11-422
Natural Resources Defense Council, Inc. v. U.S. Food and Drug Administration

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2011

(Argued: May 14, 2012 Decided: March 15, 2013 Amended: March 21, 2013)

Docket No. 11-422-cv

NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, MARGARET HAMBURG, IN HER OFFICIAL CAPACITY AS COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants-Appellees.[*]

Before: POOLER, LYNCH, *Circuit Judges*, COGAN, *District Judge*.[**]

Plaintiff-Appellant Natural Resources Defense Council ("NRDC") appeals from a judgment of the United States District Court for the Southern District of New York (Hellerstein, *J.*), granting summary judgment to defendants the Food and Drug Administration ("FDA"),

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[*] The Clerk of the Court is directed to amend the caption as set out above.

[**] The Honorable Brian M. Cogan, United States District Court for the Eastern District of New York, sitting by designation.

Kathleen Sebelius, and Margaret Hamburg. At issue is whether NRDC has standing under Article III of the U.S. Constitution to bring this action to compel FDA to finalize its regulation of triclosan and triclocarban, two chemicals used in over-the-counter antiseptic antimicrobial soap. We hold that NRDC has presented evidence of standing sufficient to withstand summary judgment as to the regulation of triclosan, but not as to the regulation of triclocarban. As to triclosan, standing may be based on exposure to a potentially dangerous product, and NRDC's evidence establishes that triclosan is potentially dangerous and that at least one of its members is frequently exposed to triclosan-containing soap. As to triclocarban, NRDC presented no evidence of members' direct exposure but relied on evidence that the proliferation of triclocarban may contribute to the development of antibiotic-resistant bacteria. This evidence is insufficiently particular to support standing.

Vacated and remanded.

AARON S. COLANGELO, Natural Resources Defense Council (Mitchell S. Bernard, Nancy Sharman Marks, Vivian H.W. Wang, Natural Resources Defense Council, New York, N.Y., *on the brief*), Washington, D.C., *for Plaintiff-Appellant*.

JOHN D. CLOPPER, Assistant United States Attorney for the Southern District of New York (Preet Bharara, United States Attorney, Sarah S. Normand, Assistant United States Attorney, *on the brief*), New York, N.Y., *for Defendants-Appellees*.

Alison M. Zieve, Public Citizen Litigation Group (Scott L. Nelson, *on the brief*),Washington, D.C., *for Amici Curiae Public Citizen, Inc., Asian American Legal Defense Fund, Bronx Health Link, Inc., Empire State Consumer Project, Equal Justice Society, Healthy Schools Network, Institute for Health and Environment at University at Albany, National Campaign to Restore Civil Rights, New York City Environmental Justice Alliance, New York Committee for Occupational Safety and Health, New York Lawyers for the Public Interest, Inc., and Center for Civil Rights, UNC School of Law, in support of Plaintiff-Appellant*.

POOLER, *Circuit Judge*:

Plaintiff-Appellant Natural Resources Defense Council ("NRDC") appeals from a judgment of the United States District Court for the Southern District of New York (Hellerstein, *J.*), granting summary judgment to defendants the Food and Drug Administration ("FDA"), Kathleen Sebelius, and Margaret Hamburg (collectively, the "government"). At issue is whether NRDC has standing under Article III of the U.S. Constitution to bring this action to compel FDA to finalize its regulation of triclosan and triclocarban, two chemicals used in over-the-counter antiseptic antimicrobial soap.

We hold that NRDC has presented evidence of standing sufficient to withstand summary judgment as to the regulation of triclosan, but not as to the regulation of triclocarban.[1] NRDC has presented sufficient evidence of standing as to triclosan because standing may be based on exposure to a potentially dangerous product, and NRDC's evidence establishes that triclosan is potentially dangerous and that at least one of its members is frequently exposed to triclosan-containing soap. As to triclocarban, NRDC presented no evidence of members' direct exposure but relied on evidence that the proliferation of triclocarban may contribute to the development of antibiotic-resistant bacteria. This evidence does not establish an injury sufficiently particularized to satisfy the injury-in-fact requirement of Article III standing. Accordingly, we vacate the district court's grant of summary judgment and remand for further proceedings.

[1] We note our receipt of Fed. R. Civ. P. 28(j) letters dated March 11, 2013, and March 12, 2013, from the Appellees and the Appellant, respectively, alerting us to the decision in *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138 (2013). The decision in *Clapper* does not alter the analysis here.

BACKGROUND

I. Regulatory Framework

This case concerns FDA's regulation of over-the-counter ("OTC") topical antiseptic antimicrobial chemicals. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FFDCA"), a new drug may not enter interstate commerce unless FDA determines that it is generally recognized as safe and effective ("GRAS/E") for the particular use described in its product labeling. *See* 21 U.S.C. § 321(p)(1) (defining a "new drug" as one that "is not generally recognized, among experts . . . as safe and effective for use under the conditions" noted in the drug's labeling); *id.* § 355(a) (prohibiting a "new drug" from entering interstate commerce without FDA approval).

