

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

JAMES SHEPHERD, Trustee for the JAMES B.
SHEPHERD TRUST, and NEW MILLENNIUM
CONCEPTS, LTD.,

Plaintiffs,

v.

ENVIRONMENTAL PROTECTION AGENCY,
MICHAEL S. REGAN, Administrator,
CHRISTINE TOKARZ, DAVID COBB, CAROL
KEMKER, AND KERIEMA NEWMAN, In
Their Personal Capacities,

Defendants.

Civil Action No. 4:23-CV-826-P

**FEDERAL DEFENDANTS' MEMORANDUM IN SUPPORT OF RESPONSE IN
OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

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Introduction

This case is about the United States Environmental Protection Agency’s authority to take enforcement action against the unlawful sale of unregistered pesticide products regulated by the Federal Insecticide Fungicide and Rodenticide Act (“FIFRA”). EPA is authorized to issue unilateral orders called Stop, Sale, Use, or Removal Orders (“SSUROs”) whenever it has reason to believe that a pesticide has been or is intended to be distributed or sold in violation of any provision of FIFRA. 7 U.S.C. § 136k(a). When EPA learned that Berkey water filters incorporated anti-microbial silver and were being sold in multiple states with claims that they could remove more than 99.999% of viruses and 100% of pathogens from water sources, the agency had the requisite reason to believe that the sale and distribution of Berkey filters violated FIFRA. EPA therefore used its authority to issue SSUROs to seven Berkey product sellers.

The entities subject to those orders are not parties in this lawsuit. Nor have they sought judicial review of those orders in another action. Instead, Plaintiffs—entities that license Berkey products—challenge the orders issued to those who manufacture components for, or distribute and sell, Berkey products. They now seek a preliminary injunction prohibiting EPA’s enforcement of orders issued to third parties.

Plaintiffs’ motion for emergency relief fails. They cannot show a likelihood of success on the merits because they have neither Article III standing nor third-party standing, and because their claims, even if justiciable, are meritless. They do not demonstrate irreparable harm both because they have not shown how they, as opposed to various third parties, have been harmed by EPA’s orders, and because any conclusory allegations of economic harm are attributable to other factors, including a widely publicized class-action lawsuit alleging that Berkey products do not perform as advertised. Finally, Plaintiffs cannot show that the public interest or balance of the equities tilts

in their favor because they have no legally cognizable interest in their manufacturers or distributors evading the law, and because the public interest in regulating pesticide consumer products predominates. Plaintiffs thus fail to meet any element of the test that courts use to evaluate entitlement to emergency injunctive relief. *See Winter v. NRDC*, 555 U.S. 7 (2008). The Court should deny their motion.

Background

A. Parties and Nonparties

Plaintiffs are James B. Shepherd, Trustee for the James B. Shepherd Trust (“JBS Trust”), and New Millennium Concepts, Ltd (“NMCL”). The beneficiaries of the JBS Trust “own equitable title to the majority partnership interest in NMCL and hold legal title to intellectual property licensed to NMCL.” Compl. ¶ 1. NMCL has an “exclusive license from the JBS Trust to market Berkey Water Filtration Products.” Compl. ¶ 29. NMCL apparently exercises its license by contracting with manufacturers and distributors to make and sell Berkey water filtration products. Compl. ¶ 2. The Berkey product line includes Berkey water filtration systems and Berkey filter elements which are used in the filtration systems. Compl. ¶ 28. There are at least two manufacturers who hold a license to construct Berkey Water Filtration Products: Berkey International and Vendor B.¹ Compl. ¶ 28. Additionally, many third-party entities distribute, sell, or package Berkey water filtration products. The third-party distributors discussed in the Complaint who received SSUROs are identified below.

¹ The Complaint and Application for Preliminary Injunction identify Berkey International as one of the manufacturers of Berkey Water Filtration Products and refers to Berkey International as Vendor A. Mot. ¶ 191. A second manufacturer of Berkey Water Filtration Products is identified as Vendor B, and the identity of that entity is not disclosed in the Complaint or Application for Preliminary Injunction. Mot. ¶ 191. As such, Federal Defendants will refer to the second manufacturer as Vendor B for clarity.

B. Legal Background

1. FIFRA's registration requirement

The Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA” or “the Act”), 7 U.S.C. §§ 136-136y, governs the production, sale, distribution, and use of pesticides. FIFRA’s principal purpose is to protect human health and the environment from unreasonable adverse effects associated with pesticides. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984). The Act makes it unlawful, with minor exceptions, for any “person in any State [to] distribute or sell to any person any pesticide that is not registered” under the Act. 7 U.S.C. § 136a(a); *see also id.* § 136j(a)(1)(A). A registration granted by EPA under FIFRA is a license which establishes the terms and conditions under which the pesticide may be lawfully sold, distributed, and used. *See id.* §§ 136a(c)(1)(A)-(F), 136a(d)(1).

A “pesticide” includes “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u).² A “substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration,” if, among other things:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise)

(1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

...

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

² An organism is a “pest” under FIFRA when it is “deleterious to man or the environment,” and is “[a]ny fungus, bacterium, virus, prion, or other microorganism,” subject to exceptions not relevant here. 40 C.F.R. § 152.5(d).

40 C.F.R. § 152.15.

EPA may not issue a registration for a pesticide use that would create “unreasonable adverse effects on the environment.” *See* 7 U.S.C. § 136a(c)(5) & (7). EPA registers a pesticide after conducting a scientific review of the risks and benefits of that pesticide. Prospective registrants must submit to EPA, as part of the application for registration, information on the risks associated with the use of the pesticide. *Id.* § 136a(c). The burden of proving that a pesticide is safe for a given use is on the proponent of registration. *Id.* § 136a(c)(1)(F); *Indus. Union Dep’t v. Am. Petroleum Inst.*, 448 U.S. 607, 653 n.61 (1980).

2. The distinction between “pesticides” and “devices” and its application to water filters

EPA also regulates “devices” under FIFRA. A “device” is “any instrument or contrivance . . . which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life,” subject to certain exceptions not relevant here. 7 U.S.C. § 136(h). Device producers, like pesticide producers, must register “establishments” in which they produce their devices, *see id.* § 136e; 40 C.F.R. pt. 167, and they are subject to prohibitions on “[m]isbranding,” 7 U.S.C. § 136(q). But unlike pesticides, devices are not subject to FIFRA’s product-specific, pre-sale registration requirements.

