this conduct, BASF continued actively and knowingly to conceal its multiple
5 obligations to deliver property to the United States Government.

6 1659. At a minimum, BASF “act[ed] in reckless disregard of the truth” of its multiple
7 obligations to deliver property to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

8 1660. After May 20, 2009, and continuing through the filing of this complaint, BASF
9 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
10 and the existence of the extensive quantity of substantial risk information its had obtained, as
11 alleged thoroughly in Section V above.

12 1661. Among the other concealment activities thoroughly alleged in Section V above, in
13 and after May 2010, BASF concealed both the existence of the substantial risk information and
14 their failure to report it by refusing to report the substantial risk information to the EPA, even
15 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
16 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
17 2010 that identified some of the defendants’ Section 8(e) reporting violations identified in this
18 complaint.

19 1662. By this and other conduct, BASF thus continued actively and knowingly to
20 conceal its multiple obligations to deliver property to the United States Government.

21 1663. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of
22 its multiple obligations to deliver property to the United States Government. 31 U.S.C. §
23 3729(b)(1)(A)(iii).

24 1664. Each day after May 20, 2009 through the filing of this complaint, TSCA required
25 BASF to deliver property by reporting the substantial risk information, and by its non-
26 compliance BASF became liable to the EPA for the additional daily penalty amounts by which
27 TSCA’s civil penalties for each of BASF’s reporting violations increased. And each day after
28

1 May 20, 2009 through the filing of this complaint, BASF continued actively and knowingly to
 2 conceal from the EPA its continuing reporting failures and the existence of the extensive quantity
 3 of substantial risk information its had obtained, as alleged thoroughly in Section V above.

4 1665. Each day after May 20, 2009 through the filing of this complaint, BASF has thus
 5 actively and knowingly concealed these additional, multiple obligations to deliver property to the
 6 United States Government, and has therefore committed multiple FCA violations on each such
 7 day.

8 1666. At a minimum, BASF has continued to “act[] in reckless disregard of the truth” of
 9 these additional, multiple obligations to deliver property to the United States Government., and
 10 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

11 **b. Bayer possessed property and failed to deliver it to the United States**
 12 **Government.**

13 1667. As alleged thoroughly above, on May 20, 2009, Bayer had “possession, custody,
 14 or control of property . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That
 15 property comprised the substantial risk information that Bayer was obligated to deliver to the
 16 United States Government under its statutory and regulatory TSCA duties and under its
 17 contractual CAP-Agreement duties.

18 1668. The United States Government would have used this property that Bayer was and
 19 continues to be obligated to pay.

20 1669. The EPA indicates that “incomplete and inaccurate information will have far-
 21 reaching effects on the Agency’s risk assessment, regulatory priority setting, and regulation
 22 development process.” TSCA Enforcement Response Policy at 18.

23 1670. The EPA has also described the vital importance that substantial risk information
 24 has to the EPA’s risk assessment and public protection activities:

25 Up-to-date information on hazard and exposure is vital in supporting EPA efforts
 26 to protect human health and the environment from risks from toxic chemicals.
 27 EPA has the responsibility under TSCA to perform needed risk assessments on
 28 chemicals. Section 8(e) is a very important part of TSCA’s section 8 information
 reporting and recordkeeping provisions that enable EPA to obtain and disseminate
 information needed to set priorities and perform risk assessments that may be

national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).

Id., CAP Agreement, Exh. 26, 56 Fed Reg. at 4128, Unit I, Background (emphasis added).

1671. As alleged thoroughly above, on May 20, 2009, Bayer “deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D).

1672. As alleged thoroughly above, on May 20, 2009, Bayer “*knowingly* deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D) (emphasis added).

1673. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)((1)(B). Rather, those terms “mean that a person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at § 3729(b)(1)(A)(ii) and (iii).

1674. Prior to May 20, 2009, Bayer, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and

1 precautionary labels with the disclosures of the other defendants, so as to
2 conceal the existence of the substantial risk information about human
3 health effects; and

- 4 d. Publicly disputed the potential for dermal- or low-level-induction of
5 respiratory sensitization or asthma, in direct contradiction of the extensive
6 substantial risk information it was concealing.

7 1675. On May 20, 2009, Bayer continued actively and knowingly to conceal from the
8 EPA its reporting failure and the existence of the extensive quantity of substantial risk
9 information it had obtained, as alleged thoroughly in Section V above.

10 1676. By this conduct, Bayer continued actively and knowingly to conceal its multiple
11 obligations to deliver property to the United States Government.

12 1677. At a minimum, Bayer “act[ed] in reckless disregard of the truth” of its multiple
13 obligations to deliver property to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

14 1678. After May 20, 2009, and continuing through the filing of this complaint, Bayer
15 has continued actively and knowingly to conceal from the EPA its continuing reporting failures
16 and the existence of the extensive quantity of substantial risk information its had obtained, as
17 alleged thoroughly in Section V above.

18 1679. Among the other concealment activities thoroughly alleged in Section V above, in
19 and after May 2010, Bayer concealed both the existence of the substantial risk information and
20 their failure to report it by refusing to report the substantial risk information to the EPA, even
21 after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in TSCA
22 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
23 2010 that identified some of the defendants’ Section 8(e) reporting violations identified in this
24 complaint.

25 1680. By this and other conduct, Bayer thus continued actively and knowingly to
26 conceal its multiple obligations to deliver property to the United States Government.