Triclosan and triclocarban are undisputedly "drugs" within the meaning of the FFDCA. FDA's determination of triclosan's and triclocarban's GRAS/E status is pending as part of FDA's comprehensive "Over-the-Counter Drug Review" process ("OTC Drug Review"). Commenced in 1972, the OTC Drug Review established FDA's "monograph" system for regulating over-the-counter drugs. *See* 21 C.F.R. § 330.10; 37 Fed. Reg. 9464 (May 11, 1972). While FDA must generally approve drugs as GRAS/E individually, the monograph system allows manufacturers to bypass individualized review. *See* 21 U.S.C. § 355; 21 C.F.R. § 330.10. Under this system, FDA issues a detailed regulation—a "monograph"—for each therapeutic class of OTC drug products. Like a recipe, each monograph sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is GRAS/E. FDA excludes from its monographs any active ingredients or uses of active ingredients that it has determined either not to be GRAS/E or for which there is insufficient data to confirm whether they are GRAS/E. Manufacturers desiring to market OTC

drugs that are excluded from the monograph may not do so without obtaining individualized FDA approval.

Through the OTC Drug Review, FDA determines the GRAS/E status of each OTC drug product and issues monographs for each category. According to FDA's evidence submitted to the district court, as of December 1, 2010, FDA had published 125 final rules through the OTC Drug Review, including final monographs and amended final monographs. The monograph for topical antiseptic antimicrobial drugs, in which triclosan and triclocarban are to be included, has not yet been finalized. In the exercise of its enforcement discretion, however, FDA permits drugs whose monograph is still pending under the OTC Review process to stay on the market, provided that FDA has not determined that the drug is "a potential health hazard." FDA Compliance Policy Guide § 450.200; 68 Fed. Reg. 75585, 75590-91 (Dec. 31, 2003).

Over the course of the OTC Drug Review, FDA has issued two tentative final monographs for topical antiseptic antimicrobials, once in 1978 and again in 1994, but has not finalized either monograph. *See* 43 Fed. Reg. 1210 (Jan. 6, 1978); 59 Fed. Reg. 31402 (June 17, 1994); Ganley Declaration ¶ 48. Both tentative monographs would have excluded triclosan because FDA had not determined that triclosan was GRAS/E for any use at the time it issued the tentative monographs.

II. Proceedings Before the District Court

NRDC brings this action under the Administrative Procedure Act, 5 U.S.C. § 500 *et seq.* ("APA"), which authorizes those "adversely affected or aggrieved" by an agency's inaction to file suit to compel an agency to take action "unreasonably delayed." 5 U.S.C. §§ 702, 706(1).[1]

[1] *See* 5 U.S.C. § 555(b) (requiring an agency to "proceed to conclude a matter presented to it" within a reasonable time); 5 U.S.C. § 702 ("A person . . . adversely affected or aggrieved by agency action . . . is entitled to judicial review thereof."); 5 U.S.C. § 551(13) (defining "agency action" to include "failure to act"); 5 U.S.C. § 701(a)(2) (precluding judicial review of agency action "committed to agency discretion by law").

NRDC alleges that FDA is unreasonably and unlawfully failing to regulate potentially dangerous substances, triclosan and triclocarban, and seeks to compel FDA to finalize its regulation of triclosan and triclocarban by issuing the final monograph regulating topical antimicrobial drug products.

Before the district court, NRDC moved for summary judgment on the merits, and the government cross-moved for summary judgment on the ground that NRDC lacked standing.

A. NRDC's Evidence of Standing

As evidence of standing, NRDC submitted declarations executed by two of its members and documents discussing the risks posed by triclosan and triclocarban.

1. NRDC Member Declarations

NRDC submitted the declarations of its members Ms. Diana Owens, a veterinary technician ("Owens Declaration"), and Dr. Megan Schwarzman, a physician, describing their exposure to triclosan in their places of work.

In her declaration, Diana Owens avers that she is exposed to triclosan in her work as a veterinary technician at an animal clinic, where she has worked for nearly twenty years. As a necessary part of her work, she washes her hands more than fifty times in the course of a single work day. The soap that she uses is that provided by the clinic—an antibacterial soap that contains triclosan. The clinic also uses triclosan-containing dish soap that Owens uses to clean animals' food and water dishes, one of Owens's job duties.