Since 1975, EPA has interpreted “devices” to include “water filters . . . (*except those containing substances or mixtures of substances which are pesticides*).” Part 162—Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, 40 Fed. Reg. 28242, 28266 (July 3, 1975) (emphasis added). As EPA explained in a 1976 guidance document, if an “article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide.” Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976).

EPA’s longstanding view is reflected in more recent guidance available on the Agency’s website. Under the heading “Products Commonly Mistaken as Devices,” EPA notes that:

Where a product that would otherwise be a device also incorporates a pesticidal substance, it may be considered a pesticide product. For example, a filter that physically traps microbial pests (generally a device) would be an antimicrobial pesticide product if it also incorporated a pesticidal substance that kills those pests to improve the efficacy of the entire system.

U.S. EPA, *Pesticide Devices: A Guide for Consumers, Pesticides*, (last updated Dec. 29, 2022).³

The same website also explains that if a water filter “contains any substance intended to disinfect the water, then the unit is generally considered a pesticide that must be registered in order to be sold and distributed.” *Id.*

Similarly, EPA’s Pesticide Registration Manual explains that if “a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3.” U.S. EPA, *Pesticide Registration Manual: Chapter 13 - Devices, Pesticide Registration*, (last updated Mar. 1, 2023).⁴ The Pesticide Registration Manual also notes that in “applying the definition of ‘device’ in FIFRA section 2(h), EPA examines each individual product on a case-by-case basis,” and that a manufacturer “uncertain about whether [its] product requires EPA registration as a pesticide . . . may request a determination from EPA.” *Id.* EPA provides those determinations within four months. *Id.*

³ <https://www.epa.gov/pesticides/pesticide-devices-guide-consumers> (last visited Aug. 16, 2023)

⁴ <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices> (last visited Aug. 16, 2023).

3. The Treated Article Exemption and its limitations

Products that are “treated with or contain[] a pesticide” may be exempt from otherwise applicable registration requirements if the pesticide with which they are treated is intended only “to protect” the articles or substances themselves, and only if that pesticide “is registered for such use.” 40 C.F.R. § 152.25. But under EPA’s longstanding interpretation, “articles or substances bearing implied or explicit public health claims against human pathogens” do not qualify for this exemption, known as the Treated Article Exemption. U.S. EPA, Pesticide Registration (PR) Notice 2000-1, Notice to Manufacturers, Formulators, Producers and Registrants of Pesticide Products (Mar. 6, 2000).⁵ Public health claims include, *inter alia*, claims “for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals)”; claims “for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site”; or “non-specific claim[s] that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.” *Id.* at 2-3.

4. EPA’s enforcement authority

EPA “is charged with choosing the means by which to enforce and achieve the goals of FIFRA.” *Sultan Chemists, Inc. v. EPA*, 281 F.3d 73, 83 (3d Cir. 2002). One enforcement option available to EPA is the issuance of a SSURO. 7 U.S.C. § 136k(a). EPA may issue SSUROs “[w]henever any pesticide or device is found by the Administrator in any State and there is reason to believe . . . that such pesticide or device has been or is intended to be distributed or sold in violation of any” provision of FIFRA. *Id.* Once issued, a SSURO prohibits the sale, use, removal

⁵ Available at <https://www.epa.gov/pesticide-registration/prn-2000-1-applicability-treated-articles-exemption-antimicrobial-pesticides> (last visited August 16, 2023).

of a pesticide, “except in accordance with the provisions of the order.” *Id.* The sale or distribution of a pesticide without a registration may also subject the seller to civil or criminal penalties. *Id.* §§ 136j(a)(1)(A), 136l.

C. Factual Background

1. Silver regulation in the United States

The United States has regulated silver as an antimicrobial pesticide pursuant to FIFRA since 1954.⁶ Ingestion of silver may cause lung and kidney lesions; breathing problems; lung and throat infections; abdominal pain; rashes, swelling, and inflammation on skin; and argyria⁷ in humans and animals. *Id.* at 2-4.

Currently, over 125 products containing silver are registered with EPA.⁸ Among other uses, silver is registered under FIFRA to inhibit the growth of bacteria within the filter unit of water filter systems designed to remove objectionable taste, odors, and color from municipally treated tap water. *Id.*⁹

2. Stop Sale, Use and Removal Orders referenced in the Complaint

In 2022, due to a statement posted on a website, EPA became aware that Berkey water filtration system products contain silver being used for an antimicrobial purpose and that Plaintiffs’ manufacturers and distributors claimed these products remove pests that threaten public health

⁶ U.S. EPA, [R.E.D. Facts Silver](#) at 2, June 1993, (last viewed on Aug. 17, 2023).

⁷ Argyria causes human and animal skin to have a bluish, grey-blue, or black color. This change in skin color is typically permanent. *Id.*

⁸ U.S. EPA, [Chemical Name: Silver](#), (last viewed on Aug. 17, 2023)

⁹ See FIFRA registrations for water filters that contain inert silver include but are not limited to EPA: [Reg. No. 58295-3](#); [EPA Reg. No. 75456-1](#); [EPA Reg. No. 71332-5](#); and [EPA Reg. No. 35900-3](#).

from water. Compl. ¶ 57; Compl. Ex. B-2 at 5-7. Due to the silver in Berkey water filtration system products and the pest removal claims, EPA Regions 2, 4 and 8 began investigating the products to determine whether they required registration under FIFRA. Compl. Ex. B-2 at 5-7. EPA's investigation confirmed that Berkey water filtration system products contain silver; that Plaintiffs' manufacturers and distributors claim these products remove public health pests from water; that these products are not registered; and that Plaintiffs' distributors were selling these products throughout the United States. Compl. Ex. B-2 at 5-7. EPA therefore issued SSUROs pertaining to Regions 2, 4, and 8 in accordance with EPA's authority under FIFRA and EPA's FIFRA Enforcement Response Policy.¹⁰

More specifically, EPA issued seven SSUROs to certain third-party distributors or manufacturers of Berkey water filtration products between December 2022 and May 2023. Compl. Exs. B-4, B-6, B-7, B-8, B-9, B-10, B-11. Most commonly, these parties' advertisements claimed the products removed "99.999%" of "viruses" and "pathogenic bacteria (and surrogates)" from water. *Id.* However, their websites contained many other public health statements. At issuance of the SSURO, each recipient was required to stop the sale, use, and distribution of the offending products and, with respect to the Region 2 and Region 8 SSUROs, to provide EPA with an update on compliance with the SSURO every 30 days until the recipient no longer had any products that violated FIFRA in its inventory. The offending entities and products are detailed in the table

¹⁰ 7 U.S.C. § 136k; U.S. EPA, *FIFRA Enforcement Response Policy*, December 2009, <https://www.epa.gov/sites/default/files/documents/fifra-erp1209.pdf> (last viewed on Aug. 13, 2023); Compl. Exs. B-4, B-6, B-7, B-8, B-9, B-10, B-11.

below.¹¹ It is undisputed that the listed products contain silver and are not registered, and that neither Plaintiff received a SSURO.

