No. 43) and DENIES as moot Plaintiff's Motion for Civil Contempt (ECF No. 48).²

I. FACTUAL AND PROCEDURAL BACKGROUND³

This case arises out of Plaintiff's challenge to California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Prop 65") insofar as it requires businesses to post cancer warnings about the presence of Listed Titanium Dioxide in certain products they sell to California consumers. Plaintiff is a nonprofit business association with a membership of approximately 600 businesses in the cosmetic industry. (ECF No. 1 ¶ 16.) Plaintiff's members are involved in the supply chain for cosmetic and personal care products that contain titanium dioxide, and Plaintiff advocates on their behalf before various government bodies. (*Id.*) Defendant is the Attorney General of the State of California and is tasked with enforcing Prop 65. (*Id.* ¶ 17.)

A. Relevant Background on Prop 65

Prop 65 is a "right-to-know" law that requires the Governor to publish and maintain a list of chemicals known to the State of California to cause cancer or reproductive toxicity ("Prop 65 List"). Cal. Health & Safety Code § 25249.8(a). A chemical is known to the state to cause cancer or reproductive toxicity if: (1) in the opinion of the state's qualified experts, it has been clearly shown — through scientifically valid testing according to generally accepted principles — to cause cancer or reproductive toxicity; (2) a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity; or (3) an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity. *Id.* § 25249.8(b). The Prop 65 List must also include those substances listed as human or animal carcinogens by the International Agency for Research on Cancer ("IARC"), and any substance within the scope of the federal Hazard Communication Standard. *Id.* § 25249.8(a); Cal. Lab. Code § 6382(b)(1), (d).

Absent an exemption, Prop 65 requires businesses with ten or more employees to provide

Plaintiff also filed a Motion for Leave to File a Supplemental Brief, which the Court DENIES as moot. (ECF No. 54.)

The following factual background is taken mostly verbatim from the Court's June 12, 2024 Order granting Plaintiff's motion for preliminary injunction (ECF No. 40) and Plaintiff's Separate Statement of Undisputed Material Facts (ECF No. 43-2). The facts are undisputed, unless otherwise noted.

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 3 of 28

a clear and reasonable warning to consumers before knowingly and intentionally exposing them to chemicals on the Prop 65 List. Cal. Health & Safety Code §§ 25249.5, 25249.6, 25249.11(b). Regulations implementing Prop 65 provide guidance to businesses and examples of what constitutes a "clear and reasonable" warning. Cal. Code Regs. tit. 27, § 25601 et seq. For example, for exposures to listed carcinogens, a business may provide a warning consisting of a black exclamation point inside a yellow equilateral triangle with a bold black outline and the word "WARNING" appearing in all capital letters and bold print, alongside the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov." *Id.* § 25603(a). Alternatively, for listed carcinogens, businesses may provide a short-form warning using the same yellow triangle and exclamation point and the word "WARNING" in all capital letters and bold print, alongside the words "Cancer -- www.P65Warnings.ca.gov." *Id.* § 25603(b). A warning that complies with these regulations is considered a "safe harbor warning" and is presumptively "clear and reasonable" under Prop 65. *Id.* § 25601(a).

Prop 65 may be enforced by the government — including the Attorney General and certain local prosecutors — or by private individuals in the public interest when various conditions are met. Cal. Health & Safety Code § 25249.7(c)–(d). Courts may enjoin violations of Prop 65 and/or assess civil monetary penalties of up to \$2,500 per day for each violation. *Id.* § 25249.7(a)–(b)(1).

B. Titanium Dioxide and Prop 65

i. Overview of Titanium Dioxide

Since the 1930s Titanium dioxide has been used as a whitening pigment in the United States and most other countries around the world. (ECF No. 43-2 ¶ 2.) Titanium dioxide is comprised of various minerals and is commonly used in cosmetic and personal care products, including toothpaste, sunscreen, and makeup. (ECF No. 1 ¶ 2; ECF No. 43-2 ¶ 1.) The U.S. Food and Drug Administration has determined titanium dioxide may be safely used in these products with some limitations. *See* 21 C.F.R. §§ 73.1575(b) (color additive in drugs),

ii.

IARC Study

73.2575(b) (cosmetics), 73.575(c) (color additive in foods), 352.10 (sunscreen). "Listed Titanium Dioxide" is a specific type of titanium dioxide that consists of airborne, unbound particles of respirable size. (ECF No. 1 ¶ 3.) Listed Titanium Dioxide is at issue in this case.⁴ (*Id.* at 27.)

IARC is considered an authoritative source by California's qualified experts, and thus, substances it lists as human or animal carcinogens must be included on the Prop 65 List. Cal. Health & Safety Code § 25249.8(a); Cal. Lab. Code § 6382(b)(1). In 2010, IARC published its findings that there is inadequate evidence for the carcinogenicity of titanium dioxide in humans but sufficient evidence for the carcinogenicity of titanium dioxide in experimental animals. (ECF No. 43-2 ¶ 4.) As a result, IARC concluded titanium dioxide is "possibly carcinogenic to humans (Group 2B)." (*Id.*) IARC based its Group 2B cancer classification for titanium dioxide primarily on two studies involving experimental rats that inhaled titanium dioxide where an increased rate of lung tumors was observed. (*Id.* ¶ 20.) The following year, the California

Throughout the case's history, and in the instant briefing on Plaintiff's motion for summary judgment, the parties and the Court have used both "titanium dioxide" and "Listed Titanium Dioxide," which are two distinct terms. The Court construes the parties' arguments as referring to Listed Titanium Dioxide, which is the substance at issue in this case. (*See* ECF No. 1.)

IARC classifies chemicals into one of four graduated categories: Group 1, Group 2A, Group 2B, or Group 3. Chemicals in <u>Group 1</u> are labeled "carcinogenic to humans" and are for chemicals for which there is sufficient evidence of carcinogenicity in humans. Chemicals in <u>Group 2A</u> are labeled "probably carcinogenic to humans" and are for chemicals for which there is limited evidence of carcinogenicity in humans or sufficient evidence of carcinogenicity in animals. Chemicals in <u>Group 2B</u> are labeled "possibly carcinogenic to humans" and are for chemicals for which there is limited evidence of carcinogenicity in humans *and* less than sufficient evidence of carcinogenicity in animals or inadequate evidence of carcinogenicity in humans but sufficient evidence of carcinogenicity in animals. Chemicals in <u>Group 3</u> are "not classifiable as to [their] carcinogenicity to humans" and are for chemicals for which there is inadequate evidence of carcinogenicity in humans and inadequate or limited evidence of carcinogenicity in animals. *Nat'l Ass'n of Wheat Growers v. Bonta (NAWG)*, 85 F.4th 1263, 1269 n.3 (9th Cir. 2023).

Defendant disputes this point, noting the following: "IARC determined there was 'sufficient evidence of carcinogenicity' in animals based on three studies on experimental animals. In addition to the Lee (1985) and Heinrich (1995) studies, IARC also based its determination on Pott F, Roller M (2005)[.]" (ECF No. 44-1 ¶ 20.)

Office of Environmental Health Hazard Assessment ("OEHHA") placed Listed Titanium Dioxide on the Prop 65 List because of IARC's Group 2B classification for titanium dioxide as required by California Health and Safety Code § 25249.8(a) and California Labor Code § 6382(b)(1). (*Id.* ¶ 33.) Subsequent research, however, has cast some doubt on IARC's conclusion that titanium dioxide is possibly carcinogenic to humans, and there remains somewhat of a scientific debate on titanium dioxide's (and therefore Listed Titanium Dioxide's) carcinogenicity in humans. (*Id.* ¶ 55.)