Owens avers that she has a slightly increased risk of ovarian cancer and is concerned about the hormone-disrupting effects of triclosan. She also expresses general concern regarding triclosan's potential to increase antibiotic resistance. Owens has attempted to raise the issue of triclosan's dangers with the clinic owner, who is responsible for providing the soap clinic

employees use in their work and purchases the soap from the wholesale store, Sam's Club. Owens reports that she has "discussed [her] concern about triclosan exposure with the clinic owner and with [her] coworkers," but to no avail: "[t]hey listen but because they do not really know about the health risks, nothing is done to limit our exposure." Beyond these discussions, Owens does not describe having taken further action to have the soaps changed at the clinic. She explains that she does not "feel comfortable asking the clinic owner, who is [her] supervisor, to spend extra time looking at the labels on soap bottles or to spend more money to purchase natural products." She does not "want to be the employee who is pushy and creates problems."

Because we conclude, *see* Discussion *infra*, that the Owens Declaration is sufficient to establish NRDC's standing, we do not discuss the declaration of Dr. Schwarzman. We observe, however, that while NRDC seeks to compel FDA to finalize its regulation of both triclosan and triclocarban, its member declarations establish the members' direct exposure only to triclosan; NRDC submitted no evidence that any of its members is directly exposed to triclocarban, and instead relies on evidence that its members are injured by triclocarban's potential, along with other antiseptic antimicrobial chemicals, to hasten the development of antibiotic-resistant bacteria.

2. Evidence of Risks posed by Triclosan and Triclocarban

NRDC principally relied on three documents to evidence the risks posed by triclosan and triclocarban: (1) an expert declaration by Sarah Janssen, M.D., Ph.D., M.P.H. ("Janssen Declaration"), (2) a letter from FDA to Representative Edward Markey, then-Chairman of the House Subcommittee on Energy and Environment, regarding regulation of topical antiseptic drug products ("Markey Letter"), and (3) a consumer notice about triclosan posted by FDA on its web site ("FDA Consumer Notice").

a. Janssen Declaration

Sarah Janssen, M.D., Ph.D., M.P.H., is a doctor, the author of scholarly articles and book chapters on the subject of endocrine-disrupting chemicals, and an expert on effects of endocrine-disrupting chemicals on human health. According to her declaration, triclosan is rapidly absorbed into the human bloodstream, which means that it "bypass[es] liver metabolism, . . . [and] therefore ha[s] a greater potential to cause toxicity to many organs in the body." The declaration primarily addresses triclosan's association with endocrine disruption. Janssen explains that triclosan is associated "with a unique type of endocrine disruption." Endocrine disruption can affect the reproductive system. In particular, recent studies on female rats show that triclosan interacts with estrogen to increase uterine weight at doses of triclosan that would not have an effect if not for the interaction with estrogen. This potential for triclosan to amplify hormone action raises concerns that triclosan may "stimulate the growth of hormone-dependent cancers." In addition, triclosan can lead to abnormal menstrual cycles in women and infertility in both women and men. Moreover, even low-dose exposure to triclosan interferes with the activity of hormones essential to the normal growth and function of reproductive systems, and animal studies have shown low doses to interfere with sex hormone synthesis.

In addition to triclosan's endocrine-disrupting properties, Janssen notes that older studies previously reviewed in the FDA OTC Drug Review linked triclosan with organ damage, brain and spleen changes, testicular damage, liver damage, and the blood disorder, methemoglobinemia. Finally, Janssen avers that "[n]umerous studies have suggested that . . . triclosan fosters antibiotic resistance in bacteria," and that "[a]t least one study has . . . associated triclocarban with promoting such resistance."

Overall, Janssen opines that "[u]se of over-the-counter topical antimicrobial products containing triclosan and triclocarban contributes to individuals' total body burden[2] and may be both significant and harmful." She continues, "The best available science indicates that . . . exposures [to triclosan and triclocarban], especially during critical periods of development, may harm human health." Thus, "[i]n [Janssen's] scientific opinion, delaying finalization of the [antimicrobial antiseptics] Monograph will prolong exposures that may cause irretrievable medical injury to those exposed."

b. Markey Letter

In the Markey Letter, FDA states that it "shares" Rep. Markey's "concern over the potential effects of triclosan and triclocarban as endocrine disruptors that have emerged since" FDA issued its most recent tentative final monograph in 1994. The letter reports on "studies in several different animal species (including mammals), that suggest triclosan may interfere with the thyroid system and have other endocrine-disrupting effects." FDA thus concludes that "existing data raise valid concerns about the effects of repetitive daily human exposure to these antiseptic ingredients."

The Markey Letter also acknowledges a lack of data regarding the long-term effects of triclosan, including dermal application, reproductive and developmental toxicity, and its potential as an endocrine disruptor, and reports that a study of triclosan by the National Center for Toxological Research is underway pursuant to FDA's request.

Finally, regarding the concern that proliferation of antiseptic antimicrobial hand soaps will lead to the development of antibiotic-resistant bacteria, FDA reported that numerous

[2] "Body burden" is not defined in the Janssen declaration. The *Oxford English Dictionary* defines "body burden" as "the total amount of a radioactive element or other (usually toxic) substance in a human or animal body."

laboratory studies "suggest that it is relatively easy for bacteria to develop altered susceptibilities to both antiseptics and antibiotics in the laboratory setting," but that there "was no definitive correlation between altered susceptibility to antibacterial active ingredients and antibiotics." Based on the data, the FDA concluded that "the possibility that antiseptics contribute to changes in antibiotic susceptibility warrants further evaluation."