Stop, Sale, Use or Removal Orders (“SSURO”)			
SSURO Recipient	Third-Party Type	Date Issued (on or about)	FIFRA Violative Products
James Enterprise, Inc. DBA Berkey Filters (Compl. Ex. B-4)	Distributor	Dec. 27, 2022	Black Berkey Filters Sport Berkey Replacement Filters, Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, Berkey Light Water Filters Sport Berkey Water Bottles
Fritz Wellness, Professional Company DBA Fritz Wellness Center (Compl. Ex. B-7)	Distributor	Feb. 27, 2023	Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters Imperial Berkey Water Filters Crown Berkey Water Filters
Eden Valley Farms LLC (Compl. Ex. B-8)	Distributor	Mar. 6, 2023	Black Berkey Filters Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters Imperial Berkey Water Filters Crown Berkey Water Filters Berkey Light Water Filters

¹¹ Vendor B, a third-party manufacturer, was issued a SSURO on February 3, 2023. Compl. Ex. B-6. It was not limited to Berkey products. In response to the SSURO, Vendor B modified its website and labels to comply with FIFRA, so EPA terminated the SSURO. Because the SSURO to Vendor B was terminated, there are no justiciable claims pertaining to Vendor B. *See Chevron U.S.A., Inc. v. Traillour Oil Co.*, 987 F.2d 1138, 1153 (5th Cir. 1993); *see also Powell v. McCormack*, 395 U.S. 486, 496 (1969) (A controversy is moot when there are no “live issues” or “the parties lack a legally cognizable interest in the outcome.”).

Mountain Mama Natural Foods, Inc (Compl. Ex. B-9)	Distributor	Mar. 7, 2023	Black Berkey Filters Big Berkey Water Filters
Good Earth Natural Foods Company, (Compl. Ex. B-10)	Distributor	May 2, 2023	Black Berkey Filters Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters Imperial Berkey Water Filters Crown Berkey Water Filters
Berkey International LLC, (Compl. Ex. B-11)	Manufacturer	May 8, 2023	Black Berkey Filters Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters

To date, the above violative products still contain silver, are being advertised for pesticidal purposes, and are not registered with EPA as pesticides or pesticidal products.¹²

D. Procedural History

On August 9, 2023, Plaintiffs filed a Complaint and an Application for Temporary Restraining Order, and Preliminary, and Permanent Injunctions against EPA. ECF No. 1. The Complaint alleges that EPA violated the Administrative Procedure Act (“APA”) by exercising its pesticide enforcement mandate under FIFRA.¹³ Further, Plaintiffs alleged that SSUROs issued to

¹² *What does Berkey Water Filter Remove? Lab Test Results*, App. at 1-39; available at https://theberkey.com/pages/test-result?_pos=1&_sid=512c81191&_ss=r (last viewed on August 16, 2023)(“**The Berkey Water Filter Systems are more powerful than any other gravity filter element currently available.** The micropores within the Berkey Filters (Black Berkey Elements) are so small that viruses and pathogenic bacteria cannot pass through them.”)

¹³ The Complaint contains a plethora of allegations that EPA violated many of Plaintiffs’ constitutional rights as well as numerous allegations of APA violations. This opposition brief is intended to address the allegations contained within Plaintiffs’ Application for Preliminary Injunction and to demonstrate why injunctive relief is inappropriate. The Federal Defendants reserve the right to assert all defenses afforded in the Federal Rules of Civil Procedure, including but not limited to those available under Rule 12(b).

the third-party distributors and manufacturers have caused irreparable harm to Plaintiffs such that injunctive relief is warranted. Notably, the Complaint “jointly refers to NMCL and Berkey International as ‘Berkey.’” Compl. Ex. A at 1, ¶4. In this opposition brief, the term “Plaintiffs” refers to James B. Shepherd and NMCL only.

On August 10, 2023, this Court denied Plaintiffs’ request for a temporary restraining order noting “TROs are extraordinary relief and are rarely issued” and set an expedited briefing schedule for Plaintiffs’ Application for Preliminary Injunction. ECF No. 6.

Legal Standards

A. Preliminary Injunction Standard

The Fifth Circuit has repeatedly cautioned “that a preliminary injunction is an extraordinary remedy which should not be granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements.” *Bluefield Water Ass’n, Inc. v. City of Starkville*, 577 F.3d 250, 253 (5th Cir. 2009) (internal quotation marks omitted). Specifically, the moving party must demonstrate that (1) “he is likely to succeed on the merits”; (2) “he is likely to suffer irreparable harm in the absence of preliminary relief”; (3) “the balance of equities tips in his favor”; and (4) “an injunction is in the public interest.” *Winter*, 555 U.S. 7, 20 (2008). *Winter* indisputably requires a plaintiff to show more than a mere “possibility” of harm; instead, the movant must prove that there is a “likelihood” of irreparable injury in the absence of an injunction. *Id.* at 21-22.

B. Jurisdictional Issues

A plaintiff bringing a case in federal court must establish a basis for the Court’s jurisdiction. *Steel Co. v. Citizens for A Better Env’t*, 523 U.S. 83, 94-95 (1998) (“The requirement that jurisdiction be established as a threshold matter ‘spring[s] from the nature and limits of the judicial power of the United States’ and is inflexible and without exception.”) (internal quotation marks

and citation omitted); *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (“It is to be presumed that a cause lies outside [a federal court’s] limited jurisdiction and the burden of establishing the contrary rests upon the party asserting jurisdiction.”) (citations omitted). Where subject matter jurisdiction does not exist, “the court cannot proceed at all in any cause,” and the case must be dismissed. *See Steel Co.*, 523 U.S. at 94 (citation omitted).