Plaintiff's members are currently embroiled in dozens of lawsuits alleging failure to warn of Listed Titanium Dioxide.⁷ (*Id.* ¶ 57.) On May 26, 2023, Plaintiff filed a Complaint against Defendant, seeking, among other things, a declaration from this Court that Prop 65's warning requirement for Listed Titanium Dioxide, as applied to cosmetic and personal care products, violates the First Amendment to the United States Constitution. (ECF No. 1.)

On June 12, 2024, the Court granted Plaintiff's motion for preliminary injunction, enjoining Defendant, his officers, employees, and agents, and all those acting in privity or concert with those individuals, including private citizen enforcers under California Health & Safety Code § 25249.7(d) from filing or prosecuting new lawsuits to enforce Prop 65's warning requirement, California Health & Safety Code § 25249.6, for cancer as applied to Listed Titanium Dioxide in cosmetic and personal care products. (ECF No. 40.) On September 10, 2024, Plaintiff filed the instant motion for summary judgment. (ECF No. 43.)

II. STANDARD OF LAW

Summary judgment is appropriate when the moving party demonstrates no genuine issue of any material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). Under summary judgment practice, the moving party always bears the initial responsibility of informing the

Defendant disputes this statement as phrased, arguing it is speculative and Plaintiff's declarant lacks foundation to offer an opinion about events that might occur in the future. (ECF No. 44-1 ¶ 57.) However, that argument applies to the second half of the assertion in paragraph 57, noting that Plaintiff's members "experience a significant burden as a result of [Prop] 65 enforcement on Listed Titanium Dioxide." (*Id.*) Defendant does not object to the fact that Plaintiff's members are currently embroiled in dozens of lawsuits alleging failure to warn.

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 6 of 28

district court of the basis of its motion, and identifying those portions of "the pleadings, depositions, answers to interrogatories, and admissions on file together with affidavits, if any," which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "[W]here the nonmoving party will bear the burden of proof at trial on a dispositive issue, a summary judgment motion may properly be made in reliance solely on the pleadings, depositions, answers to interrogatories, and admissions on file." *Id.* at 324 (internal quotation marks omitted). Indeed, summary judgment should be entered against a party who does not make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Id.* at 322.

If the moving party meets its initial responsibility, the burden then shifts to the opposing party to establish that a genuine issue as to any material fact does exist. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585–87 (1986); *First Nat'l Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 288–89 (1968). In attempting to establish the existence of this factual dispute, the opposing party may not rely upon the denials of its pleadings but is required to tender evidence of specific facts in the form of affidavits, and/or admissible discovery material, in support of its contention that the dispute exists. Fed. R. Civ. P. 56(c). The opposing party must demonstrate that the fact in contention is material, *i.e.*, a fact that might affect the outcome of the suit under the governing law, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986), and that the dispute is genuine, *i.e.*, the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* at 251–52.

In the endeavor to establish the existence of a factual dispute, the opposing party need not establish a material issue of fact conclusively in its favor. *First Nat'l Bank*, 391 U.S. at 288–89. It is sufficient that "the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Id.* Thus, the "purpose of summary judgment is to 'pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Matsushita*, 475 U.S. at 587 (quoting Rule 56(e) advisory committee's note on 1963 amendments).

In resolving the summary judgment motion, the court examines the pleadings, depositions,

1 answer
2 R. Civ
3 of the
4 facts p
5 at 255
6 obliga
7 Nielse
8 1987)
9 "must
10 Matsu

11

12

13

14

15

16

17

18

19

20

21

answers to interrogatories, and admissions on file, together with any applicable affidavits. Fed.

R. Civ. P. 56(c); SEC v. Seaboard Corp., 677 F.2d 1301, 1305–06 (9th Cir. 1982). The evidence

of the opposing party is to be believed, and all reasonable inferences that may be drawn from the

facts pleaded before the court must be drawn in favor of the opposing party. Anderson, 477 U.S.

at 255. Nevertheless, inferences are not drawn out of the air, and it is the opposing party's

obligation to produce a factual predicate from which the inference may be drawn. Richards v.

Nielsen Freight Lines, 602 F. Supp. 1224, 1244–45 (E.D. Cal. 1985), aff'd, 810 F.2d 898 (9th Cir.

1987). Finally, to demonstrate a genuine issue that necessitates a jury trial, the opposing party

"must do more than simply show that there is some metaphysical doubt as to the material facts."

Matsushita, 475 U.S. at 586. "Where the record taken as a whole could not lead a rational trier of

fact to find for the nonmoving party, there is no 'genuine issue for trial.'" Id. at 587.

III. ANALYSIS

Plaintiff argues the compelled cancer warning under Prop 65 with respect to Listed Titanium Dioxide⁸ is unconstitutional, a permanent injunction should issue, and declaratory relief is appropriate. (ECF No. 43-1 at 12–25.) The Court will address each of these issues in turn.

A. Whether the Prop 65 Warning for Listed Titanium Dioxide is Constitutional

"It is the purpose of the First Amendment to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail, rather than to countenance monopolization of that market, whether it be by the Government itself or a private licensee." *Red Lion Broad. Co. v. F.C.C.*, 395 U.S. 367, 390 (1969) (citations omitted). "The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish." *Sorrell v. IMS*

24

25

22

28

²³

The Court notes the two Prop 65 safe harbor warnings for Listed Titanium Dioxide in this case are the same as those listed in the Court's June 12, 2024 Order: (1) a black exclamation point inside a yellow equilateral triangle with a bold black outline and the word "WARNING" appearing in all capital letters and bold print, alongside the words, "This product can expose you to chemicals including titanium dioxide (airborne, unbound particles of respirable size), which is known to the State of California to cause cancer. For more information go to

²⁷

www.P65Warnings.ca.gov."; or (2) a black exclamation point inside a yellow equilateral triangle with a bold black outline and the word "WARNING" appearing in all capital letters and bold print, alongside the words "Cancer -- www.P65Warnings.ca.gov." (ECF No. 40 at 14.)

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 8 of 28

Health Inc., 564 U.S. 552, 578–79 (2011) (quoting Edenfield v. Fane, 507 U.S. 761, 767 (1993)). "While the paradigmatic First Amendment right lies in protections against speech restrictions, the Court has long held the 'right to speak and the right to refrain from speaking are complimentary components' of free speech principles." NAWG, 85 F.4th at 1275 (quoting Wooley v. Maynard, 430 U.S. 705, 714 (1977)). "Indeed, in the context of protected speech, the First Amendment's guarantee of freedom of speech makes no distinction of 'constitutional significance' 'between compelled speech and compelled silence." Id. (quoting Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc., 487 U.S. 781, 796–97 (1988)). "Although commercial speech is afforded less protection than private, noncommercial speech, it is still entitled to the protections of the First Amendment." Id. "This holds true for both corporations and individuals alike." Id.