Consistent with the Markey Letter, in a declaration submitted by FDA, FDA witness Charles J. Ganley, Director of the Office of Drug Evaluation and Research IV at FDA's Center for Drug Evaluation and Research, attributes FDA's delay in issuing the final monograph for antiseptic antimicrobial chemicals to the need for further evaluation of concerns raised by new data, including that antiseptic active ingredients may act as endocrine disruptors, that antimicrobial products—including triclosan and triclocarban—may play a role in the development of antimicrobial and antibiotic resistance, and that the proliferation of antimicrobial products raises concerns about the long-term health effects of higher levels of exposure to these substances.

c. FDA Consumer Notice

Similarly, the FDA Consumer Notice informs consumers that FDA does not have evidence that triclosan-containing soap provides extra health benefits over soap and water. It acknowledges that "[a]nimal studies have shown that triclosan alters hormone regulation," but cautions that "data showing effects in animals don't always predict effects in humans," and reassures consumers that triclosan "is not currently known to be hazardous to humans." It advises consumers who may be concerned to "wash with regular soap and water" instead of triclosan-containing soaps.

B. Decision of the District Court

The district court granted summary judgment in favor of FDA and dismissed the suit for lack of standing. Assuming without deciding that exposure to triclosan was cognizable as an injury for standing purposes, the district court concluded that NRDC lacked standing because its members could avoid their workplace exposure to triclosan by purchasing antimicrobial-free soap for use at work.

DISCUSSION

"[T]he irreducible constitutional minimum of standing" derives from Article III, Section 2 of the U.S. Constitution, which limits federal judicial power to "cases" and "controversies." U.S. Const. art. III, § 2; *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). To establish that a case or controversy exists so as to confer standing under Article III, a plaintiff must satisfy three elements: (a) the plaintiff must suffer an "injury in fact," (b) that injury must be "fairly traceable" to the challenged action, and (c) the injury must be likely to be "redressed by a favorable decision" of the federal court. *Id.* at 560-61 (alteration omitted). A membership organization like NRDC may assert the standing of its members if, among other requirements not at issue here, it establishes that at least one of its members has standing to sue individually. *Summers v. Earth Island Inst.*, 555 U.S. 488, 494, 498 (2009).

We review de novo both a district court's grant of summary judgment and its determination of standing. *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011); *Schick v. Berg*, 430 F.3d 112, 115 (2d Cir. 2005). A grant of summary judgment is proper only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In considering the evidence, the court must "resolve all ambiguities, and credit all factual inferences that could rationally be drawn, in

favor of the party opposing summary judgment," *Brown v. Henderson*, 257 F.3d 246, 251 (2d Cir. 2001) (quotation marks omitted), even if contrary inferences might reasonably be drawn, *Kaytor v. Elec. Boat Corp.*, 609 F.3d 537, 545 (2d Cir. 2010). The party asserting jurisdiction, here NRDC, bears the burden of proof as to standing. *Lujan*, 504 U.S. at 561. To defend against summary judgment for lack of standing, a plaintiff "must set forth by affidavit or other evidence specific facts" supporting standing, as is generally required under Rule 56. *Id.* (internal quotation marks omitted); Fed. R. Civ. P. 56(c).

This appeal requires us to determine whether NRDC has presented sufficient evidence to withstand summary judgment for lack of standing as to triclosan and triclocarban. The inquiry as to triclosan concerns two elements of Article III standing: the injury-in-fact requirement and the requirement that the injury be fairly traceable to the challenged conduct. First, we must determine whether NRDC's evidence establishes a genuine dispute of material fact as to whether at least one of its members' exposure to triclosan at the workplace satisfies the injury-in-fact requirement. At issue is whether exposure to triclosan constitutes an injury under Article III notwithstanding the scientific uncertainty as to whether triclosan is harmful to human health. We hold that NRDC's evidence is sufficient to satisfy the injury-in-fact requirement notwithstanding the scientific uncertainty as to triclosan's harmfulness to humans.

We must next determine whether the injury of triclosan exposure is "fairly traceable" to the challenged action—here, FDA's alleged delay in finalizing its regulation of topical antiseptic antimicrobial over-the-counter drugs. At issue is whether the potential avoidability of triclosan exposure at the workplace—either by purchasing triclosan-free soap or by advocating with employers to supply triclosan-free soap—renders the exposure "self-inflicted" so as to vitiate the causal link between FDA's alleged regulatory delay and NRDC members' triclosan exposure.

We hold that neither the availability of triclosan-free soap for purchase nor the possibility that NRDC members' employers might be willing to supply triclosan-free soap prevents NRDC from establishing that the triclosan exposure is fairly traceable to FDA's alleged unreasonable delay in regulating triclosan.