1 1681. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
2 its multiple obligations to deliver property to the United States Government. 31 U.S.C. §
3 3729(b)(1)(A)(iii).

4 1682. Each day after May 20, 2009 through the filing of this complaint, TSCA required
5 Bayer to deliver property by reporting the substantial risk information, and by its non-
6 compliance Bayer became liable to the EPA for the additional daily penalty amounts by which
7 TSCA’s civil penalties for each of Bayer’s reporting violations increased. And each day after
8 May 20, 2009 through the filing of this complaint, Bayer continued actively and knowingly to
9 conceal from the EPA its continuing reporting failures and the existence of the extensive quantity
10 of substantial risk information its had obtained, as alleged thoroughly in Section V above.

11 1683. Each day after May 20, 2009 through the filing of this complaint, Bayer has thus
12 actively and knowingly concealed these additional, multiple obligations to deliver property to the
13 United States Government, and has therefore committed multiple FCA violations on each such
14 day.

15 1684. At a minimum, Bayer has continued to “act[] in reckless disregard of the truth” of
16 these additional, multiple obligations to deliver property to the United States Government., and
17 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

18 c. **Dow possessed property and failed to deliver it to the United States**
19 **Government.**

20 1685. As alleged thoroughly above, on May 20, 2009, Dow had “possession, custody, or
21 control of property . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That
22 property comprised the substantial risk information that Dow was obligated to deliver to the
23 United States Government under its statutory and regulatory TSCA duties and under its
24 contractual CAP-Agreement duties.

25 1686. The United States Government would have used this property that Dow was and
26 continues to be obligated to pay.

1687. The EPA indicates that “incomplete and inaccurate information will have far-reaching effects on the Agency’s risk assessment, regulatory priority setting, and regulation development process.” TSCA Enforcement Response Policy at 18.

1688. The EPA has also described the vital importance that substantial risk information has to the EPA’s risk assessment and public protection activities:

Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals. EPA has the responsibility under TSCA to perform needed risk assessments on chemicals. Section 8(e) is a very important part of TSCA’s section 8 information reporting and recordkeeping provisions that enable EPA to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).

Id., CAP Agreement, Exh. 26, 56 Fed Reg. at 4128, Unit I, Background (emphasis added).

1689. As alleged thoroughly above, on May 20, 2009, Dow “deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D).

1690. As alleged thoroughly above, on May 20, 2009, Dow “*knowingly* deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D) (emphasis added).

1691. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)(1)(B). Rather, those terms “mean that a person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at § 3729(b)(1)(A)(ii) and (iii).

1692. Prior to May 20, 2009, Dow, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed

substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;

b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;

c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and

d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1693. On May 20, 2009, Dow continued actively and knowingly to conceal from the EPA its reporting failure and the existence of the extensive quantity of substantial risk information it had obtained, as alleged thoroughly in Section V above.

1694. By this conduct, Dow continued actively and knowingly to conceal its multiple obligations to deliver property to the United States Government.

1695. At a minimum, Dow “act[ed] in reckless disregard of the truth” of its multiple obligations to deliver property to the United States Government. 31 U.S.C. § 3729(b)(1)(A)(iii).

1696. After May 20, 2009, and continuing through the filing of this complaint, Dow has continued actively and knowingly to conceal from the EPA its continuing reporting failures and the existence of the extensive quantity of substantial risk information its had obtained, as alleged thoroughly in Section V above.

1 1697. Among the other concealment activities thoroughly alleged in Section V above, in
2 and after May 2010, Dow concealed both the existence of the substantial risk information and
3 their failure to report it by refusing to report the substantial risk information to the EPA, even
4 after one of the *Bice* plaintiffs' experts, who had extensive experience and expertise in TSCA
5 Section 8(e) reporting compliance, provided deposition and affidavit testimony in and after May
6 2010 that identified some of the defendants' Section 8(e) reporting violations identified in this
7 complaint.

8 1698. By this and other conduct, Dow thus continued actively and knowingly to conceal
9 its multiple obligations to deliver property to the United States Government.

10 1699. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
11 its multiple obligations to deliver property to the United States Government. 31 U.S.C. §
12 3729(b)(1)(A)(iii).

13 1700. Each day after May 20, 2009 through the filing of this complaint, TSCA required
14 Dow to deliver property by reporting the substantial risk information, and by its non-compliance
15 Dow became liable to the EPA for the additional daily penalty amounts by which TSCA's civil
16 penalties for each of Dow's reporting violations increased. And each day after May 20, 2009
17 through the filing of this complaint, Dow continued actively and knowingly to conceal from the
18 EPA its continuing reporting failures and the existence of the extensive quantity of substantial
19 risk information its had obtained, as alleged thoroughly in Section V above.

20 1701. Each day after May 20, 2009 through the filing of this complaint, Dow has thus
21 actively and knowingly concealed these additional, multiple obligations to deliver property to the
22 United States Government, and has therefore committed multiple FCA violations on each such
23 day.