C. Merits Issues

To state a claim under the APA, a plaintiff must identify a final agency action that is not committed to agency discretion by law. 5 U.S.C. § 701(a)(2). To the extent agency action is reviewable under the APA, the Court’s inquiry is guided by a deferential standard of review. The party asserting an APA challenge bears the burden of demonstrating that the agency’s action was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A); *ExxonMobil Pipeline Co. v. U.S. Dep’t of Transp.*, 867 F.3d 564, 571 (5th Cir. 2017). In conducting this inquiry, the court’s review is limited to the administrative record compiled by the agency. *Fed. Power Comm’n v. Transcon. Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976). The arbitrary or capricious standard of review is deferential and narrow, and a court may not substitute its judgment for that of the agency. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The court asks only “whether the [agency’s] decision was based on a consideration of the relevant factors” and “whether [the agency] has [made] a clear error in judgment.” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). Particular deference is given to an agency regarding technical matters in its area of expertise. *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983).

Argument and Authorities

A. Plaintiffs are Unlikely to Succeed on the Merits.

To demonstrate entitlement to the extraordinary remedy of a preliminary injunction, Plaintiffs must establish that they are likely to succeed on the merits. Plaintiffs have wholly failed to meet this burden; their motion must therefore be denied.

1. Plaintiffs lack standing in their own right.

As a threshold matter, Plaintiffs are unlikely to succeed on the merits because they lack Article III standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). To establish standing, a plaintiff must show that he or she suffered an injury that is (1) “concrete, particularized, and actual or imminent”; (2) “fairly trace[able] to the challenged action, and not . . . th[e] result [of] the independent action of some third party not before the court”; and (3) “it must be likely as opposed to merely speculative that the injury will be redressed by a favorable decision.” *Id.* (internal quotation marks omitted). The burden rests with Plaintiffs to prove this “indispensable part” of their case. *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990).

First, Plaintiffs have failed to demonstrate that they have suffered a concrete, particularized injury from EPA’s issuance of SSUROs to other parties.¹⁴ Plaintiffs, neither of whom is Berkey International, rely on alleged injuries suffered by Berkey International after it was issued a SSURO, as well as claiming that they have lost market share. Plaintiffs have, however, offered no evidence that a SSURO issued to Berkey International somehow injured Plaintiffs in a manner

¹⁴ Plaintiffs’ failure to demonstrate injury is further discussed in paragraph B of the Argument and Authorities Section of this opposition brief, entitled “Plaintiffs have failed to Demonstrate They are Likely to Suffer Irreparable Harm in the Absence of an Injunction.”

sufficient to demonstrate injury-in-fact and establish standing. Injuries to Berkey International are not automatically injuries to Plaintiffs.

Second, Plaintiffs have failed to demonstrate that any injury is traceable to EPA's issuance of SSUROs as opposed to a pending class-action lawsuit against NMCL, which holds a license to market Berkey products. Compl. ¶ 29.¹⁵ On December 19, 2022, NMCL posted a statement online acknowledging the grave impact the class action had on consumers' opinions about the quality of Berkey products. Compl Ex. B-19 at 229-239 ("Over the past couple months we have been receiving inquiries from customers regarding Berkey's involvement in litigation for the Black Berkey filters. We asked the manufacturer of Berkey products (New Millennium Concepts, LTD) to release a statement to our customers so that they would feel at more ease in understanding the merits of this lawsuit.") Plaintiffs offer no evidence that their alleged decreased market share in 2023, or the injuries to Berkey that Plaintiffs seek to rely on, are attributable to EPA's issuance of SSUROs to third parties rather than the lawsuit that NMCL is actively and publicly fighting.

Third, there is no evidence that a favorable decision in this case would redress Plaintiffs' self-professed injuries. No matter what happens in this case, the class action will still be pending against NMCL. And all that this Court could do even if plaintiffs prevailed would be to "set aside" the SSUROs. See 5 U.S.C. § 706(2). Nothing this Court can do would stop the public's concerns about the allegations in the class action.

Plaintiffs have, in sum, failed to establish that they have suffered any actual injury; that, if they have, that injury is traceable to the third-party SSUROs; or that there is any relief that this Court could grant that would address their phantom injuries.

¹⁵ NMCL's class action lawsuit is currently in the U.S. District Court for the Northern District of Texas, Dallas Division. The docket associated with the case can be found at 3:22-cv-728.

2. Plaintiffs have failed to demonstrate third-party standing.

Plaintiffs also have no standing to bring suit on behalf of third-party manufacturers. *See Ward v. Santa Fe Indep. Sch. Dist.*, 393 F.3d 599, 606 (5th Cir. 2004) (A plaintiff typically “must assert his or her own legal rights and interests and cannot rest a claim to relief on the legal rights or interests of third parties.”) (citing *Warth v. Seldin*, 422 U.S. 490, 499 (1975)).

Here, the damages Plaintiffs allege are not their own. Plaintiffs assert Berkey International has millions of dollars in wholesale inventory and is paying costs to store that inventory, as well as suffering loss in market share, employees, and sales revenue. Mot. ¶ 184.¹⁶ Plaintiffs offer insufficient evidence that these alleged losses have actually occurred, let alone that they were caused by the issuance of SSUROs as opposed to the pending class action lawsuit, normal market forces, or some other factor. Regardless, any claimed injury to Berkey International is Berkey International’s to raise, not Plaintiffs’.

As the Supreme Court and the Fifth Circuit have observed, exceptions to the traditional standing rules are rare and there are mandatory circumstances that must exist to support a grant of third-party standing. “The Supreme Court crafted a prudential exception to the traditional rule against third-party standing where ‘the party asserting the right has a ‘close’ relationship with the person who possesses the right’ and ‘there is a ‘hindrance’ to the possessor's ability to protect his own interests.’” *Vote.Org v. Callanen*, 39 F.4th 297, 303-04 (5th Cir. 2022) (quoting *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004)). Plaintiffs have not alleged any bar to Berkey International seeking redress from a court of law or evidence of a close relationship of the type that would lend itself to a grant of third party standing. Simply put, if Berkey International feels it has suffered the

¹⁶ To differentiate between Plaintiffs’ motion for emergency relief and their Complaint, EPA cites paragraphs contain in Plaintiffs’ motion as “Mot. ¶ []” and paragraphs in their complaint as “Compl. ¶ [].”

type of injury that is cognizable, Berkey International should bring a claim on its own behalf in accordance with the traditional mandates of standing.