The inquiry as to triclocarban requires us to determine whether the existence of a chemical that may contribute to the development of antimicrobial- or antibiotic-resistant bacteria satisfies the injury-in-fact requirement. We hold that it does not.

I. Triclosan

Since NRDC need only show that at least one of its members has standing to sue individually in order to establish representational standing, we focus exclusively on the declaration of Diana Owens because it is sufficient to satisfy this requirement as to triclosan.

A. Injury in Fact

We begin by considering whether NRDC presented sufficient evidence to withstand summary judgment as to whether at least one of its members' workplace exposure to triclosan satisfies the injury-in-fact requirement of Article III standing. NRDC argues that at least one of its members suffers an injury in fact because its evidence shows that its members are exposed to triclosan in the workplace and that triclosan may be dangerous to human health. The government responds principally that NRDC's evidence is insufficient to establish an injury in fact because there is no evidence that triclosan actually harms human health and because NRDC has not produced quantitative evidence of the risk that triclosan may harm human health.

1. Establishing Injury in Fact Based on Exposure to a Potentially Harmful Product

Injury in fact is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (citation and internal quotation marks omitted). Here, the FFDCA establishes an interest in the public being protected "from products not proven to be safe and effective for their alleged uses." *United State*s *v. Diapulse Corp. of Am.*, 457 F.2d 25, 27-28 (2d Cir. 1972). Owens's declaration, which we accept as true, establishes that, in her work as a veterinary technician, she is frequently exposed to soap that contains triclosan—a chemical that has not been proven to be safe and effective for use in soap. NRDC's evidence shows that triclosan has endocrine-disrupting properties and may cause cancer and other health problems. FDA argues that this alleged injury is not sufficiently "actual or imminent" to satisfy Article III because there is scientific uncertainty as to whether triclosan is actually harmful to humans.

This court's leading case on risk-based injury is *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003). In *Baur*, this court held that "exposure to potentially harmful products" may satisfy the injury-in-fact requirement of Article III standing in "the specific context of food and drug safety suits." *Id.* at 634. This court explained that, in such cases, "the relevant 'injury' for standing purposes may be exposure to a sufficiently serious risk of medical harm—not the anticipated medical harm itself." *Id.* at 641. That is, the injury contemplated by exposure to a potentially harmful product is not the future harm that the exposure risks causing, but the present exposure to risk.

To establish injury in fact based on exposure to a potentially harmful product, a plaintiff must show "a credible threat of harm" due to that exposure. *Id.* at 637. "[T]he injury-in-fact

analysis is highly case-specific, and the risk of harm necessary to support standing cannot be defined according to a universal standard." *Id.* (citation omitted). Under *Baur*, whether a plaintiff has established a credible threat of harm sufficient to confer standing based on exposure to a potentially harmful product is a qualitative inquiry in which the court should consider both the probability of harm and the severity of the potential harm. *Id.*

2. Exposure to Triclosan as Injury in Fact

There is no genuine dispute that triclosan is potentially harmful and that NRDC member Owens is exposed to triclosan at her workplace; whether NRDC has presented sufficient evidence regarding injury in fact thus turns on whether, under *Baur*, NRDC has demonstrated a "credible threat of harm" due to Owens's triclosan exposure. Under *Baur*, to determine whether there is evidence of a credible threat of harm, we consider the probability of harm in relation to its severity.

As to the severity of the harm triclosan could cause, the evidence, taken in the light most favorable to NRDC, shows that triclosan has endocrine-disrupting properties, easily absorbs into the human bloodstream, and may contribute to the growth of cancer. Owens avers that she is at a slightly increased risk of ovarian cancer. There is also evidence that triclosan can disrupt thyroid regulation, and earlier FDA studies cited concerns about liver damage.

Regarding the probability of harm, Owens's declaration establishes that she washes her hands with triclosan-containing soap more than fifty times in a typical workday. The evidence is silent, however, as to the precise likelihood that such frequent exposure to triclosan harms humans. In considering how this uncertainty as to triclosan's harmfulness affects the standing inquiry, this court's analysis in *Baur* is instructive. In *Baur*, plaintiff Baur satisfied the injury-in-fact requirement so as to withstand a motion to dismiss his suit challenging regulations that

permitted beef from "downed" cattle to enter the food supply.[3] Baur alleged that downed cattle were particularly likely to be infected with Bovine Spongiform Encephalopathy ("BSE") and that eating beef from BSE-infected cattle would put consumers at risk of contracting variant Creutzfeldt Jakob disease ("vCJD"), a deadly and incurable disease transmissible to humans by cattle with BSE. *Baur*, 352 F.3d at 628. Baur alleged that he was a regular eater of beef and argued that he was injured for standing purposes because the presence in the market of beef from downed cattle put him at risk of eating BSE-infected beef and thereby contracting vCJD.