24 1702. At a minimum, Dow has continued to "act[] in reckless disregard of the truth" of
25 these additional, multiple obligations to deliver property to the United States Government., and
26 has therefore committed multiple FCA violations on each day. 31 U.S.C. § 3729(b)(1)(A)(iii).

d. **Huntsman possessed property and failed to deliver it to the United States Government.**

1703. As alleged thoroughly above, on May 20, 2009, Huntsman had “possession, custody, or control of property . . . to be used[] by the Government.” 31 U.S.C. § 3729(a)(1)(D). That property comprised the substantial risk information that Huntsman was obligated to deliver to the United States Government under its statutory and regulatory TSCA duties and under its contractual CAP-Agreement duties.

1704. The United States Government would have used this property that Huntsman was and continues to be obligated to pay.

1705. The EPA indicates that “incomplete and inaccurate information will have far-reaching effects on the Agency’s risk assessment, regulatory priority setting, and regulation development process.” TSCA Enforcement Response Policy at 18.

1706. The EPA has also described the vital importance that substantial risk information has to the EPA’s risk assessment and public protection activities:

Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals. EPA has the responsibility under TSCA to perform needed risk assessments on chemicals. Section 8(e) is a very important part of TSCA’s section 8 information reporting and recordkeeping provisions that enable EPA to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).

Id., CAP Agreement, Exh. 26, 56 Fed Reg. at 4128, Unit I, Background (emphasis added).

1707. As alleged thoroughly above, on May 20, 2009, Huntsman “deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D).

1708. As alleged thoroughly above, on May 20, 2009. Huntsman “*knowingly* deliver[ed], or cause[d] to be delivered, less than all of that . . . property.” 31 U.S.C. § 3729(a)(1)(D) (emphasis added).

1709. Under the FCA, “the terms ‘knowing’ and ‘knowingly’ . . . require no proof of specific intent to defraud.” 31 U.S.C. § 3729(b)(1)(B). Rather, those terms “mean that a person, with respect information . . . acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.” *Id.* at § 3729(b)(1)(A)(ii) and (iii).

1710. Prior to May 20, 2009, Huntsman, individually and in conspiracy with the other defendants, had:

- a. Refused to report the substantial risk information to the EPA, even as it continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously-obtained or –developed substantial risk information, and even as internal III communications reminded it of that previously-obtained or –developed substantial risk information;
- b. Refused to report the substantial risk information to the EPA, even as it reported the results of animal studies that it claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response;
- c. “Harmonized” or “standardized” the hazard and/or health effects disclosures in its TDI, MDI, and PMDI Material Safety Data Sheets and precautionary labels with the disclosures of the other defendants, so as to conceal the existence of the substantial risk information about human health effects; and
- d. Publicly disputed the potential for dermal- or low-level-induction of respiratory sensitization or asthma, in direct contradiction of the extensive substantial risk information it was concealing.

1 1711. On May 20, 2009, Huntsman continued actively and knowingly to conceal from
2 the EPA its reporting failure and the existence of the extensive quantity of substantial risk
3 information it had obtained, as alleged thoroughly in Section V above.

4 1712. By this conduct, Huntsman continued actively and knowingly to conceal its
5 multiple obligations to deliver property to the United States Government.

6 1713. At a minimum, Huntsman “act[ed] in reckless disregard of the truth” of its
7 multiple obligations to deliver property to the United States Government. 31 U.S.C. §
8 3729(b)(1)(A)(iii).

9 1714. After May 20, 2009, and continuing through the filing of this complaint,
10 Huntsman has continued actively and knowingly to conceal from the EPA its continuing
11 reporting failures and the existence of the extensive quantity of substantial risk information its
12 had obtained, as alleged thoroughly in Section V above.

13 1715. Among the other concealment activities thoroughly alleged in Section V above, in
14 and after May 2010, Huntsman concealed both the existence of the substantial risk information
15 and their failure to report it by refusing to report the substantial risk information to the EPA,
16 even after one of the *Bice* plaintiffs’ experts, who had extensive experience and expertise in
17 TSCA Section 8(e) reporting compliance, provided deposition and affidavit testimony in and
18 after May 2010 that identified some of the defendants’ Section 8(e) reporting violations
19 identified in this complaint.

20 1716. By this and other conduct, Huntsman thus continued actively and knowingly to
21 conceal its multiple obligations to deliver property to the United States Government.

22 1717. At a minimum, Huntsman has continued to “act[] in reckless disregard of the
23 truth” of its multiple obligations to deliver property to the United States Government. 31 U.S.C.
24 § 3729(b)(1)(A)(iii).

25 1718. Each day after May 20, 2009 through the filing of this complaint, TSCA required
26 Huntsman to deliver property by reporting the substantial risk information, and by its non-
27 compliance Huntsman became liable to the EPA for the additional daily penalty amounts by
28

1 which TSCA's civil penalties for each of Huntsman's reporting violations increased. And each
 2 day after May 20, 2009 through the filing of this complaint, Huntsman continued actively and
 3 knowingly to conceal from the EPA its continuing reporting failures and the existence of the
 4 extensive quantity of substantial risk information its had obtained, as alleged thoroughly in
 5 Section V above.

6 1719. Each day after May 20, 2009 through the filing of this complaint, Huntsman has
 7 thus actively and knowingly concealed these additional, multiple obligations to deliver property
 8 to the United States Government, and has therefore committed multiple FCA violations on each
 9 such day.

10 1720. At a minimum, Huntsman has continued to "act[] in reckless disregard of the
 11 truth" of these additional, multiple obligations to deliver property to the United States
 12 Government., and has therefore committed multiple FCA violations on each day. 31 U.S.C. §
 13 3729(b)(1)(A)(iii).