In sum, Plaintiffs have failed to establish standing, and for that reason are unlikely to succeed on the merits.

3. Even if they are justiciable, Plaintiffs' claims fail on the merits.

In their motion for emergency relief, Plaintiffs devote just two sentences to the merits of their claims, asserting without elaboration or analysis that they:

have adequately shown that the EPA's actions are arbitrary and capricious, and the result of an abuse of discretion, as no colorable argument exists to say that Berkey filters employ electrodes to generate ions. Plaintiffs have adequately shown that the EPA violated the APA and the procedural due process rights of Plaintiffs.

Mot. ¶ 200. This is inadequate. And Plaintiffs cannot remedy the defect later because “[a]rguments raised for the first time in a reply brief are generally waived.” *Jones v. Cain*, 600 F.3d 527, 541 (5th Cir. 2010); *see also Hollis v. Lynch*, 827 F.3d 436, 451 (5th Cir. 2016) (“A passing reference is insufficient to prevent waiver”) (cleaned up).

Out of an abundance of caution, however, EPA addresses what appear to be Plaintiffs' merits arguments based on the allegations as laid out in their complaint. Assuming without conceding that arguments appearing only in the Complaint could be used to bolster Plaintiffs' motion for a preliminary injunction, they fail for the reasons set forth below.

a. Several of Plaintiffs' merits arguments attack a strawman.

To issue a SSURO, EPA need only have “reason to believe” that a “pesticide or device has been or is intended to be distributed or sold in violation of any” provision of FIFRA. 7 U.S.C. § 136k(a). The Agency easily clears that low bar. As explained above, EPA had—at the very least—“reason to believe” that: (1) the SSURO recipients had sold products containing a “substance or mixture of substances intended for preventing, destroying, repelling, or mitigating

any pest,” 7 U.S.C. § 136(u); (2) that they did so while making claims that exceeded those allowed under the Treated Article Exemption; and (3) that they did not register their products as required under 7 U.S.C. § 136a(a). The SSUROs were therefore reasonable. Plaintiffs do nothing to disturb this conclusion by insisting that “Berkey Filters” do not “employ electrodes to generate ions.” Mot. ¶ 200. Instead, they attack a straw man: EPA’s supposed reliance on a 2007 guidance document titled “Pesticide Registration; Clarification for Ion-Generating Equipment,” 72 Fed. Reg. 54039 (Sept. 21, 2007).

In fact, the SSUROs of which Plaintiffs complain make no mention of the 2007 guidance. And for good reason: as Plaintiffs themselves allege, the 2007 guidance document “has no bearing on non-electrical water filters.” Compl. ¶ 41. That document served only to “clarif[y]” EPA’s “position on the distinction between devices and pesticides with regard to ion-generating equipment”—that is, “equipment that uses electrodes to emit chemical substances for pesticidal purposes,” such as “washing machines containing electrodes that emit silver, copper, or zinc ions and ion generators used in swimming pools to kill algae and as an adjunct to the chlorination process.” 72 Fed. Reg. at 54039-40. Clarification was necessary, EPA explained, because the agency was unaware of these ion-generating commercial products in 1976 when EPA last published guidance in the Federal Register parsing the statutory distinction between a pesticide and a device. *Id.* at 54040. In that 1976 guidance document, EPA explained that an article would be deemed a “pesticide” or a “device” depending on whether it used “mechanical means to trap, destroy, repel, or mitigate any pest”—the hallmarks of a “device”—or whether it “incorporate[d] a substance or mixture of substances to prevent, destroy, repel, or mitigate any pest,” in which case it would be a pesticide. 41 Fed. Reg. at 51065.

The 2007 guidance did not alter that basic scheme; it simply applied EPA’s longstanding

statutory interpretation to a new class of products. *See* 72 Fed. Reg. at 54040. Thus, nothing in the 2007 guidance altered EPA’s decades-old position that “water filters and air filters” are devices, unless they “contain substances or mixtures of substances which are pesticides.” 40 Fed. Reg. at 28266. It was that longstanding interpretation of statutory text that underpinned EPA’s issuance of the SSUROs. To the extent that allegations elsewhere in the Complaint are even relevant to Plaintiffs’ motion, Plaintiffs’ discussion of the 2007 guidance document, Compl. ¶¶ 40-41, 45, and the various legal arguments that they base on that discussion, Compl. ¶¶ 89-113, are beside the point.¹⁷

b. Plaintiffs’ other statutory and constitutional claims lack merit.

Plaintiffs also assert that EPA impermissibly legislated (in violation of the nondelegation doctrine) and failed to faithfully execute the laws by “re-writing and significantly expanding the definition of ‘pesticide.’” Compl. ¶ 123; *accord* Compl. ¶ 144. These claims do not withstand scrutiny. As noted above, FIFRA defines “pesticide” to include “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u). The silver in Black Berkey filters is a “substance intended for preventing, destroying, repelling, or mitigating” microbial organisms that meet the statutory definition of “pest,” and is therefore a “pesticide.” *See supra* p. 3. Plaintiffs object to this straight-forward application of statutory text. And while they never clearly state the basis of their objection, they appear to argue based on ambiguous and selectively quoted legislative history that a pesticide ceases to be a

¹⁷ While Plaintiffs do not appear to allege that the 2007 guidance document could only be issued following notice and comment, such a claim would be time-barred under 28 U.S.C. § 2401(a), the six-year statute of limitations for civil suits against the United States. *See Am. Stewards of Liberty v. Dep’t of Interior*, 960 F.3d 223, 229 n.3 (5th Cir. 2020).

pesticide when it is incorporated in a product. Compl. ¶¶ 152-55. But Plaintiffs identify no textual basis for their claim. And “legislative history is not the law.” *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1814 (2019). The allegations contained in counts four and five of the Complaint therefore fail.