In the commercial speech context, the Supreme Court has articulated two tests for determining the constitutionality of governmental action. First, there is the test set forth in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York (Central Hudson)*, 447 U.S. 557 (1980). Under that test, the government may restrict or prohibit commercial speech that is not misleading or related to illegal activity, as long as the restriction or prohibition directly advances a substantial governmental interest and is not more extensive than necessary. *Id.* at 564. Second, there is the less stringent test set forth in *Zauderer v. Off. of Disciplinary Couns. of Supreme Ct. of Ohio*, 471 U.S. 626 (1985). Under *Zauderer*, the government may compel commercial speech so long as it is reasonably related to a substantial governmental interest, and the compelled speech is (1) purely factual, (2) noncontroversial, and (3) not unjustified or unduly burdensome. *Am. Beverage Ass'n v. City & Cnty. of San Francisco*, 916 F.3d 749, 755–56 (9th Cir. 2019) (en banc). The Court will first evaluate whether the *Zauderer* exception applies to the Prop 65 warning for Listed Titanium Dioxide. Because the Court finds it does not, it will then evaluate whether the warning satisfies intermediate scrutiny under *Central Hudson*.

i. Whether the Zauderer Exception Applies

The Ninth Circuit has previously categorized *Zauderer* as an "exception for compelled speech," and the Supreme Court has stated *Zauderer* review is applicable only "in certain contexts." *NAWG*, 85 F.4th at 1275 (citations omitted). "To qualify for review under *Zauderer*,

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 9 of 28

the compelled commercial speech at issue must disclose 'purely factual and uncontroversial information.'" *Id.* (citation omitted). Accordingly, the Ninth Circuit has explained that for a court to determine if a Prop 65 warning qualifies for the *Zauderer* exception, it "must first determine whether it concerns 'purely factual and uncontroversial information' before considering whether it is reasonably related to a substantial government interest and is not 'unjustified or unduly burdensome.'" *Id.* (citing *Am. Beverage Ass'n*, 916 F.3d at 755–56).

Plaintiff argues Defendant has the burden to demonstrate the Prop 65 warnings with respect to Listed Titanium Dioxide comply with the *Zauderer* standard. (ECF No. 43-1 at 12.) Plaintiff contends Defendant cannot meet this burden because the warnings are not "purely factual and uncontroversial" and are "unjustified [and] unduly burdensome." (*Id.* at 12–22.) The Court will address each of these issues in turn.

a) Purely Factual

On Plaintiff's motion for preliminary injunction, this Court previously found the Prop 65 warning for Listed Titanium Dioxide was not "purely factual," especially considering the organization that prompted Listed Titanium Dioxide's inclusion on the Prop 65 List — IARC — specifically found that there is inadequate evidence for the carcinogenicity of titanium dioxide in humans. (ECF No. 40 at 16.) The question before the Court at this juncture, then, is whether there have been sufficient developments in the evidentiary record or to the warning language since the Court's prior Order to change the conclusion that the Prop 65 warning for Listed Titanium Dioxide is not purely factual.

Defendant carries the burden to establish the applicable Prop 65 warning for Listed Titanium Dioxide meets the *Zauderer* standard. 471 U.S. at 641. "Information that is purely factual is necessarily 'factually accurate,' but that alone is not enough to qualify for the *Zauderer* exception." *NAWG*, 85 F.4th at 1276 (citation omitted). The Ninth Circuit pointed to its decision in *CTIA* – *The Wireless Ass'n v. City of Berkeley (CTIA II)*, 928 F.3d 832, 843 (9th Cir. 2019), *cert. denied*, 140 S. Ct. 658 (2019), to illustrate this point. *NAWG*, 85 F.4th at 1276. In *CTIA II*, the Ninth Circuit found *Zauderer* review was appropriate to apply to the City of Berkeley's ordinance requiring cell phone retailers to inform prospective purchasers of the risk of radio-

frequency ("RF") radiation from carrying cell phones on their person. 928 F.3d at 838. The court found the RF warning was "purely factual" because "it only required the disclosure of accurate, factual information." *Id.* The court used a sentence-by-sentence analysis to find each sentence factually accurate and none contained an "inflammatory warning" as CTIA had argued. *Id.* at 838, 846–48. The court also recognized "that a statement may be literally true but nonetheless misleading and, in that sense, untrue." *Id.* at 847. Judge Friedland dissented in part, faulting the majority for "pars[ing] the sentences individually" and noting that "[t]aken as a whole, the most natural reading of the disclosure warns that carrying a cell phone in one's pocket is unsafe" but "Berkeley has not attempted to argue, let alone prove, that message is true." *Id.* at 853. "Since *CTIA II*, the Ninth Circuit has adopted Judge Friedland's approach — i.e., requiring that courts consider the overall impression delivered by a compelled warning in evaluating whether it meets *Zauderer*'s 'purely factual' requirement." *Cal. Chamber of Commerce v. Bonta (Cal. Chamber II)*, No. 2:19-cv-02019-DJC-JDP, 2025 WL 1284779, at *9 (E.D. Cal. May 2, 2025) (citing *NAWG*, 85 F.4th at 1279).

Plaintiff argues Prop 65 requires a message that products containing Listed Titanium

Plaintiff argues Prop 65 requires a message that products containing Listed Titanium Dioxide will increase consumers' risk of cancer. (ECF No. 43-1 at 13–14.) Plaintiff further argues this Court previously found it "reasonable to the average consumer" to conclude from reading this warning that Listed Titanium Dioxide causes cancer in humans or will increase a consumer's risk of cancer. (Id. at 14.)

In opposition, Defendant parses the language of the Prop 65 warning sentence-by-sentence and asserts the warning is factually accurate (i.e., that the product can expose you to Listed Titanium Dioxide and that Listed Titanium Dioxide is known to the State of California to cause cancer). (ECF No. 44 at 13.) Defendant asserts the warning is not misleading because "the fact that a chemical found to cause cancer in animal studies *is* a possible human carcinogen, one that may cause cancer or increase the chance of cancer, regardless of the sufficiency of the

Plaintiff also argues its consumer survey confirms the Court's plain reading of the warning. (ECF No. 43-1 at 15–17.) However, because the Court does not rely on this argument to reach its conclusion, the Court declines to address the parties' arguments regarding the consumer survey.

epidemiological evidence." (*Id.* at 13–14.) Defendant maintains the Court's prior conclusion that the California electorate passed Prop 65 out of an interest in "chemicals that are carcinogenic to *humans*, not animals" is a misunderstanding of the science and a misreading of *AFL-CIO v*. *Deukmejian*, 212 Cal. App. 3d 425 (1989). (*Id.* at 14–15 (emphasis in original).) According to Defendants, Prop 65 is not limited in its application to chemicals known to cause cancer only in humans. (*Id.*)

In reply, Plaintiff argues Defendant misunderstands — Plaintiff is not contesting IARC's classifications or even the value of animal studies in assessing chemical carcinogenicity. (ECF No. 46 at 4.) Rather, Plaintiff is contesting the compulsion of a cancer warning that misleads consumers into believing a product will increase their risk of cancer when the sum of all available evidence does not indicate it will. (*Id.*) Plaintiff notes that the issue in *Deukmejian* — whether the listing mechanism comports with the statute's legal framework — is different from whether a warning requirement comports with the First Amendment. (*Id.* at 6.) Plaintiff contends Defendant does not contest the Court's plain reading of the compelled warning and nowhere does he argue it is unreasonable for an ordinary consumer reading the warning to understand it to mean using the product may give them cancer or increase their chances of getting cancer. (*Id.*)

The Court finds there have not been sufficient developments in the evidentiary record or to the warning language since its prior Order to change the conclusion that the Prop 65 warning for Listed Titanium Dioxide is not purely factual. Defendant's argument that the Prop 65 warning is factually true when parsed out sentence-by-sentence does exactly what Judge Friedland warned about in CTIA II — the "approach misses the forest for the trees." 928 F.3d at 853. This conclusion is supported by the Ninth Circuit's opinion in NAWG, 85 F.4th at 1280 and another Eastern District court's opinion in Cal. Chamber II, 2025 WL 1284779, which this Court finds persuasive. The Ninth Circuit in NAWG considered a similar Prop 65 warning for glyphosate and held the warning did not qualify for Zauderer review despite being factually true because it still "convey[ed] the overall message that glyphosate is unsafe which is, at best,

The Court notes that none of the parties argue there has been a change to the Prop 65 warning language and therefore does not consider this question.