14 **D. Each defendant made, used, or caused to be made or used, a false record or**
 15 **statement material to an obligation to pay or transmit money to the United States**
 16 **Government.**

17 1721. An entity violates the FCA when it "knowingly makes, uses, or causes to be made
 18 or used, a false record or statement material to an obligation to pay or transmit money or
 19 property to the Government." 31 U.S.C. § 3729(a)(1)(G).

20 1722. Under the FCA, "the term 'material' means having a natural tendency to
 21 influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C.
 22 § 3729(b)(4).

23 **1. False records or statements about dermal-induction health effect.**

24 1723. Through the Diisocyanates Panel of the ACC, the defendants have recently
 25 disputed the potential for dermal induction of respiratory sensitization directly to the EPA. In
 26 their February 26, 2013 comments to the EPA's proposed MDI Action Plan, each defendant
 27 disputed the EPA's statement in the MDI Action Plan that "[b]oth inhalation and dermal
 28 exposures to diisocyanates are thought to contribute to the development of isocyanate asthma"

1 (ACC's February 26, 2013 Comments to MDI Action Plan at 9, Exh. 3). In commenting on that
2 statement, each defendant represented to the EPA that "the role that dermal contact with
3 diisocyanates plays in the development of occupational asthma remains unresolved for humans."
4 *Id.*, Exh. 3 at 10.

5 1724. According to the substantial risk information about the dermal-induction health
6 effect that each defendant possessed in February 2013, which each defendant had knowingly
7 failed to report to the EPA, and which each defendant is continuing to conceal, that statement is
8 false.

9 1725. Each defendant, by having concealed the substantial risk information about the
10 dermal-induction health effect, as alleged thoroughly above, is estopped from contending that its
11 February 26, 2013 statement is true.

12 1726. By sending, causing to be sent, or agreeing to send the ACC's February 26, 2013
13 Comments to MDI Action Plan, each defendant knowingly made, or caused to be made, a false
14 statement to the United States Government, and thereby violated the FCA.

15 1727. At a minimum, by sending, causing to be sent, or agreeing to send that letter, each
16 defendant "act[ed] in reckless disregard of the truth or falsity of the information" in the letter,
17 and thereby violated the FCA. 31 U.S.C. § 3729(b)(1)(A)(iii).

18 1728. By omitting the substantial risk information about the dermal-induction health
19 effect from their February 2013 comments to the EPA's MDI Action Plan, BASF, Bayer, Dow,
20 and Huntsman each represented to the EPA that they neither possessed nor were aware of
21 substantial risk information about the dermal-induction health effect.

22 1729. By making such a false representation to the EPA, BASF, Bayer, Dow, and
23 Huntsman each knowingly made, or caused to be made, a false statement to the United States
24 Government, and thereby violated the FCA.

25 1730. At a minimum, by making such a false representation to the EPA, each defendant
26 "act[ed] in reckless disregard of the truth or falsity of the information" in the letter, and thereby
27 violated the FCA. 31 U.S.C. § 3729(b)(1)(A)(iii).

1 1731. At the time that each defendant made this statement, or caused it to be made, it
2 was obligated to pay money to the United States Government in the form of:

- 3 a. Accumulated civil penalties for its multiple, continuing violations of its
4 TSCA Section 8(e) reporting obligations, as specified in detail above; and
5 b. The damages for each defendant's breach of its CAP Agreement with the
6 EPA, as specified in detail above.

7 1732. At the time that each defendant made this statement, or caused it to be made, it
8 was obligated to transmit property to the United States Government in the form of:

- 9 a. Multiple separate items of substantial risk information about the dermal-
10 induction and low-level-inhalation health effects of TDI, MDI, and PMDI,
11 immediately reportable to the EPA under TSCA Section 8(e), as specified
12 in detail above; and
13 b. Multiple separate items of substantial risk information about the dermal-
14 induction and low-level-inhalation health effects of TDI, MDI, and PMDI
15 that each defendant was required to provide to the EPA under its CAP
16 Agreement with the EPA, as specified in detail above.

17 1733. Each defendant's statement and misrepresentations about the dermal-induction
18 health effect were material to an obligation to pay or transmit money or property to the United
19 States Government. As alleged thoroughly above, these statements are part of each defendant's
20 extensive campaign to conceal from the EPA their multiple statutory, regulatory, and contractual
21 reporting violations, as well as the existence of the substantial risk information itself.

22 1734. By concealing their prior violations, each defendant also concealed from the EPA
23 its liability for civil penalties and contract damages.

24 1735. By concealing the existence of the substantial risk information, each defendant
25 also concealed from the EPA its obligation to provide the substantial risk information to the
26 EPA.

2. **False records or statements about low-level-inhalation-induction health effect.**

1736. Through the Diisocyanates Panel of the ACC, each defendant recently disputed the potential for low-level inhalation exposures to cause respiratory sensitization. In their February 26, 2013 comments to the EPA's proposed MDI Action Plan, each defendant disputed the EPA's statement in the MDI Action Plan that "[b]oth inhalation and dermal exposures to diisocyanates are thought to contribute to the development of isocyanate asthma" (Feb. 26, 2013 ACC Comments to MDI Action Plan at 9, Exh. 3). In commenting on that statement, each defendant represented to the EPA: "The ability of diisocyanates to induce respiratory sensitization in some individuals, and asthma in some cases, is a known potential adverse health effect in humans *after exposure to concentrations above workplace exposure limits.*" *Id.*, Exh. 3 at 10 (emphasis added).