The *Baur* court concluded that Baur had established a credible threat of harm even though the likelihood that Baur would contract vCJD by eating beef from a food supply that included beef from downed cattle was uncertain. *Id.* at 641. Baur did not allege that BSE was present in the United States, nor did he quantify the risk that BSE was present in the United States or allege that there was a particular likelihood that BSE had entered the United States. Moreover, even assuming BSE had entered the United States, Baur made no allegations as to the likelihood that he would consume beef from downed cattle. Instead, Baur alleged only that BSE *may* be present in the United States and argued that, if it were, the government would be unable to detect it. *Id.* at 638-41.

This court nonetheless concluded that Baur had established a credible threat of harm sufficient to remove his claimed injury from the realm of speculation due to his exposure to a beef market that included beef from downed cattle. We reached this decision based primarily on *Baur*'s allegations that: "(1) a form of BSE may already [have been] present in the United States, (2) available testing methods [did] not adequately detect BSE in downed cattle," and (3) the challenged federal regulations allowed meat from downed cattle to enter the food stream. *Id.* at

[3] "'Downed' is an industry term used to describe animals that collapse for unknown reasons and are too ill to walk or stand prior to slaughter." *Baur*, 352 F.3d at 628.

640. It was significant, too, that the government itself raised concerns about the inadequacy of the testing methods in place. *See id.* at 639.

Considering NRDC's evidence in light of the analysis in *Baur*, we conclude that NRDC has established a credible threat notwithstanding the uncertainty as to triclosan's harmfulness to humans. Just as plaintiff Baur was able to establish a credible threat based on allegations that BSE may be present in the United States and that the challenged regulatory regime in place would be unable to detect it, NRDC's evidence shows that triclosan may be harmful, that FDA is unable to determine whether it is, and that FDA's failure to regulate allows triclosan to enter the market without its safety having been confirmed. Moreover, just as in *Baur*, the government's own report confirmed the plaintiff's concerns as to the inadequacy of testing methods. Here, FDA has stated that triclosan presents "valid concerns," and FDA has nominated triclosan for a toxicology study, including a study of its carcinogenicity. Further, the record evidence shows that FDA admits that it has insufficient data on triclosan's long-term health effects and that FDA itself is concerned about the long-term effects of triclosan exposure. Just as the government in *Baur* could not confirm that meat from downed cattle was not infected with BSE, the government in the instant case cannot confirm that exposure to triclosan-containing soaps is safe for humans.

Considering the potential harms caused by triclosan-containing soap together with FDA's inability to confirm that the soap will not cause these harms, and keeping in mind that the FFDCA establishes an interest in being protected from products of unproven safety, we conclude that NRDC has presented evidence sufficient to withstand summary judgment that member Owens's frequent exposure to triclosan is an injury in fact under Article III. In the instant case, NRDC's members were actually exposed to a substance that FDA admits may be unsafe. NRDC

has also submitted medical evidence regarding the dangerousness of exposure to triclosan, which went unrebutted by FDA. Furthermore, it is also certain that the availability of triclosan in the marketplace, which directly leads to the members' exposure, is a result of FDA not yet having issued the final monograph for topical antiseptic antimicrobials. This case is not one where a "highly attenuated chain of possibilities," including uncertainty about possible government conduct, must occur for the plaintiff to be injured. *See Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1148 (2013). Unlike the claimed injury in *Clapper*, here, the injury alleged by NRDC is not "highly speculative." *Id.* Rather, NRDC has made a particularized showing that FDA's failure to regulate triclosan led to "increased health-related uncertainty" arising from exposure to triclosan, a form of injury that this Court has recognized as sufficient to constitute an injury in fact. *See New York Public Interest Research Group v. Whitman* ("*NYPIRG*"), 321 F.3d 316, 325 (2d Cir. 2003). The injury at issue in this case is not one of speculative future injury, as in *Clapper*, 133 S. Ct. at 1147-49, but is based on the actual, present health risk arising out of actual, present exposure to triclosan.

The government argues that the uncertainty as to triclosan's harmfulness bars NRDC from establishing a credible threat under *Baur*. Given *Baur*'s treatment of uncertainty, the government's argument lacks merit. What is more, this court squarely held in *NYPIRG*, that a plaintiff may establish injury in fact in the environmental context based on the "increased health-related uncertainty" that arose from exposure to unregulated emissions. *NYPIRG*, 321 F.3d at 325 (emphasis omitted). We rejected any distinction between actual exposure to excess pollutants and uncertainty about such exposure as "one largely without a difference." *Id.* at 326. We reasoned that both actual and uncertain exposure caused personal and economic harm and that, "[t]o the extent that this distinction [wa]s meaningful, it affect[ed] the extent, not the

existence, of the injury." *Id.*; *see also LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002) (petitioner had standing to challenge emissions even if pollutant levels remained within air quality standards because statute recognized that within-standards pollution levels still had "potentially adverse [e]ffects").