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 12 of 28

disputed" and "elevate[d] one side of a legitimately unresolved scientific debate." 85 F.4th at 1280–81. The court noted that even accepting "that each sentence [of the warning] is entirely and literally true, that is not enough," as "the totality of the warning may [] be nonetheless misleading." Id. at 1279. The Cal. Chamber II court came to a similar conclusion when considering a Prop 65 warning for dietary acrylamide, noting that the warning "conveys the onesided message that people who consume dietary acrylamide will increase their risk of cancer without sufficient scientific consensus to support that message." 2025 WL 1284779, at *11–12. The court concluded the state's reliance on the Ninth Circuit's approval of the RF warning in CTIA II was inapposite, as the CTIA II warning "only pointed to federal guidelines regarding [RF] exposure and stated certain uses of cell phones would cause the user to exceed those guidelines" — the warning "did not make any claims that failure to comply with those guidelines would cause any particular effect[.]" Id. at *11. The court reasoned that the Prop 65 warning for dietary acrylamide was dissimilar, as the warning's statement "that a food contains a chemical that is 'probably,' 'likely,' or 'reasonably anticipated' to be carcinogenic heavily implies that, by ingesting that food, the consumer will increase their risk of cancer." *Id.* Similarly here, even though each sentence on its own may be factually true, "the totality

Similarly here, even though each sentence on its own may be factually true, "the totality of the warning" is nonetheless misleading and Defendant's argument "ignores the reality that it conveys the 'core message" that using a cosmetic or personal care product containing Listed Titanium Dioxide poses a risk of cancer in humans. NAWG, 85 F.4th at 1279; Cal. Chamber II, 2025 WL 1284779, at *11. Further, a number of courts in the Ninth Circuit considering other Prop 65 warnings have similarly found that "[s]tatements are not necessarily factual and uncontroversial just because they are technically true." Cal. Chamber of Comm. v. Becerra (Cal. Chamber I), 529 F. Supp. 3d 1099, 1118 (E.D. Cal. 2021) (citing cases). As the Court previously noted, it is reasonable for the average consumer to read the warning requirement and conclude that Listed Titanium Dioxide may cause them cancer or increase their chances of obtaining cancer. (ECF No. 40 at 16.) Defendant does not point to anything in the evidentiary record to show this is true, much less any "sufficient scientific consensus" to support this message. Cal. Chamber II, 2025 WL 1284779, at *11.

The Court finds Defendant's citation to *Deukmejian* to be unpersuasive. Defendant contends IARC's determination that titanium dioxide is "possibly carcinogenic to humans" is consistent with scientific studies that demonstrate that "[a]ll known human carcinogens that have been studied adequately for carcinogenicity in experimental animals have produced positive results in one or more animal species." (ECF No. 44 at 14.) Defendant notes the *Deukmejian* court explained that "[f]or recognized human carcinogens, the first evidence of carcinogenicity frequently is found in test animals; only afterwards are cancer effects looked for, and found, in humans." (*Id.* (quoting *Deukmejian*, 212 Cal. App. 3d at 438 n.7).) However, the Prop 65 language is only "factual" if consumers can discern Defendant's underlying logic:

- The IARC Working Group concluded there was "sufficient evidence of [titanium dioxide] carcinogenicity" in animals based on three studies on experimental animals: two inhalation studies, Heinrich (1995) and Lee (1985); and one intratracheal study, Pott and Roller (2005). (ECF No. 44 at 13; ECF No. 44-1¶ 109.)
- "Because IARC found there was 'sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide," but 'inadequate evidence' in humans, it classified titanium dioxide as 'possibly carcinogenic to humans' (Group 2B)." (ECF No. 44-1¶ 105.)
- "All known human carcinogens that have been studied adequately for carcinogenicity in experimental animals have produced positive results in one or more animal species[,]" and "[f]or several agents, 'carcinogenicity in experimental animals was established or highly suspected before epidemiological studies confirmed their carcinogenicity in humans[.]" (Id. ¶¶ 96–97.)

See Cal. Chamber I, 529 F. Supp. 3d at 1117 (applying a similar chain of underlying logic for a Prop 65 warning for acrylamide). The Court finds that consumers are unlikely to discern this logic from the face of the Prop 65 warning for Listed Titanium Dioxide. Consumers who read the Prop 65 warning will probably believe using the cosmetics or personal care products increases their personal risk of cancer. *Id.* Accordingly, Defendant's citation to *Deukmejian* (as it pertains to adding to the Prop 65 List IARC Group 2 chemicals for which there is sufficient evidence that

exposure causes cancer in animals) is insufficient to persuade the Court the Prop 65 warning for Listed Titanium Dioxide is "purely factual" and not misleading. (ECF No. 44 at 15 (citing *Deukmejian*, 212 Cal. App. 3d at 437); *see also* ECF No. 46 at 5 fn. 1.)

*b) Uncontroversial*¹¹

Zauderer also requires the information in commercial speech to be uncontroversial. The Ninth Circuit has explained Nat'l Inst. Of Fam. & Life Advocs. v. Becerra (NIFLA), 585 U.S. 755 (2018) "tells us that the topic of the disclosure and its effect on the speaker is probative of determining whether something is subjectively controversial." NAWG, 85 F.4th at 1277. In NIFLA, a group of medical providers and crisis pregnancy centers challenged a California state law that required "licensed" abortion clinics to notify women that California provides "immediate free or low-cost access" to family planning services (including abortion) and provide a phone number. 585 U.S. at 760–65. The Ninth Circuit interpreted NIFLA "as not saying broadly that any purely factual statement that can be tied in some way to a controversial issue is, for that reason alone, controversial," but rather "what made the notice in NIFLA controversial was the fact that it forced the clinic to convey a message fundamentally at odds with its mission." NAWG, 85 F.4th at 1277 (cleaned up) (internal quotation marks and citation omitted).

The Ninth Circuit also clarified that "an objective evaluation of 'controversy' is also an important consideration." *Id.* On two occasions, the Ninth Circuit has held that a Prop 65 cancer warning was "controversial" where there was "robust disagreement by reputable scientific sources." *Id.* at 1278 (finding a Prop 65 glyphosate warning was controversial where the IARC and EPA were "on opposite sides of the scientific debate" and "scientific consensus is much less evenly distributed"); *Cal. Chamber of Commerce v. Council for Educ. and Rsch. on Toxics* (*CERT*), 29 F.4th 468, 478 (9th Cir. 2022), *reh'g denied*, 51 F.4th 1182 (Oct. 26, 2022) (finding a Prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. National

Prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Nation

The prop 65 acrylamide warning was controversial where the EPA, IARC, and U.S. Warning was controversial warning warning warning was controversial warning was controversial warning warning warning warning w

Even though the Court finds the Prop 65 warning is not purely factual — thereby precluding review under *Zauderer* — because the Ninth Circuit and courts in the Eastern District of California have considered the question of purely factual and uncontroversial together, in an abundance of caution the Court will also address the parties' arguments regarding whether the Prop 65 warning is uncontroversial. *See, e.g., NAWG*, 85 F.4th at 1278–80; *Cal. Chamber I*, 529 F. Supp. 3d at 1117–20; *Cal. Chamber II*, 2025 WL 1284779, at *8–12.

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 15 of 28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Toxicology Program each classified acrylamide as some level of carcinogen, while the American Cancer Society, National Cancer Institute, and an epidemiologist who reviewed 56 studies concluded it was not carcinogenic). Finally, the information must not be misleading to the average consumer and cannot improperly elevate "one side of a legitimately unresolved scientific debate." *Id.* at 1279.