1737. According to the substantial risk information about the low-level-inhalation-induction health effect that each defendant possessed in February 2013, which each defendant had knowingly failed to report to the EPA, and which each defendant is continuing to conceal, that statement is misleading, as it falsely implies that only those inhalation exposures above the regulatory or recommended exposure limits can cause adverse health effects.

1738. Each defendant, by having concealed the substantial risk information about the low-level-inhalation-induction health effect, as alleged thoroughly above, is estopped from contending that its February 26, 2013 statement is true.

1739. By sending, causing to be sent, or agreeing to send the ACC's February 26, 2013 Comments to MDI Action Plan, each defendant knowingly made, or caused to be made, a false statement to the United States Government, and thereby violated the FCA.

1740. At a minimum, by sending, causing to be sent, or agreeing to send that letter, each defendant "act[ed] in reckless disregard of the truth or falsity of the information" in the letter, and thereby violated the FCA. 31 U.S.C. § 3729(b)(1)(A)(iii).

1741. By omitting the substantial risk information about the low-level-inhalation-induction health effect from their February 2013 comments to the EPA's MDI Action Plan,

1 BASF, Bayer, Dow, and Huntsman each represented to the EPA that they neither possessed nor
2 were aware of substantial risk information about the low-level-inhalation-induction health effect.

3 1742. By making such a false representation to the EPA, BASF, Bayer, Dow, and
4 Huntsman each knowingly made, or caused to be made, a false statement to the United States
5 Government, and thereby violated the FCA.

6 1743. At a minimum, by making such a false representation to the EPA, each defendant
7 “act[ed] in reckless disregard of the truth or falsity of the information” in the letter, and thereby
8 violated the FCA. 31 U.S.C. § 3729(b)(1)(A)(iii).

9 1744. At the time that each defendant made this statement, or caused it to be made, it
10 was obligated to pay money to the United States Government in the form of:

- 11 a. Accumulated civil penalties for its multiple, continuing violations of its
- 12 TSCA Section 8(e) reporting obligations, as specified in detail above; and
- 13 b. The damages for each defendant’s breach of its CAP Agreement with the
- 14 EPA, as specified in detail above.

15 1745. At the time that each defendant made this statement, or caused it to be made, it
16 was obligated to transmit property to the United States Government in the form of:

- 17 a. Multiple separate items of substantial risk information about the dermal-
- 18 induction and low-level-inhalation health effects of TDI, MDI, and PMDI,
- 19 immediately reportable to the EPA under TSCA Section 8(e), as specified
- 20 in detail above; and
- 21 b. Multiple separate items of substantial risk information about the dermal-
- 22 induction and low-level-inhalation health effects of TDI, MDI, and PMDI
- 23 that each defendant was required to provide to the EPA under its CAP
- 24 Agreement with the EPA, as specified in detail above.

25 1746. Each defendant’s false representation about the low-level-inhalation-induction
26 health effect were material to an obligation to pay or transmit money or property to the United
27 States Government. As alleged thoroughly above, these statements are part of each defendant’s
28

1 extensive campaign to conceal from the EPA their multiple statutory, regulatory, and contractual
2 reporting violations, as well as the existence of the substantial risk information itself.

3 1747. By concealing their prior violations, each defendant also concealed from the EPA
4 its liability for civil penalties and contract damages.

5 1748. By concealing the existence of the substantial risk information, each defendant
6 also concealed from the EPA its obligation to provide the substantial risk information to the
7 EPA.

8 COUNT I

9 **KNOWING CONCEALMENT OR KNOWING AND IMPROPER AVOIDANCE OF** 10 **AN OBLIGATION TO PAY OR TRANSMIT MONEY TO THE GOVERNMENT** 11 **31 U.S.C. § 3729(A)(1)(G)**

12 1749. KBT&F re-alleges each preceding paragraph as fully and completely as if set
13 forth in this Count I.

14 1750. On May 20, 2009, each defendant had a duty to pay money to the United States
15 Government. The money that each defendant had a duty to pay consisted of:

- 16 a. Accumulated civil penalties for its multiple, continuing violations of its
17 TSCA Section 8(e) reporting obligations, as specified in detail above; and
- 18 b. The damages for its breach of its CAP Agreement with the EPA, as
19 specified in detail above.

20 1751. On May 20, 2009, each defendant knowingly concealed, or knowingly and
21 improperly avoided or decreased, multiple obligations to pay money to the United States
22 Government. Each defendant's concealment or avoidance of each separate obligation to pay
23 money to the United States Government is a separate violation of the FCA.

24 1752. On each day after May 20, 2009 through the date of this complaint, each
25 defendant has become liable for multiple, additional duties to pay money to the United States
26 Government. The additional money that each defendant had a daily duty to pay consists of:

- a. The additional, daily penalty amounts by which its civil penalties for its multiple, continuing violations of its TSCA Section 8(e) reporting obligations increased, as specified in detail above; and
- b. The additional daily penalty amounts by which its damages for its breach of its CAP Agreement with the EPA increased, as specified in detail above.