While the Court need go no further, Plaintiffs’ invocation of the nondelegation doctrine and the Take Care Clause fail for other reasons as well. “The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government.” *Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019) (plurality). The prohibition runs to Congress, not to agencies. *See Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 472 (2001) (“In a delegation challenge, the constitutional question is whether the statute has delegated legislative power to the agency.”). In arguing that EPA violated the nondelegation doctrine by “significantly expanding” the scope of its delegated authority, Compl. ¶ 123, Plaintiffs get things exactly backwards. Plaintiffs’ reliance on the Take Care Clause is similarly misplaced. The Supreme Court has long “distinguished between claims of constitutional violations and claims that an official has acted in excess of his statutory authority,” *Dalton v. Specter*, 511 U.S. 462, 472 (1994), and the latter “are not ‘constitutional’ claims,” *id.* at 473. Plaintiffs’ passing reference to the Take Care Clause cannot transform what is, at bottom, an argument about the meaning of 7 U.S.C. § 136(u), into a dispute of constitutional dimensions.

Plaintiffs fare no better under the 14th Amendment’s Due Process Clause (Compl. ¶¶ 161-70), which “applies only to state actors, not federal actors,” *Newsome v. E.E.O.C.*, 301 F.3d 227,

232 (5th Cir. 2002) (citing *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954)). EPA, an agency of the Federal government, is not a state actor. Plaintiffs' 14th Amendment claim therefore fails.¹⁸

So too does their claim under the Ninth and 10th Amendments, which they read to “protect[] from government interference” “every water filter that uses a gravity-fed element comprising a porous medium to capture contaminants.” Compl. ¶ 175. This argument is unmoored from the Constitution's text or precedent. No such right exists.

c. Plaintiffs have not pled claims against federal officials in their individual capacities.

Plaintiffs purport to assert personal capacity APA claims against four EPA employees, seeking vacatur of EPA final agency actions, declaratory and injunctive relief, and money damages. *See* Compl. ¶¶ 5; 89-176; *see also* ECF 1-5, Civil Cover Sheet (cause of action arises pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 553, 701-06, and seeks injunctive relief against EPA administrative rule). But Plaintiffs have not asserted a cause of action or identified a statute or regulation that otherwise authorizes a personal capacity suit for money damages against these individual federal officials. Their claims should therefore be construed as claims against the government.

The “APA does not provide for individual-capacity claims” against federal officials. *Triplett v. Fed. Bureau of Prisons*, No. 3:08-CV-1252-K, 2008 WL 4378430, at *4 (N.D. Tex. Sept. 25, 2008). Nor does the APA allow claims for money damages. *Armendariz-Mata v. U.S. Dep't of Just., Drug Enf't Admin.*, 82 F.3d 679, 682 (5th Cir. 1996). Instead, it “provides a means

¹⁸ Elsewhere in their Complaint, Plaintiffs cite the Fifth Amendment, but only in reference to a “void for vagueness” challenge to EPA's 2007 guidance document. Compl. ¶¶ 106-113. That guidance document was not a basis for the challenged actions (*see supra* Section A.3.b) and so Plaintiffs' Fifth Amendment challenge misses the mark.

to obtain non-monetary relief against the United States, a federal agency, or a federal officer acting in an official capacity” in limited circumstances. *Triplett*, 2008 WL 4378430, at *4 (citing *Lane v. Pena*, 518 U.S. 187, 196, (1996)); *see also See Scott v. Flowers*, 910 F.2d 201, 213 (5th Cir. 1990) (holding equitable relief is only available against government officials in their official capacities).

The Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, which Plaintiffs also invoke, does not provide an independent cause of action against individual federal officials; it simply provides an additional remedy once jurisdiction otherwise exists on a different ground. *In re B-727 Aircraft Serial No. 21010*, 272 F.3d 264, 270 (5th Cir. 2001). Even then, “[d]eclaratory relief is inappropriate in individual capacity suits” against federal officials. *Gerlich v. U.S. Dep’t of Just.*, 659 F. Supp. 2d 1, 19 n.20 (D.D.C. 2009); *see also Flowers*, 910 F.2d at 213; *Biron v. Upton*, No. 4:15-CV-205-P, 2020 WL 85146, at *9 (N.D. Tex. Jan. 7, 2020) (Pittman, J.) (explaining declaratory relief is unavailable against federal officers in their individual capacities related to actions taken in the course of the federal employment).

For these reasons the United States construes Plaintiffs’ claims against individually named officials to be claims against EPA and respectfully requests that the Court do the same. *See Jefferson v. Harris*, 170 F. Supp. 3d 194, 217 (D.D.C. 2016) (construing APA claim brought against the federal government and federal officials in their personal capacities only as an official capacity claim against government).

B. Plaintiffs have Failed to Demonstrate That They Are Likely to Suffer Irreparable Harm in the Absence of an Injunction.

Plaintiffs have failed to allege, much less demonstrate, any irreparable harm to either of the two named Plaintiffs that will result if an injunction is not granted. Most, if not all, of Plaintiffs’ claims of irreparable harm involve claims of loss from competition in the marketplace, such as

loss of market share, revenue, and business opportunities. *See, e.g.*, Mot. ¶¶ 181, 193. Courts are reluctant to find that such claims constitute irreparable harm, especially where, as here, Plaintiffs have failed to explain why they could not regain these competitive losses if the law is complied with. *See Astellas Pharma US, Inc. v. FDA*, 642 F. Supp. 2d 10, 22-23 (D.D.C. 2009); *Biovail Corp. v. FDA*, 519 F. Supp. 2d 39, 48-49 (D.D.C. 2007). Likewise, general claims of loss of market share, lost sales, and the like, without evidence, are insufficient to establish irreparable harm. *See Pruvit Ventures, Inc. v. Forever Green Int'l LLC*, No. 4:15-cv-571-ALM-CAN, 2015 WL 9876952, at *3 (E.D. Tex. Dec. 23, 2015).

Additionally, economic loss is not irreparable harm absent evidence that, without a temporary injunction, the very existence of the movant's business is threatened. *See Digit. Generation, Inc. v. Boring*, 869 F. Supp. 2d 761, 781 (N.D. Tex. 2012).¹⁹ No such evidence exists in this case as to the two named Plaintiffs, whose business, according to the Complaint, appears to be licensing to others the right to manufacture and sell Berkey products. Compl. ¶ 29.