Plaintiff maintains the warning is objectively controversial, as there is no evidence from the IARC, any scientist, or any government authority — that titanium dioxide in fact causes cancer in humans. (ECF No. 43-1 at 17.) Plaintiff elaborates that when IARC classified titanium dioxide as a Group 2B possible human carcinogen, it explicitly acknowledged there was "inadequate evidence in humans," which meant the available evidence did not show the presence or absence of a causal association. (Id.) Plaintiff contends the only evidence that supported IARC's classification were the Lee (1985) and Heinrich (1995) studies that involved rat inhalation, but the rat lung-overload model has no relevance to cancer risk or hazard in humans. (*Id.* at 17–18.) Plaintiff notes its expert Dr. Paolo Boffetta concluded in his report that the "available evidence from human studies [] cannot be credibly relied on to conclude that exposure to [titanium dioxide] causes any cancer." (Id. at 18 (emphasis in original).) Plaintiff asserts Defendant has presented no expert evidence to refute this report and Defendant's own expert agreed with Dr. Boffetta's central conclusion that the weight of the epidemiological evidence does not show a positive association between titanium dioxide and cancer. (Id. at 18.) Plaintiff maintains Defendant cannot show there is a "strong scientific consensus" that rat tumors found in the lung overload experiments imply human carcinogenicity. (Id. at 19–20.) Plaintiff also argues the warning is subjectively controversial because its members are "forced to convey a message fundamentally at odds with their businesses." (*Id.* at 20 (citing *NAWG*, 85 F.4th at 1278).)

In opposition, Defendant contends triable issues of material fact exist regarding whether the Prop 65 warning is uncontroversial, as IARC and other health agencies have found titanium dioxide is a possible human carcinogen based on positive cancer findings in animal studies. (ECF No. 44 at 18.) Defendant maintains that Plaintiff "attempts to gin up controversy" by inaccurately characterizing the animal studies results and Defendant's expert testimony, as well as confusing

hazard assessment principles with risk assessment principles. (Id.)

Here, as an initial matter, Defendant does not dispute Plaintiff's argument that it requires Plaintiff's members to convey a message that they fundamentally disagree with. (ECF No. 43-1 at 20 ("[Plaintiff's] members are 'forced to convey a message fundamentally at odds with their businesses."); see ECF No. 44.) The Court therefore finds the Prop 65 warning for Listed Titanium Dioxide to be subjectively controversial. See NAWG, 85 F.4th at 1277. The Court also finds the Prop 65 warning for Listed Titanium Dioxide to be objectively controversial because there is a robust scientific debate over whether Listed Titanium Dioxide causes cancer in humans.

Both parties' experts agree there is robust scientific debate. Plaintiff correctly notes "there is a decades-long debate over the human risk relevance of chronic inhalation studies where rats exposed to poorly soluble low toxicity particles like titanium dioxide develop particleoverload related lung tumors," which is explained in Dr. Amy Madl's (Plaintiff's expert) report and confirmed by Dr. Charles W. Jameson, Ph.D. (Defendant's expert). (ECF No. 46 at 8.) Dr. Madl confirms in her report that "animal and human evidence does not support that titanium dioxide in any form is a human carcinogen" and "[t]here has been considerable debate over the last three decades about the relevance of particle-overload related lung tumors in rats following chronic inhalation exposures to poorly soluble low toxicity particles for human risk assessment." (ECF No. 43-22 at 4, 17.) Dr. Madl then explains that based on human epidemiology studies of titanium dioxide manufacturing workers and key differences between rats and other species on the adverse outcome pathway, 12 "the chronic-overload inhalation studies of titanium dioxide in rats have no relevance for determining the lung cancer risks in humans exposed for a lifetime to titanium dioxide in any form." (Id. at 17.) Further, Dr. Jameson indeed confirmed during his deposition that he "hear[d] that debate over and over again" on the "relevance of particleoverload-related lung tumors in rats following chronic inhalation exposures to poorly soluble low toxicity particles for human risk assessment." (ECF No. 43-13 at 12.) Dr. Jameson confirmed

27

28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

²⁶

Adverse outcome pathway ("AOP") is defined by the Organization for Economic Cooperation and Development ("OECD") as a sequential progression of events in an organism from the first contact of a toxicant at a molecular level to a final adverse outcome at the individual or population level. (ECF No. 43-22 at 17.)

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 17 of 28

"the debate stems from the fact that the lung overload in the rats which leads to tumor formation in the lungs is argued in a number of papers that it is not relevant to the human situation because humans do not have particle overload. Or they haven't been documented that they have particle overload." (*Id.* at 21.) Dr. Jameson then conceded "lung overload [] was the mechanism for carcinogenicity or tumorigenicity in the rat [titanium dioxide] studies[.]" (*Id.* at 13.)

Next, the parties dispute the results of the animal studies, their experts' reports and testimony, and conclusions by government health authorities. The Court will consider each of these sets of arguments in turn.

1. Animal Studies Results

As stated previously, Plaintiff maintains the only evidence that supported IARC's classification were the Lee (1985) and Heinrich (1995) studies that involved rat inhalation, but the rat lung overload model has no relevance to cancer risk or hazard in humans. (ECF No. 43-1 at 17–18.) Defendant disputes this point, noting that the IARC determination was also made based on the Pott and Roller (2005) study, which observed statistically significant increases in benign and/or malignant tumors in female rats. (ECF No. 44 at 19.) Defendant asserts that based on these three studies, the IARC Working Group determined the criteria for "sufficient evidence of carcinogenicity" in animals had been met. (*Id.* at 18–19.) Defendant also argues Plaintiff's focus on lung overload is misplaced, as: (1) lung overload is relevant in cancer *risk* assessments and IARC conducts *hazard* assessments (the first step of a risk assessment); (2) whether lung overload occurs in humans is an open question; (3) Dr. Madl did not address the Pott and Roller study where overload conditions were not reported; and (4) lung overload is not the only mechanism that can cause cancer. (*Id.* at 19–20.)

Here, the Court agrees with Plaintiff that Defendant has a narrow framing of the matter, as the key issue is whether there is a scientific consensus around Listed Titanium Dioxide's carcinogenicity in *humans*. (ECF No. 46 at 8; *see also* ECF No. 40 at 15–16 (noting "Prop 65 is principally concerned about chemicals that are carcinogenic to *humans*, not animals").) The Prop 65 warning does not indicate anything about cancer in "experimental animals" and, as stated previously, the warning is reasonably understood to mean that it does in fact cause cancer in

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 18 of 28

humans. While the Court acknowledges Defendant's argument that "sufficient evidence of carcinogenicity" in experimental animals is part of the overall evaluation of a chemical's potential to cause cancer in humans (ECF No. 44 at 19), Defendant still does not point to any conclusive scientific studies or evidence to establish Listed Titanium Dioxide causes cancer in humans. ¹³

With respect to Defendant's arguments about lung overload, the Court will address them point by point. First, the Court notes that both parties agree the first step of a risk assessment involves a cancer hazard assessment. (ECF No. 44 at 20; ECF No. 46 at 10.) However, Plaintiff is correct that Prop 65 warnings are ultimately concerned about communicating to consumers known *risks*, not mere hazards. (ECF No. 46 at 10–11 (citing *NAWG*, 85 F.4th at 1269 ("At its core, the function of Prop 65 is to inform consumers of risks, not hazards.")).) As another court has noted, "the distinction between hazard and risk is significant." *NAWG*, 85 F.4th at 1269. "[A] hazard indicates that at some theoretical level of exposure, the chemical is capable of causing cancer," whereas risk "is the likelihood that cancer will occur at a real-world level of exposure." *Id*. The Court therefore finds Defendant's argument about IARC and its hazard assessments for "sufficient evidence of carcinogenicity" in *animals* to be unpersuasive. (ECF No. 44 at 20.) Defendant's expert, Dr. Jameson, confirms in his deposition testimony that there is no risk for cancer in humans because particle overload does not happen in humans:

What I was trying — the point I was trying to get across is that Dr. Madl's argument that because of particle overload it is not a carcinogen is — is not appropriate for a hazard assessment determination. That's what I was trying to get across in here, but that's — what's worded here is not clear.