1753. On each day after May 20, 2009, each defendant knowingly concealed, or knowingly and improperly avoided or decreased, these additional, multiple obligations to pay money to the United States Government. Each defendant's concealment or avoidance of each separate additional obligation to pay money to the United States Government is a separate violation of the FCA.

1754. Each defendant's knowing concealment or knowing and improper avoidance of its multiple obligations to pay money to the United States Government has caused the United States Government to sustain damages, in an amount to be determined at trial, but not less than each defendant's total civil penalties for its multiple, continuing violations of TSCA Section 8(e), and the damages for their respective breaches of the CAP Agreement, all as specified in detail above.

1755. Each defendant is therefore liable to the United States Government for three times the amount of these damages sustained by the Government. 31 U.S.C. § 3729(a)(1).

1756. Each defendant is therefore also liable to the United States Government for civil penalties of not less than \$5,000 and not more than \$10,000 for each violation prior to September 29, 1999, and for not less than \$5,500 and not more than \$11,000 for each violation on and after September 29, 1999. 31 U.S.C. § 3729(a)(1), as adjusted by the Department of Justice in "Civil Monetary Penalties Inflation Adjustment," 64 Fed. Reg. 47099 at 47103-47104, Section 85.3(a)(9), August 30, 1999.

1757. Each defendant is therefore also liable to plaintiff-relator KBT&F for its reasonable attorneys' fees, costs, and other expenses, as required by 31 U.S.C. § 3730(d).

COUNT II

**KNOWING CONCEALMENT OR KNOWING AND IMPROPER AVOIDANCE OF
AN OBLIGATION TO PAY OR TRANSMIT PROPERTY TO THE GOVERNMENT**
31 U.S.C. § 3729(A)(1)(G)

1758. KBT&F re-alleges each preceding paragraph as fully and completely as if set forth in this Count II.

1759. On May 20, 2009, each defendant had a duty to transmit property to the United States Government. The property that each defendant had a duty to transmit consisted of:

- a. Multiple separate items of substantial risk information about the dermal-induction and low-level-inhalation health effects of TDI, MDI, and PMDI, immediately reportable to the EPA under TSCA Section 8(e), as specified in detail above; and
- b. Multiple separate items of substantial risk information about the dermal-induction and low-level-inhalation health effects of TDI, MDI, and PMDI that each defendant was required to provide to the EPA under its CAP Agreement with the EPA, as specified in detail above.

1760. On May 20, 2009, each defendant knowingly concealed, or knowingly and improperly avoided or decreased, multiple obligations to transmit property to the United States Government. Each defendant's concealment or avoidance of each separate obligation to transmit property to the United States Government is a separate violation of the FCA.

1761. On each day after May 20, 2009 through the date of this complaint, each defendant has had recurring, daily duty to transmit property to the United States Government. The property that each defendant had a recurring, daily duty to transmit consists of:

- a. The multiple separate items of substantial risk information about the dermal-induction and low-level-inhalation health effects of TDI, MDI, and PMDI, for which TSCA Section 8(e) imposed on each defendant a daily duty to report, as specified in detail above; and

1 b. The multiple separate items of substantial risk information about the
2 dermal-induction and low-level-inhalation health effects of TDI, MDI, and
3 PMDI, for which TSCA Section 8(e) and the CAP Agreement imposed on
4 each defendant a recurring, daily duty to report, as specified in detail
5 above.

6 1762. On each day after May 20, 2009, each defendant knowingly concealed, or
7 knowingly and improperly avoided or decreased, these additional, multiple obligations to
8 transmit property to the United States Government. Each defendant's concealment or avoidance
9 of each separate additional obligation to transmit property to the United States Government is a
10 separate violation of the FCA.

11 1763. Each defendant's knowing concealment or knowing and improper avoidance of its
12 multiple obligations to transmit property to the United States Government has caused the United
13 States Government to sustain damages, in an amount to be determined at trial, but not less than
14 each defendant's total civil penalties for its multiple, continuing violations of TSCA Section 8(e)
15 or its net profits for the sale of isocyanate products during the period of its non-compliance with
16 Section 8(e) and the damages for their respective breaches of the CAP Agreement, all as
17 specified in detail above.

18 1764. Each defendant is therefore liable to the United States Government for three times
19 the amount of these damages sustained by the Government. 31 U.S.C. § 3729(a)(1).

20 1765. Each defendant is therefore also liable to the United States Government for civil
21 penalties of not less than \$5,000 and not more than \$10,000 for each violation prior to September
22 29, 1999, and for not less than \$5,500 and not more than \$11,000 for each violation on and after
23 September 29, 1999. 31 U.S.C. § 3729(a)(1), as adjusted by the Department of Justice in "Civil
24 Monetary Penalties Inflation Adjustment," 64 Fed. Reg. 47099 at 47103-47104, Section
25 85.3(a)(9), August 30, 1999.

26 1766. Each defendant is therefore also liable to plaintiff-relator KBT&F for its
27 reasonable attorneys' fees, costs, and other expenses, as required by 31 U.S.C. § 3730(d).

COUNT III

**KNOWINGLY DELIVERING LESS THAN ALL THE MONEY OR PROPERTY TO
THE GOVERNMENT
31 U.S.C. § 3729(A)(1)(D)**

1767. KBT&F re-alleges each preceding paragraph as fully and completely as if set forth in this Count III.

1768. On May 20, 2009, each defendant had possession, custody, or control of property and money to be used by the Government.