There is no evidence of the terms of any of the license agreements or of licensing revenues. Berkey products are still being offered for sale by numerous sellers on Amazon and elsewhere.²⁰ Indeed, some of the retailers that received SSUROs are still advertising Berkey products for sale

¹⁹ This is true even if alleged financial losses will not be recoverable. *See Biovail*, 519 F. Supp. 2d at 49.

²⁰https://www.amazon.com/Berkey-Gravity-Fed-Elements-Fluoride-Reduction/dp/B0CBVKJXNH/ref=sr_1_5?crid=2AGT3LNV909Y5&keywords=big+berkey&qid=1692285199&srefix=big+berkey%2Caps%2C144&sr=8-5&ufe=app_do%3Aamzn1.fos.c3015c4a-46bb-44b9-81a4-dc28e6d374b3 (last visited Aug. 17, 2023).

on their own websites.²¹ Therefore, even assuming Plaintiffs have incurred or may experience financial losses, there is no evidence that they risk going out of business during the pendency of this lawsuit.

Indeed, there is no evidence that the two named Plaintiffs have experienced or will suffer any injury at all, much less irreparable harm. Plaintiffs impermissibly attempt to rely on alleged injuries to other nonparty entities whose only relationship with Plaintiffs is as a licensee. These alleged injuries cannot constitute irreparable harm for purposes of a preliminary injunction.

1. Plaintiffs cannot establish irreparable harm based on alleged injuries to their licensees or other nonparties.

Plaintiffs make a number of hyperbolic claims of harm without evidence or specifics. *See, e.g.,* Mot. ¶ 197. Plaintiffs' specific allegations of harm, however, refer to alleged injuries to nonparties, not the two named Plaintiffs. For example:

- Plaintiffs assert that they have lost market share because of the SSUROs. *See, e.g.,* Mot. ¶ 181. But these assertions are undermined by the allegations that the trust merely licenses intellectual property to NMCL, Compl. ¶ 29, which has granted licenses to others to manufacture and sell Berkey-branded products, Compl. ¶ 29. Any losses of market share would have been experienced, not by the two named Plaintiffs, but by licensees of NMCL. These licensees are not parties to this lawsuit.
- Plaintiffs allege specific injuries purportedly experienced by an entity called Berkey International, Compl. ¶ 78; Mot. ¶¶ 182-184, which is alleged to be a manufacturer licensed by the trust, Compl. ¶ 28. Plaintiffs also allege injuries to "Berkey," which, as noted above, they have defined to jointly refer to Plaintiff NMCL and Berkey International. Compl. ¶ 29. The allegations of injury to "Berkey" appear to refer to Berkey International. *See* Mot. ¶ 182 (claiming that Berkey International has been forced to lay off employees and referring to Berkey International as both "Berkey International" and "Berkey").
- Plaintiffs allege that an unnamed vendor of Berkey International was forced to lay off employees. Mot. ¶ 183.

²¹ *See* <https://www.fritzwellness.com/water> (Fritz Wellness) (last visited Aug. 17, 2023); <https://edenvalleyfood.com/product/big-berkey-water-filter/> (Eden Valley Farms) (last visited Aug. 17, 2023).

Plaintiffs cannot establish irreparable harm based on alleged injuries to others who are not parties to this suit. *See Winter*, 555 U.S. at 20 (“A plaintiff seeking a preliminary injunction must establish that *he* is likely to suffer irreparable harm in the absence of preliminary relief”) (emphasis added); *see also Morice v. Hosp. Serv. Dist. # 3*, No. 18-7945, 2019 WL 1517954, at *7 (E.D. La. Apr. 8, 2019) (“Dr. Morice lacks standing to seek injunctive relief for harm that will occur to others, even to others who would allegedly benefit from such injunctive relief”); *Smith v. Okolona Mun. Separate Sch. Dist.*, No. CIV. A. 1:97cv226-D, 1997 WL 560922, at *2 (N.D. Miss. July 31, 1997) (“It is some showing of ‘irreparable harm’ to Dr. Smith that must be demonstrated to this court, and not to third persons not parties to this lawsuit.”); *see also supra* Section A(2) at 15-16 (Plaintiffs have failed to demonstrate third-party standing). Furthermore, even if an injury were experienced by a licensee, it does not follow that any injury, much less irreparable harm, will result for the licensor. For example, if the license were for a fixed period for a flat fee, a subsequent loss of market share by the licensee would not necessarily result in any injury or harm to the licensor. Therefore, Plaintiffs’ allegations of injuries to their licensees fail to demonstrate irreparable harm to Plaintiffs that will support the issuance of an injunction.²²

2. Plaintiffs’ allegations that EPA’s issuance of the SSUROs caused a loss of market share and other injuries are implausible on their face. More likely explanations exist.

Plaintiffs allege they have suffered a loss of market share, damage to reputation, loss of revenue, and loss of business opportunities because of the SSUROs issued to nonparties. *See, e.g.*, Mot. ¶¶ 181, 197. The most specific allegation is Plaintiffs’ claim that the issuance of SSUROs

²² Additionally, four of the SSUROs were issued to nonparty retail sellers of Berkey products. These entities are not alleged to be affiliated with the two named Plaintiffs, other than having the right to sell Berkey products. Plaintiffs do not allege any injuries to any of these retailers, and, in any event, such allegations would not demonstrate irreparable harm to Plaintiffs.

caused a decline in sales on Amazon since February 2023. However, a consumer researching Berkey products on the web would encounter little information about the SSUROs. The consumer could, however, find:²³

- A July 2022 New York Times' Wirecutter article expressly declining to recommend the "Big Berkey" entitled "The Big Berkey Water Filter: Uncertified and Inconvenient." Tim Hefferman, *The Big Berkey Water Filter: Uncertified and Inconvenient*, N.Y. TIMES WIRECUTTER (July 22, 2022), App. 40-63, available at <https://www.nytimes.com/wirecutter/reviews/big-berkey-water-filter-system/>
- Multiple references to the pending class action lawsuit against NMCL, including Internet posts encouraging consumers not to buy Berkey products because of that lawsuit.²⁴
- Several recent Internet postings referencing the fact that Berkey products are banned in California because they are not NMF/ANSI certified.²⁵ Some of them are critical of Berkey products.²⁶ Additionally, Google searches related to Berkey products repeatedly returned suggestions to search for "Why are Berkey products banned in California?"²⁷

With respect to the SSUROs, a search for "Berkey SSURO"²⁸ returned a link to the listing on EPA's website about the SSURO issued to James Enterprises (but not the other SSUROs). This

²³ The Google searches that produced these results were performed in Washington, D.C. on August 15, 2023. The Google search engine is inherently dynamic, and the same search terms may return different results depending on a number of factors including the location where the search is performed, the searcher's previous searches, and changes to Google's algorithm. *See* Sabina Plimmer, [Why Do I Get Different Google Results in Different Locations?](#) (last visited Aug. 15, 2023). Accordingly, the search terms and first page of each of the search results discussed herein has been printed in hard copy and are included in the appendix. In each case, the hardcopy is multiple printed pages.