Dr. Madl is using the argument because of particle overload, it caused — she admits it causes tumors in animals, it causes lung tumors in animals because of the particle overload, but she is trying to make the argument that would not be — apparently is not relevant to the human case because you don't have particle overload, at least it hasn't been documented there is particle overload in humans for titanium dioxide as it relates to lung cancer, I guess is what you could say.

These points apply equally to Defendant's additional arguments that both the Heinrich and Lee studies were conducted using maximum tolerated dose levels and statistically significant increases in lung tumors were observed. (ECF No. 44 at 20.) The issue is not carcinogenicity in experimental animals, but rather carcinogenicity in *humans*.

So from a risk assessment standpoint, that may be a valid argument because you can say, you know, the particle overload doesn't happen in humans and that's the mechanism for the causation of cancer in animals and so therefore from a risk assessment standpoint, there is — there is no hazard — or no risk for cancer under those circumstances.

But nonetheless the particle overload in the rats leads to lung tumors and so therefore it causes a positive effect in the rats so it causes cancer in rats and that is a definition of an animal carcinogen.

(ECF No. 43-13 at 12 (emphasis added).) Dr. Jameson then confirmed that the particle overload and lung tumors in rats was sufficient for IARC's 2B classification. (*Id.*)

Second, with respect to whether lung overload occurs in humans, the parties agree that this is an open question and disputed. (ECF No. 44 at 20 (citing ECF No. 44-1 at 12 (noting that whether "[t]he AOP for particle overload leading to tumorigenic responses is exclusive to rats" is disputed, as "[a]side from data on mice and hamsters, there is no definitive data on other species, including humans, to conclude that particle overload leading to tumorigenic responses is exclusive to rats")); ECF No. 46 at 10 (citing ECF No. 44-1 at 11) (noting it is "undisputed" that "[h]umans have not been shown to experience particle overload stemming from exposure to [titanium dioxide]").) Further, Defendant does not dispute that "particle clearance — the process by which respirable solid particles like titanium dioxide are cleared from the lungs — varies between rats and humans." (ECF No. 46 at 10 (citing ECF No. 44-1 ¶¶ 27–28).)

Third, with respect to the Pott and Roller study, Defendant contends Dr. Madl did not address this study where lung overload conditions were not observed. (ECF No. 44 at 20 (citing ECF No. 44-1 ¶¶ 20, 113).) As citation for this assertion, Defendant points to IARC Monograph Vol. 93 (which references the Pott and Roller study briefly) but does not actually introduce this study as evidence. (Id.) IARC Monograph Vol. 93 does not state anywhere that lung overload conditions were not observed in the Pott and Roller study. (See ECF No. 43-4.) Plaintiff asserts lung overload conditions were present in the Pott and Roller intratracheal study (ECF No. 46 at

Further, there is no citation to this study in Defendant's Separate Statement of Genuine Disputes of Material Facts. (*See* ECF No. 44-1.)

9), but similarly does not introduce the study as evidence and only cites to Table 3.1 on intratracheal instillation of titanium dioxide from the Pott and Roller study.¹⁵ Ultimately, because the Pott and Roller study was not introduced in evidence, the Court cannot adequately ascertain the veracity of the parties' arguments.

Fourth, with respect to whether lung overload is the sole mechanism that can cause cancer, Defendant asserts the IARC also noted "Listed Titanium Dioxide causes inflammation, cell injury, and DNA damage," and "[t]he ability to induce chronic inflammation is a characteristic of many human carcinogens, and is recognized as a key characteristic of carcinogens." (ECF No. 44 at 20 (citing ECF No. 44-1 ¶ 125, 126).) However, Plaintiff is correct that Dr. Jameson testified that "[o]verload in titanium dioxide in the lungs of the rats caused the lung tumors to be seen" (ECF No. 43-13 at 13) and Dr. Madl went on to explain that "[t]he retention of particles in the alveolar lumen . . . in rats is an initiating sequence in the AOP that ultimately leads to inflammation, fibrosis, and tumor formation following particle overload conditions" (ECF No. 43-22 at 18–19). Plaintiff is therefore correct, based on this logic, that the lung overload "sets into motion a sequence of pulmonary effects, which includes inflammation." (ECF No. 46 at 10 n.5.)

At a minimum, the foregoing arguments reflect a "robust disagreement by reputable scientific sources" as to the human relevance of the chronic inhalation studies in rats. *CERT*, 29 F.4th at 478.

2. Expert Reports and Testimony

As stated previously, Plaintiff asserts the Prop 65 warning is unsupported by the evidence. (ECF No. 43-1 at 17.) Plaintiff contends Defendant's expert Dr. Jameson testified that the

If lung overload occurs with intratracheal instillation, Plaintiff did not adequately explain why or how this is the case. Plaintiff actually appears to assert that this does not happen, as it later states that "[a]n intratracheal rat 'screening' study that observes tumor formation supplies far less compelling and relevant evidence than inhalation studies." (ECF No. 46 at 9.) Further, Plaintiff's citation to paragraph 24 in Dr. Madl's declaration for the assertion that "particle overload is initiated at about 4 mg for titanium dioxide" appears to be irrelevant (*id.*), as neither paragraph 24 nor the rest of the Madl declaration provide any citation for the assertion that lung overload conditions were present in the Pott and Roller study.

Heinrich study was poorly designed. (*Id.* at 18.) Plaintiff further contends, with respect to the epidemiological data, that its expert Dr. Paolo Boffetta concluded in his nearly 30-page expert report that the "available evidence from human studies [] cannot credibly be relied on to conclude that exposure to [titanium dioxide] causes *any* cancer." (*Id.* at 18 (emphasis in original).) Plaintiff notes that Defendant has presented no evidence to refute Dr. Boffetta's report, but when Dr. Jameson was asked about it, he noted Defendant "did not ask [him] to comment on the Boffetta report" and admitted that he only "skimmed through" the Boffetta report and "didn't read it in any detail." (*Id.* (citing ECF No. 43-13 at 5).)

In opposition, Defendant does not address Plaintiff's arguments regarding Dr. Boffetta's report, but instead asserts Plaintiff's reliance on Dr. Jameson's statement that the Heinrich study is poorly designed does not consider Dr. Jameson's full explanation that "[j]ust because a study is not designed very well . . . you can still get useful data out of those studies if you see a positive response[.]" (ECF No. 44 at 20–21.) Defendant notes Dr. Jameson also explained that despite not being well-designed, the Heinrich study "still showed there was an increase of tumors observed in rats, which supports IARC's finding of 'sufficient evidence of carcinogenicity' in animals." (*Id.* at 21.) Defendant also notes Dr. Jameson's testimony is consistent with the European Chemical Agency's ("ECHA") Committee for Risk Assessment, which considered the results from the Heinrich study even though it was not "carried out in accordance with standard testing guidelines," as the "results were 'sufficiently reliable, relevant and adequate for the assessment of the carcinogenic potential of [titanium dioxide]." (*Id.*) Defendant further clarifies that the European Court of Justice annulled a European Union regulation in part due to the Committee for Risk Assessment's evaluation of the data from the Heinrich study, not the Heinrich study itself. (*Id.*)

Here, the Court finds particularly persuasive Plaintiff's argument that Dr. Jameson appears to agree with Dr. Boffetta's central conclusion that "the weight of the epidemiological

Defendant also notes ECHA considered the Lee study despite its faults (ECF No. 44 at 21), but the Court declines to address this argument because it was not directly raised by Plaintiff in its motion (*see* ECF No. 43-1).

evidence does not show a positive association between titanium dioxide and cancer[.]" (ECF No. 43-1 at 19.) Indeed, when asked whether he agrees with this assertion, Dr. Jameson testified "this statement makes sense that it does not support the hypotheses that exposure to [titanium dioxide] in any form increases the risk of lung or any other cancer in humans because the data is inadequate." (ECF No. 43-13 at 7.) Tellingly, Defendant does not dispute any of Plaintiff's arguments regarding the Boffetta report in his opposition. (*See* ECF No. 44.) Finally, with respect to Dr. Jameson's statements regarding the Heinrich study, even if there were useful data from the study, Defendant still fails to establish that this data provides evidence of carcinogenicity of Listed Titanium Dioxide in humans.