1769. Each defendant had possession of the money specified in Count I.

1770. Each defendant had possession of the property specified in Count II.

1771. The United States Government would have used the money in each defendant's possession, custody, or control.

1772. The United States Government would have used the property in each defendant's possession, custody, or control.

1773. On May 20, 2009, each defendant knowingly failed to deliver to the United States Government the money that was to be used by the United States Government.

1774. In May 20, 2009, each defendant knowingly failed to deliver to the United States Government the property that was to be used by the United States Government.

1775. On each day after May 20, 2009, each defendant had possession, custody, or control of money and property to be used by the United States Government.

1776. On each day after May 20, 2009 through the date of this complaint, each defendant has become liable for multiple, additional duties to pay money to the United States Government, as specified in Count I, and had possession, custody, or control of that money.

1777. On each day after May 20, 2009 through the date of this complaint, each defendant has had recurring, daily duty to transmit property to the United States Government, as specified in Count II, and had possession, custody, or control of that property.

1 1778. The United States Government would have used this additional money in each
2 defendant's possession, custody, or control.

3 1779. The United States Government would have used this property in each defendant's
4 possession, custody, or control.

5 1780. On each day after May 20, 2009, each defendant knowingly failed to deliver to
6 the United States Government the additional property that was to be used by the United States
7 Government.

8 1781. On each day after May 20, 2009, each defendant knowingly failed to deliver to
9 the United States Government the additional money that was to be used by the United States
10 Government.

11 1782. Each defendant's knowing failure to deliver to the United States Government this
12 money or property to be used by the United States Government has caused the United States
13 Government to sustain damages, in an amount to be determined at trial, but not less than each
14 defendant's total civil penalties for its multiple, continuing violations of TSCA Section 8(e) or its
15 net profits for the sale of isocyanate products during the period of its non-compliance with
16 Section 8(e) and the damages for their respective breaches of the CAP Agreement, all as
17 specified in detail above.

18 1783. Each defendant is therefore liable to the United States Government for three times
19 the amount of these damages sustained by the Government. 31 U.S.C. § 3729(a)(1).

20 1784. Each defendant is therefore also liable to the United States Government for civil
21 penalties of not less than \$5,000 and not more than \$10,000 for each violation prior to September
22 29, 1999, and for not less than \$5,500 and not more than \$11,000 for each violation on and after
23 September 29, 1999. 31 U.S.C. § 3729(a)(1), as adjusted by the Department of Justice in "Civil
24 Monetary Penalties Inflation Adjustment," 64 Fed. Reg. 47099 at 47103-47104, Section
25 85.3(a)(9), August 30, 1999.

26 1785. Each defendant is therefore also liable to plaintiff-relator KBT&F for its
27 reasonable attorneys' fees, costs, and other expenses, as required by 31 U.S.C. § 3730(d).
28

COUNT IV

**KNOWINGLY MAKING OR USING A FALSE RECORD
MATERIAL TO AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY
TO THE GOVERNMENT
31 U.S.C. § 3729(A)(1)(G)**

1786. KBT&F re-alleges each preceding paragraph as fully and completely as if set forth in this Count IV.

1787. On February 26, 2013, each defendant sent or caused to be sent a letter to the EPA from the Diisocyanates Panel of the ACC. Each defendant was a member of the ACC on February 26, 2013 and approved the content of the letter sent on its behalf.

1788. As alleged thoroughly above, each defendant in that letter knowingly made, used, or caused to be made or used four false statements:

- a. Each defendant represented to the EPA that “the role that dermal contact with diisocyanates plays in the development of occupational asthma remains unresolved for humans;”
- b. By omitting the substantial risk information about the dermal-induction health effect from their February 2013 comments to the EPA’s MDI Action Plan, each defendant represented to the EPA that they neither possessed nor were aware of substantial risk information about the dermal-induction health effect;
- c. Each defendant represented to the EPA: “The ability of diisocyanates to induce respiratory sensitization in some individuals, and asthma in some cases, is a known potential adverse health effect in humans *after exposure to concentrations above workplace exposure limits*,” which misleadingly and falsely implies that only exposures above the regulatory or recommended exposure limits can cause adverse health effects; and
- d. By omitting the substantial risk information about the low-level-inhalation-induction health effect from their February 2013 comments to

1 the EPA's MDI Action Plan, BASF, each defendant represented to the
2 EPA that they neither possessed nor were aware of substantial risk
3 information about the low-level-inhalation-induction health effect.

4 1789. Each statement is material to each defendant's multiple obligations to pay money
5 or transmit money or property to the United States Government, and therefore constitutes
6 multiple violations of the FCA.

7 1790. By knowingly making, using, or causing to be made or used a false statement
8 material to an obligation to pay or transmit money or property to the United States Government,
9 each defendant has caused the United States Government to sustain damages, in an amount to be
10 determined at trial, but not less than each defendant's total civil penalties for its multiple,
11 continuing violations of TSCA Section 8(e) or its net profits for the sale of isocyanate products
12 during the period of its non-compliance with Section 8(e) and, the damages for their respective
13 breaches of the CAP Agreement, all as specified in detail above.

14 1791. Each defendant is therefore liable to the United States Government for three times
15 the amount of these damages sustained by the Government. 31 U.S.C. § 3729(a)(1).