The government maintains that *Baur* and *NYPIRG* are distinguishable from NRDC's case because they concerned chemicals known to be dangerous, whereas triclosan's potential risks are uncertain. The gravamen of this argument is that a plaintiff may establish standing notwithstanding uncertainty as to *exposure* to a substance so long as the substance is unquestionably harmful, but that a plaintiff may not establish standing based on unquestionable exposure to a potentially dangerous substance if there is any uncertainty as to its *dangerousness*.

Baur renders this purported distinction untenable. In *Baur*, this court explicitly recognized that injury based on exposure to potentially or actually harmful products can take at least two forms: (1) "uncontested exposure to a potentially harmful substance," as here, and (2) "potential exposure to an undisputedly dangerous contaminant," as in *Baur* and *NYPIRG*. *Baur*, 352 F.3d at 634 n.8. In *Baur*, the risk of exposure to BSE was uncertain, but it was clear that BSE was harmful. Here, in contrast, the evidence is clear that Owens is frequently exposed to triclosan, but the risk that triclosan will harm her is uncertain. The *Baur* court explained that there was "no reason to distinguish" between these two scenarios: "In both types of cases, standing should rest on all of [the] relevant facts underlying the plaintiff's claim, not on the happenstance of which particular facts happen to be in dispute." *Id.* In short, an injury like that of NRDC member Owens, based on definite exposure to a substance of uncertain dangerousness, is not necessarily any less "actual" or "imminent" than an injury based on uncertain exposure to an undisputedly dangerous contaminant. In each case, whether the plaintiff has satisfied the injury-in-fact requirement must be based on the specific circumstances.

3. Plaintiff's Summary Judgment Burden to Establish Risk-Based Standing

Next, the government contends that NRDC's evidence is insufficient to withstand summary judgment because *Baur* requires a plaintiff asserting standing based on enhanced risk to present quantitative evidence of the "precise risk" in order to withstand summary judgment. NRDC did not submit such quantitative evidence, but neither *Baur* nor any other authority of which we are aware articulates such a requirement. Rather, to defend against summary judgment for lack of standing, a plaintiff "must set forth by affidavit or other evidence specific facts" supporting standing, as is generally required under Rule 56. *Lujan*, 504 U.S. at 561 (internal quotation marks omitted); Fed. R. Civ. P. 56. Those "specific facts" need not necessarily include quantitative data.

To the extent *Baur*'s discussion of statistical evidence bears on the question before us, *Baur* supports NRDC's position given that *Baur* addressed a motion to dismiss rather than a motion for summary judgment. The *Baur* court declined to require statistical evidence at the motion-to-dismiss stage principally because it reasoned that requiring such evidence would conflate the standing inquiry with the inquiry into the merits of the agency's regulatory decision. *See Baur*, 352 F.3d at 643. We agree that "the evaluation of the amount of tolerable risk is better analyzed as an administrative decision governed by the relevant statutes rather than a constitutional question governed by Article III." *Id.* Here, the merits determination will include consideration of "the nature and extent of the interests prejudiced by delay" and whether "human health and welfare are at stake." *See Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) (setting forth test for determining if agency action is unreasonably delayed). We reject FDA's invitation to "raise the standing hurdle higher than the necessary showing for

success on the merits." *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

NRDC has produced evidence that sets forth specific facts as to the risks of triclosan exposure by presenting both an expert declaration and FDA's own statements confirming its concern as to the risks of triclosan exposure. Accordingly, we conclude that NRDC has satisfied its burden on summary judgment of demonstrating that at least one of its members' exposure to triclosan constitutes an "injury in fact" to confer standing under Article III.

B. Causation

We now consider whether NRDC lacks standing because, as the district court determined, its members' exposure to triclosan is avoidable. This inquiry concerns the causation or "traceability" requirement of Article III standing. To satisfy this requirement, "there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" *Lujan*, 504 U.S. at 560 (citation omitted). The government argues that NRDC lacks standing because its members' alleged injury is "self-inflicted" because they may avoid triclosan exposure in the workplace by purchasing triclosan-free soap to bring to work and because they have not demonstrated that their employers are unwilling to provide triclosan-free soap. We disagree.

To be sure, a plaintiff may not establish injury for standing purposes based on a "self-inflicted" injury. *See St. Pierre v. Dyer*, 208 F.3d 394, 403 (2d Cir. 2000). An injury is self-inflicted so as to defeat the causation necessary to establish standing, however, "only if . . . the injury is so completely due to the plaintiff's own fault as to break the causal chain." *Id.* at 402. Under this standard, NRDC member Owens's exposure to triclosan is not self-inflicted.