The Court also finds Defendant's argument regarding the epidemiological evidence to be unsubstantiated. Defendant notes the "IARC evaluated several epidemiological studies, including the Boffetta (2004) study" and found "inadequate evidence of carcinogenicity[.]" (ECF No. 44 at 22.) Defendant then argues that "just as the epidemiological evidence is inadequate to conclude that there is a casual association between exposure to Listed Titanium Dioxide and cancer, it is also inadequate to conclude that there is an *absence* of a causal connection." (*Id.*) However, the Court agrees with Plaintiff that Defendant "cannot ignore expert testimony that directly conflicts with his preferred, but unsubstantiated, inference from the rat studies," especially as Defendant does not dispute Dr. Boffetta's central conclusion. (ECF No. 46 at 11.)

3. Government Health Authorities

Plaintiff argues government authorities that have reviewed the two aforementioned rat studies on which the IARC classification is based — Lee (1985) and Heinrich (1995) — have found they are unreliable as indicators that titanium dioxide poses a cancer risk in humans. (ECF No. 43-1 at 20.) Plaintiff contends ECHA found the Lee study to be unreliable and irrelevant for purposes of human cancer risk assessment.¹⁷ (*Id.*; *see also* ECF No. 44-1 ¶ 31.) Defendant

Plaintiff also argues the European Court of Justice annulled a regulation that required labeling of titanium dioxide as carcinogenic by inhalation. (ECF No. 43-1 at 20; ECF No. 44-1 ¶ 32.) Defendant disputes this point "to the extent Plaintiff contends that this reflects the current status of titanium dioxide regulation in the EU," as "[t]he court's annulment has since been suspended, pending appeal by France's Agency for Food Environmental and Occupational Health & Safety (ANSES) filed in February 2023." (*Id.* ¶ 32.) The Court notes, however, that it remains

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 23 of 28

disputes this point regarding ECHA's conclusion, noting the complete sentence says, "[the Committee for Risk Assessment] takes the view, that these exposure conditions represent excessive exposure which invalidates the results of the Lee et al. (1985) study on their own for classification purposes." (ECF No. 44-1 ¶ 31.) Defendant then notes the Committee considered data from Lee (1985), Heinrich (1995), and other studies to conclude inhalable titanium dioxide is a "suspected human carcinogen." (*Id.*) However, it still appears that Plaintiff's assertion that ECHA found the Lee study to be unreliable is undisputed.

Further, Plaintiff asserts the U.S. Food and Drug Administration ("FDA") has long accepted titanium dioxide as safe and appropriate for use in cosmetics and other products. (ECF No. 43-1 at 20; ECF No. 44-1 ¶ 3.) While Defendant disputes this point "as phrased" (ECF No. 44-1 ¶ 3), the Court notes that federal regulations provide that "[t]he color additive titanium dioxide may be safely used in cosmetics, including cosmetics intended for use in the ar[e]a of the eye, in amounts consistent with good manufacturing practice." 21 C.F.R. § 73.2575(b).

Finally, Plaintiff notes California's OEHHA has not evaluated either the Lee or Heinrich study but has listed titanium dioxide automatically based on IARC's classification. (ECF No. 43-1 at 20; ECF No. 44-1 ¶¶ 33–34.) Defendant does not address this point in his opposition, nor does he otherwise dispute this fact. (*See* ECF Nos. 44, 44-1.)

Based on the foregoing, the parties admit that there is a clear debate over whether Listed Titanium Dioxide causes cancer in humans. The Court finds the Prop 65 warning would likely improperly elevate "one side of a legitimately unresolved scientific debate." *CERT*, 29 F.4th at 1279. Accordingly, the Court finds the Prop 65 warning is controversial.

In sum, because the Court finds the Prop 65 warning for Listed Titanium Dioxide is not purely factual and uncontroversial, *Zauderer*'s lower standard of scrutiny does not apply. The Court need not and does not consider the parties' arguments as to whether the warning is not unjustified or unduly burdensome. The Prop 65 warning for Listed Titanium Dioxide must satisfy intermediate scrutiny under *Central Hudson* to be constitutional.

undisputed that the European Court of Justice annulled the European Regulation.

ii. Whether the Warning is Constitutional Under Central Hudson

Under the intermediate scrutiny standard set forth in *Central Hudson*, "the government may restrict or prohibit commercial speech that is neither misleading nor connected to unlawful activity, so long as the governmental interest in regulating the speech is substantial." *CTIA II*, 928 F.3d at 842 (citing *Central Hudson*, 447 U.S. at 564). "The restriction or prohibition must 'directly advance the governmental interest asserted,' and must not be 'more extensive than is necessary to serve that interest." *Id.* (quoting *Central Hudson*, 447 U.S. at 566).

Plaintiff argues that while California has a substantial interest in public health, that is insufficient to validate the state's compelled speech. (ECF No. 43-1 at 22.) Plaintiff contends the Prop 65 warnings in this case are misleading, compelled cancer warnings on cosmetics for Listed Titanium Dioxide do not directly advance California's interest, and, on the contrary, enforcing safe harbor regulations for "speculative, conjectural, or tentative" risks "inevitably dilute[es] the force of any specific warning given." (*Id.* (citation omitted).) Plaintiff maintains the warning also fails intermediate scrutiny because California has "more narrowly tailored" options to inform the public about cancer risks. (*Id.* at 23.)

In opposition, Defendant argues there is a "reasonable" fit between the required disclosure and California's interest in protecting consumers from exposure to carcinogens. (ECF No. 44 at 25.) Defendant maintains, at a minimum, there exists a triable issue of material fact regarding whether Listed Titanium Dioxide warnings can be compelled under *Central Hudson*. (*Id.*)

Here, the Court finds that "California unquestionably has a substantial interest in preserving the health of its citizens." *NAWG*, 85 F.4th at 1283 (citation omitted). However, much like *NAWG*, the Court notes that compelling businesses "to warn consumers of a potential 'risk' never confirmed by any regulatory body . . . does not advance that interest." *Id.* Plaintiff is correct that "California could employ various other means to promote its (minority) view that [a Prop 65 chemical] puts humans at risk of cancer 'without burdening [businesses] with unwanted speech." (ECF No. 46 at 12 (citing *NAWG*, 85 F.4th at 1283).) As Plaintiff notes, California could use "more narrowly tailored" options to inform the public about cancer risks, such as posting information about the chemical on its website, funding scientific research, and pursuing

public awareness campaigns. (ECF No. 43-1 at 23 (citing *NAWG*, 85 F.4th at 1283; *Cal. Chamber I*, 529 F. Supp. 3d at 1121).) Accordingly, the Court finds the Prop 65 warning for Listed Titanium Dioxide does not satisfy the intermediate scrutiny standard set forth in *Central Hudson*.

B. Whether a Permanent Injunction Should Issue

Even though the Court finds the Prop 65 warning for Listed Titanium Dioxide violates the First Amendment, Plaintiff must also establish: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). Further, when the government is a party, the balance of equities and public interest factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014).