16 1792. Each defendant is therefore also liable to the United States Government for civil
17 penalties of not less than \$5,000 and not more than \$10,000 for each violation prior to September
18 29, 1999, and for not less than \$5,500 and not more than \$11,000 for each violation on and after
19 September 29, 1999. 31 U.S.C. § 3729(a)(1), as adjusted by the Department of Justice in "Civil
20 Monetary Penalties Inflation Adjustment," 64 Fed. Reg. 47099 at 47103-47104, Section
21 85.3(a)(9), August 30, 1999.

22 1793. Each defendant is therefore also liable to plaintiff-relator KBT&F for its
23 reasonable attorneys' fees, costs, and other expenses, as required by 31 U.S.C. § 3730(d).

COUNT V**CONSPIRACY****31 U.S.C. § 3729(A)(1)(C)**

1794. KBT&F re-alleges each preceding paragraph as fully and completely as if set forth in this Count V.

1795. Each defendant conspired with one or more of the other defendants to commit a violation or multiple violations of 31 U.S.C. § 3729(a)(1)(G).

1796. Each defendant conspired with one or more of the other defendants to commit a violation or multiple violations of 31 U.S.C. § 3729(a)(1)(D).

1797. By conspiring to violate these provisions of the FCA, each defendant has caused the United States Government to sustain damages, in an amount to be determined at trial, but not less than each defendant's total civil penalties for its multiple, continuing violations of TSCA Section 8(e) or its net profits for the sale of isocyanate products during the period of its non-compliance with Section 8(e) and the damages for their respective breaches of the CAP Agreement, all as specified in detail above.

1798. Each defendant is therefore liable to the United States Government for three times the amount of these damages sustained by the Government. 31 U.S.C. § 3729(a)(1).

1799. Each defendant is therefore also liable to the United States Government for civil penalties of not less than \$5,000 and not more than \$10,000 for each violation prior to September 29, 1999, and for not less than \$5,500 and not more than \$11,000 for each violation on and after September 29, 1999. 31 U.S.C. § 3729(a)(1), as adjusted by the Department of Justice in "Civil Monetary Penalties Inflation Adjustment," 64 Fed. Reg. 47099 at 47103-47104, Section 85.3(a)(9), August 30, 1999.

1800. Each defendant is therefore also liable to plaintiff-relator KBT&F for its reasonable attorneys' fees, costs, and other expenses, as required by 31 U.S.C. § 3730(d).

1 **PRAYER FOR RELIEF**

2 WHEREFORE, *qui tam* plaintiff and relator (KBT&F), on behalf of itself and the United
3 States, demands judgment against each defendant as follows:

4 All damages sustained by the United States Government by each defendant's actions and
5 omissions under Counts I through V, trebled as required by law,;

6 Civil penalties for each violation of the FCA, as required by law;

7 KBT&F's reasonable attorneys' fees, costs, and other expenses, as required by 31 U.S.C.
8 § 3730(d);

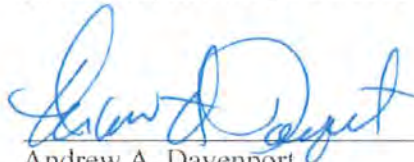
9 Prejudgment interest as allowed by law; and

10 Such other relief as this Court may deem just and proper.

11 **PLAINTIFF DEMANDS A JURY TRIAL AS TO ALL ISSUES.**

12
13
14 Dated: September 24, 2015

15 KASOWITZ, BENSON, TORRES & FRIEDMAN LLP

16 
17
18 Andrew A. Davenport
19 (Admitted Pro Hac Vice)

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Telephone: (415) 421-6140
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CERTIFICATE OF SERVICE

**United States ex rel. Kasowitz, Benson, Torres & Friedman LLP v. BASF Corp., et al.,
Case No. 15-2262-DMR (Under Seal Filing)**

I, Jordan Mendoza, certify that I am an employee of the law firm Kasowitz, Benson, Torres & Friedman LLP and am a person of such age and discretion to be competent to serve papers. I certify that I am causing a copy of:

PLAINTIFF AND RELATOR'S AMENDED *QUI TAM* COMPLAINT

to be served this date on the United States in accordance with 31 U.S.C. § 3730(b)(2) and Federal Rule of Civil Procedure 4 as follows:

1. By personal service according to Federal Rule of Civil Procedure 4(i)(1)(A)(i) on the United States Attorney for this district, at:

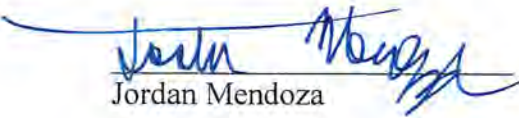
Mr. Brian J. Stretch
Acting United States Attorney
Ms. Erica Blachman Hitchings
Assistant United States Attorney
United States Attorney's Office
Federal Courthouse
450 Golden Gate Avenue
San Francisco, California 94102-3495

2. By certified mail according to Federal Rule of Civil Procedure 4(i)(1)(B) on the Attorney General of the United States at:

Hon. Loretta E. Lynch, Attorney General of the United States
C/O Michael Granston, Director, Civil Frauds Section,
C/O Daniel Anderson, Deputy Director, Civil Frauds Section
United States Department of Justice
Civil Division
950 Pennsylvania Ave., NW
Washington, D.C. 20530-0001

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 24 2015 at San Francisco, California.


Jordan Mendoza