NRDC's evidence shows that FDA's conduct contributes to Owens's triclosan exposure because triclosan would not be available on the market but for FDA's failure to finalize its regulation. Neither Owens's failure to purchase triclosan-free soap nor her failure to advocate more forcefully with her employer is sufficient to break the causal chain.

As to the availability of triclosan-free soap to bring to the workplace, incurring the expense of buying such soap would itself constitute an injury in fact. Even a small financial loss is an injury for purposes of Article III standing. *See United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 689 n.14 (1973) ("[A]n identifiable trifle is enough for standing."). Because NRDC would have standing based on Owens's financial injury even if she avoided triclosan exposure by buying triclosan-free soap, the availability of triclosan-free soap does not defeat NRDC's standing.

Equally unavailing is the government's argument that NRDC lacks standing because its members did not sufficiently establish that their employers were unwilling to provide triclosan-free soap. We explained in *St. Pierre* that "[s]o long as the defendants have engaged in conduct that may have contributed to causing the injury, it would be better to recognize standing." *St. Pierre*, 208 F.3d at 402 (internal quotation marks omitted). Here, the failure to take affirmative action to advocate with an employer does not render the exposure to triclosan at the hands of the employer "self-inflicted" so as to defeat standing because FDA's allegedly unreasonable delay in regulating triclosan remains a contributing factor to Owens's exposure; according to NRDC's evidence, but for FDA's challenged inaction, triclosan-containing soaps would not be available on the market. We therefore conclude that NRDC has satisfied the requirement that its members' injury be "fairly traceable" to the challenged action.

II. Triclocarban

NRDC provided no evidence that its members were directly exposed to triclocarban. Its theory of standing as to triclocarban thus cannot be that, under *Baur*, its members are exposed to a potentially dangerous substance. Instead, NRDC argues that its members suffer injury in fact due to FDA's alleged delay in finalizing its regulation of triclocarban because the proliferation of triclocarban, together with other antimicrobial antiseptic chemicals, may lead to the development of antibiotic-resistant bacteria. The government argues that this injury is not cognizable under Article III because the NRDC's members suffer at the hands of this risk "in no way that distinguishes them from the population at large"—that is, that their claimed injury is not sufficiently concrete and particularized, as required to establish injury in fact. *See Lujan*, 504 U.S. at 560.

At oral argument, NRDC maintained that we need not reach this question if we were to determine, as we have, that NRDC had standing to challenge the alleged delay in regulating triclosan. NRDC reasoned that because FDA regulates triclosan and triclocarban by means of the same monograph, if NRDC were to succeed on the merits in compelling FDA to finalize its regulation of triclosan, FDA would necessarily also be compelled to finalize its regulation of triclocarban. While NRDC may be correct as a practical matter, we are aware of no obligation on FDA's part to promulgate regulations of triclosan and triclocarban simultaneously. As we observed in *Baur*, "a plaintiff must demonstrate standing for each claim and form of relief sought." *Baur*, 352 F.3d at 641 n.15. Here, NRDC seeks finalization of the entire monograph governing topical antimicrobial drug products. To pursue such broad relief, however, NRDC "must also demonstrate a credible threat of [harm]" from the other chemicals it seeks to compel FDA to regulate. *Id.* While it may not be practicable for FDA to finalize its regulation of

triclosan without also finalizing its regulation of other antimicrobial drug products, NRDC has only established standing to compel FDA to finalize its regulation of triclosan, and its standing as to triclosan does not entitle it to seek regulation of other antimicrobial drug products should it prove practicable for FDA to sever its regulation of these substances. We therefore are not persuaded that it is unnecessary to this appeal to determine whether NRDC has standing as to triclocarban, and we hold that NRDC lacks standing as to triclocarban.

In the Markey letter, FDA itself recognized a risk that antibiotic-resistant bacteria would develop. But apart from appearing insufficiently particular to establish injury, this claim seems too causally remote to fit comfortably within the *Baur* standard. The basis for standing for the regulation of triclosan, discussed above, is based on direct, frequent exposure to triclosan combined with the known fact that triclosan enters the human bloodstream, is an endocrine disruptor, and may cause cancer. Exposure to triclosan in this manner is a present injury in which triclosan may work changes directly upon the human body; whether those changes are ultimately harmful may be uncertain, but there is no uncertainty that any harm will be directly caused by frequent direct exposure to triclosan.

The claim that the proliferation of triclocarban may lead to the development of antibiotic-resistant bacteria, in contrast, involves unspecified bacteria or microbes that NRDC members may not ever come into contact with. And in order for those bacteria or microbes to harm plaintiffs, there must be an intermediate step in which triclocarban causes those bacteria to become resistant to antibiotics. This claim thus seems less like a present injury and more like a *threatened* injury that is contingent and far-off rather than imminent. We therefore conclude that NRDC lacks standing as to the regulation of triclocarban.

CONCLUSION

For the reasons stated above, the judgment of the district court hereby is VACATED and the case is REMANDED to the district court for further proceedings consistent with this opinion.