Plaintiff argues that in the time since this Court held it was entitled to a preliminary injunction, Defendant cannot point to any factual or legal development that would alter the Court's determination that the warning requirement as applied to Listed Titanium Dioxide was likely unconstitutional. (ECF No. 43-1 at 24.) Defendant does not make any arguments about the remainder of the permanent injunction factors in his opposition. (*See* ECF No. 44.) In reply, Plaintiff notes Defendant does not contest Plaintiff has satisfied the elements for obtaining injunctive relief. (ECF No. 46 at 12–13.)

Here, the Court finds its analysis of the permanent injunction factors is largely the same as in its order granting a preliminary injunction. (ECF No. 40.) The Court finds Plaintiff has sufficiently demonstrated it will suffer irreparable harm in the absence of a permanent injunction. See Lydo Enterprises, Inc. v. City of Las Vegas, 745 F.2d 1211, 1214 (9th Cir. 1984) ("Any loss of First Amendment freedoms, even briefly, can constitute irreparable injury." (citation omitted)). Because Plaintiff has suffered constitutional violations, remedies at law are inadequate to compensate for injuries. See Am. Trucking Ass'ns, Inc. v. City of Los Angeles, 559 F.3d 1046, 1059 (9th Cir. 2009) ("Unlike monetary injuries, constitutional violations cannot adequately be

Case 2:23-cv-01006-TLN-JDP Document 56 Filed 08/12/25 Page 26 of 28

remedied through damages and therefore generally constitute irreparable harm."). The Court also finds a permanent injunction is in the public interest and the balance of the equities tips in Plaintiff's favor. The balance of equities must tip in favor of those whose First Amendment rights are being violated. *Doe v. Harris*, 772 F.3d 563, 583 (9th Cir. 2014). Moreover, the public interest favors the proper exercise of First Amendment rights. *Id.*; *Am. Beverage Ass'n*, 916 F.3d at 758. Because all the requisite factors have been met, the Court will grant Plaintiff's requested injunction.

C. Whether Declaratory Relief is Appropriate

The Declaratory Judgments Act states: "In a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a). The procedural requirements for a declaration under 28 U.S.C. § 2201 are the following: (1) "the court must inquire whether there is a case of actual controversy within its jurisdiction"; and (2) if so, "the court must decide whether to exercise that jurisdiction." *Am. States. Ins. Co. v. Kearns*, 15 F.3d 142, 143–44 (9th Cir. 1994). Courts have held the first requirement "is identical to Article III's constitutional case or controversy requirement." *Id.*

Plaintiff argues it is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the warning requirement for cancer as applied to Listed Titanium Dioxide in cosmetics and personal care products violates the First Amendment. (ECF No. 43-1 at 24–25.) In opposition, Defendant simply notes that if the Court were inclined to grant the instant motion, any injunction or declaration should be limited to the general consumer product "known to the State" safe harbor warning language described in the moving papers. (ECF No. 44 at 25.) Defendant maintains there is no other basis for the Court to conclude that no other safe harbor warning could be constitutional. (*Id.*) In reply, Plaintiff notes Defendant does not contest Plaintiff has satisfied the elements for obtaining declaratory relief. (ECF No. 46 at 12–13.) Plaintiff argues the problem with limiting relief to "the general safe harbor warning is that it opens the door for the State to repeatedly craft new warnings in hopes that one passes muster under the First Amendment, with each one forcing [Plaintiff's] members to spend more resources on a new constitutional

challenge." (Id. at 13.)

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

Here, the Court agrees with Plaintiff that the procedural requirements for a declaration under 28 U.S.C. § 2201 have been met. First, Plaintiff is correct, the first prong is identical to establishing Article III standing. (ECF No. 43-1 at 25.) The Court notes that throughout the pendency of this action, Defendant has not challenged Plaintiff's standing. Further, while Defendant objects to this statement as speculative (and noting the declarant lacks foundation to offer an opinion about events that might occur in the future), Plaintiff does also represent that its "members currently embroiled in the dozens of lawsuits alleging failure to warn of Listed Titanium Dioxide and threatened with additional claims will continue to incur expenses and damages for litigation, reformulation and testing, and/or unwarranted warnings." (Id. (citing ECF No. 44-1 ¶ 57).) Second, the Court also agrees with Plaintiff that "declaratory relief would provide needed clarity as to the constitutionality of a misleading and controversial warning requirement." (Id.) The Court also notes declaratory relief is appropriate to clarify and settle "the legal relations in issue" and such relief "will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding." Bilbrey by Bilbrey v. Brown, 738 F.2d 1462, 1470 (9th Cir. 1984). Accordingly, the Court finds declaratory relief is warranted and will grant Plaintiff's request.

Finally, the Court finds unpersuasive Defendant's argument that any injunction or declaration should be limited to the general consumer product "known to the State" safe harbor warning language described in the moving papers. [ECF No. 44 at 25.] Defendant is correct that the court was presented with a variety of options in *NAWG*, all of which it rejected as misleading and controversial. (*Id.* (citing *NAWG*, 85 F.4th at 1263).) However, as other courts in the Eastern District have explained, "[t]he State cannot 'put the burden on commercial speakers to draft a warning that both protects their right not to speak and complies with Prop[] 65." *Cal.*

25

26

27

The Court also finds unpersuasive Defendant's citations to: (1) *S. Cal. Gas Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003), as this case does not stand for the proposition that a plaintiff must offer evidence about the factual accuracy or effect on consumers of other warnings, as Defendant contends; and (2) *Platt v. Moore*, 15 F.4th 895, 910 (9th Cir. 2021), as Plaintiff is not seeking a cross-appeal nor requesting an advisory opinion. (ECF No. 44 at 25.)

Chamber I, 529 F. Supp. 3d at 1119 (citing Nat'l Ass'n of Wheat Growers v. Becerra, 468 F. Supp. 3d 1247, 1261 (E.D. Cal. 2020)). The Court agrees with Plaintiff that "[c]hanges [to] the wording' of the safe harbor 'do[] not change the fact that a deep scientific debate still exists,' nor the fact that average consumers reading the warning will still be misled." (ECF No. 46 at 13 (quoting NAWG, 85 F.4th at 1282).) Further, as the Cal. Chamber I court explained, "[i]f the seas beyond the safe harbor are so perilous that no one risks a voyage, then the State has either compelled speech that is not purely factual, or its regulations impose an undue burden." 529 F. Supp. 3d at 1119 (citing Am. Beverage Ass'n, 916 F.3d at 757).

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Plaintiff's Motion for Summary Judgment. (ECF No. 43.) Defendant Rob Bonta, in his official capacity as Attorney General of the State of California, the State of California's officers, employees, and agents, and all those acting in privity or concert with those individuals, including private citizen enforcers under California Health & Safety Code § 25249.7(d), are hereby ENJOINED from filing or prosecuting new lawsuits to enforce Prop 65's warning requirement, California Health & Safety Code § 25249.6, for cancer as applied to Listed Titanium Dioxide (i.e., titanium dioxide that consists of airborne, unbound particles of respirable size) in cosmetics and personal care products. This Order does not alter any existing consent decrees, settlements, or agreements related to Prop 65 warning requirements. The Court further DECLARES that Prop 65's warning as applied to Listed Titanium Dioxide is unconstitutional and violative of the First Amendment of the United States Constitution.

Plaintiff asserts in its Motion for Civil Contempt against EHA that if the Court grants its Motion for Summary Judgment and enters judgment for Plaintiff, this pending Motion for Civil Contempt would be moot. (ECF No. 48 at 11.) As the Court grants Plaintiff's Motion for Summary Judgment, it DENIES as moot the pending Motion for Civil Contempt (ECF No. 48) and the Motion for Leave to File a Supplemental Brief (ECF No. 54).

IT IS SO ORDERED.

Date: August 11, 2025

TROY L. NUNLEY

CHIEF UNITED STATES DISTRICT JUDGE