²⁴ *See, e.g.*, [u/Ecstatic-Fun-2390, Do not order from berkeywaterfilter.com, r/Berkey, https://www.reddit.com/r/Berkey/comments/zmu6el/do_not_order_from_berkeywaterfiltercom/](https://www.reddit.com/r/Berkey/comments/zmu6el/do_not_order_from_berkeywaterfiltercom/) (last visited Aug. 17, 2023).

²⁵ To be clear, the ban is not recent, but there are many recent articles and postings on the Internet discussing the ban, and many of those do not say when the ban went into effect.

²⁶ *See* Eva Hagen, [Here's Why Berkey Water Filters Are Banned in California](#), greenmatters (July 12, 2023 9:42 A.M. ET), (last visited August 16, 2023).

²⁷ Google, "[Berkey water filter lawsuit 2023](#)" Search, (last visited Aug. 15, 2023).

²⁸ Google, "[Berkey SSURO](#)" Search, (last visited Aug. 15, 2023) (last visited Aug. 15, 2023).

posting provides no details other than that the SSURO was issued and that the matter is on EPA's enforcement docket.²⁹ This search produced little else related to the claims in this suit, other than a link to a PDF of the Complaint that is posted on the website of Plaintiffs' counsel.³⁰

Additionally, although Plaintiffs' only claim of loss of market share for which any details are provided is based on Amazon statistics, research revealed nothing suggesting that either of the two Plaintiffs or any of the entities that received SSUROs sell Berkey products on Amazon.³¹ Further, a sampling of the reviews of some of the Berkey products sold on Amazon did not locate any negative reviews based on the issuance of the SSUROs, but did find negative reviews urging consumers not to buy Berkey products because of the class action lawsuit or because Berkey products are not NSF/ANSI certified.³²

Thus, the claim that the issuance of the SSUROs somehow caused a decline in Amazon sales is implausible. To the extent Berkey products have actually lost market share on Amazon or elsewhere, the cause is much more likely to be the New York Times' negative review, the class action lawsuit, and the California ban, all of which have much greater public visibility than the

²⁹U.S. EPA, *James Enterprise, Inc. DBA Berkey Filters*, EPA Administrative Enforcement Dockets, <https://yosemite.epa.gov/oa/rhc/epaadmin.nsf/0c8d39c3f340d0df8525756d004e6e72/ed48b74553c2dcfc85258925007f0a57!OpenDocument> (last visited Aug. 15, 2023).

³⁰ Plaintiffs' Original Complaint, *Shepherd v. EPA*, (No. 4:23-cv-00826-Y), <https://www.norredlaw.com/documents/01-Original-Complaint.pdf> (last visited Aug. 15, 2023).

³¹ It is not possible to review (or to include hard copies of) all the information on Amazon's website about Berkey products. However, searching Amazon for "Berkey" followed by the name of one of the Plaintiffs or one of the recipients of the SSUROs did not return anything suggesting that any of them sell Berkey products through Amazon.

³² See, e.g., SR, Berkey Class Action Lawsuit, [Comment to Travel Berkey Gravity-Fed Water Filter with 2 Black Berkey Elements](#) (Aug. 4, 2023) (last visited Aug. 14, 2023).

SSUROs. The same is true for Plaintiffs' other, general claims of harm, such as loss of reputation and business opportunities.

Accordingly, Plaintiffs have failed to establish that irreparable harm will result to either of them absent a preliminary injunction.

C. The Balance of the Equities and the Public Interest Weigh Against an Injunction.

Plaintiffs bear the burden of proof as to all the elements required for a preliminary injunction. *See Kern River Gas Transmission Co. v. Coastal Corp.*, 899 F.2d 1458, 1462 (5th Cir. 1990). Therefore, because Plaintiffs cannot demonstrate either a likelihood of success on the merits or irreparable harm, their Motion can be denied without further inquiry. The Court need not consider anything else. However, the other factors—the balance of equities and the public interest—also favor denial of injunctive relief.

Where, as here, the opposing party is the government, the balance of equities and the public interest are merged into a single inquiry. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

Plaintiffs cite two public interest factors that they claim support temporary equitable relief: (1) EPA's alleged change in its position as to whether registration is required for Berkey water filters; and (2) the claim that, if Berkey water filters cannot be purchased, consumers will be forced to rely on inferior imitations. Mot. ¶¶ 201-202. Neither of these supports injunctive relief.

As discussed above, Berkey water filters contain inert silver, the ingestion of which can cause health problems in humans and animals. Silver has been regulated as an anti-microbial pesticide for almost 70 years, and water filter manufacturers that use silver to inhibit the growth of bacteria and other microbes have registered their water filters as pesticides with EPA.

Thus, EPA has not changed its position, and, when EPA discovered that Berkey water filters contain silver and were being marketed with broad public health claims, it acted consistently

with its long-standing policy. Given the harm that can be caused by the ingestion of silver, and the fact that other manufacturers have registered their silver-containing water filters, the public interest does not favor allowing anyone to continue to sell Berkey's unregistered products.

Additionally, consumers have other alternatives besides imitations of Berkey filters. For example, as noted in the New York Times article discussed above, there are pitcher and under the sink water filters that are NMF/ANSI certified (which Berkey products are not) and are smaller, cheaper, and easier to maintain.

Thus, Plaintiffs have failed to demonstrate that the public interest favors a preliminary injunction.

Conclusion

For the reasons set forth above, Plaintiffs' motion for a preliminary injunction should be denied.

Respectfully submitted,

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Certificate of Service

On August 17, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Shari M. Howard
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