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SECOND CIRCUIT REVIEW

Expert Analysis

# Court Holds Environmental Group Has Standing to Challenge FDA's Inaction

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This month we discuss *Natural Resources Defense Council v. U.S. Food and Drug Administration*,[1] in which the U.S. Court of Appeals for the Second Circuit vacated and remanded the district court's decision granting summary judgment to the Food and Drug Administration (FDA). The Natural Resources Defense Council (NRDC) sought to compel the FDA to finalize its regulation of two chemicals found in many hand soaps. In its decision, written by Judge Rosemary S. Pooler and joined by Judge Gerard E. Lynch and Judge Brian M. Cogan,[2] the court concluded that the NRDC had Article III standing to bring an action to compel the FDA to finalize its regulation of triclosan, but not of triclocarban.

The court held that the NRDC presented sufficient evidence to withstand summary judgment as to triclosan of a member's direct exposure to a potentially dangerous product, but that the NRDC did not satisfy the injury-in-fact element as to triclocarban. The court further held that an individual's ability to avoid the injury does not negate standing.

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## Background

Plaintiff NRDC filed suit under the Administrative Procedure Act (APA) to compel the FDA to finalize its regulation of triclosan and triclocarban, two chemicals used in over-the-counter antiseptic antimicrobial soap (e.g., hand soaps). The APA authorizes those "adversely affected or aggrieved" by an agency's inaction to file suit to compel an agency to take action that is "unreasonably delayed."[3] The NRDC alleged that in not finalizing its directive applicable to the two drugs, the FDA is unreasonably and unlawfully failing to regulate these potentially dangerous substances.

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires the FDA to determine that a new drug is generally recognized as safe and effective (S&E) for the particular use described in its product labeling before it can enter interstate commerce. Though the FDA must generally approve drugs as S&E individually, the FDA has established a process for over-the-counter (OTC) drugs called the "monograph" system, which allows certain classes of drugs to bypass individualized review.[4] Under the system, the FDA issues a detailed regulation—a "monograph"—for each class of OTC drug products. Each monograph sets out the FDA-approved active ingredients for a given class of OTC drugs and provides the conditions under which each active ingredient is considered to be S&E. If a manufacturer wishes to market an OTC drug that is excluded from the monograph system, it must obtain individualized FDA approval.

The FDA also permits drugs whose monograph is still pending under its OTC review process to stay on the market, so long as the FDA has not specifically determined that the drug is "a potential health hazard."[5] The FDA has issued two tentative monographs for the topical antiseptic antimicrobial class of drugs—of which triclosan and triclocarban are included—in 1978 and 1994. Neither monograph has ever been finalized. Both tentative monographs would have excluded triclosan and triclocarban.[6] The practical effect of the FDA's failure to finalize either monograph over the past 30-plus years is that the drugs can be marketed even though the FDA has never determined that they are S&E.

The NRDC thus sued the FDA, Health and Human Services Secretary Katherine Sebelius and Margaret Hamburg, commissioner of food and drugs (collectively, the "government"), to challenge the government's delay in finalizing the pertinent regulations, and submitted evidence of the possible harmful effects of triclosan and triclocarban. The NRDC submitted: (1) in support of its associational standing, two NRDC members' declarations describing their exposure to triclosan in their workplaces; (2) an expert declaration regarding the risks of triclosan and triclocarban; (3) a letter from the FDA regarding regulation of topical antiseptic drug products (FDA letter); and (4) a consumer notice about triclosan posted by the FDA.

In the first declaration, Diana Owens, a veterinary technician, averred that she washes her hands more than 50 times in the course of one work day with hand soap provided by the clinic that contains triclosan. She expressed concern regarding the hormone-disrupting effects of triclosan, particularly in light of her slightly increased risk of ovarian cancer. Owens stated that she had discussed her concern regarding triclosan with the clinic owner and other employees, but had not taken further action to avoid using triclosan, such as bringing her own soap to the office.[7]

The expert declaration addressed various potential negative health effects of triclosan, including endocrine disruption, infertility in men and women, hormone-dependent cancers, and organ damage. Additionally, the declaration stated that triclosan may foster antibiotic resistance in bacteria, and that both triclosan and triclocarban may harm human health. In the FDA letter, the FDA stated that it shared "concern over the potential effects of triclosan and triclocarban as endocrine disruptors" and that "existing data raise valid concerns about the effects of repetitive daily human exposure to these antiseptic ingredients."[8]

The district court held that the NRDC lacked standing because its members could avoid their workplace exposure to triclosan by purchasing their own triclosan-free soap for use at work.[9] Plaintiff subsequently appealed.[10]

The Second Circuit clarified what is required to establish injury-in-fact in the context of consumer food and drug suits when the effects of exposure to a particular drug are still undetermined.

### Second Circuit's Decision

The Second Circuit determined that the NRDC satisfied all elements of Article III standing with respect to triclosan, including the injury-in-fact requirement and the requirement that the injury be fairly traceable to the challenged conduct, but found that the NRDC did not have standing with respect to triclocarban. The court noted that the FFDCA establishes an interest in public protection "from products not proven to be safe and effective for their alleged uses," and held that evidence of exposure to a substance whose harmfulness is still uncertain can be sufficient to satisfy the injury-in-fact requirement.[11]

Additionally, the court held that the NRDC member's ability to avoid the alleged injury caused by triclosan did not vitiate the causation element of standing. The court distinguished NRDC's standing with respect to triclosan and triclocarban because the NRDC provided evidence of a particular member's exposure to triclosan, and specific evidence of the potential harm to her, whereas with triclocarban, the NRDC only provided evidence of triclocarban's potential to hasten the development of antibiotic resistant bacteria and the general harm this could pose to NRDC members.

**Triclosan.** The court addressed whether exposure to triclosan constituted an injury that is sufficiently actual or imminent, as required under *Lujan v. Defenders of Wildlife*,[12] notwithstanding the uncertainty as to whether triclosan is harmful to human health, and that the NRDC did not produce any quantitative evidence of its possible harm to human health. The court rejected the government's argument that exposure to a substance of uncertain dangerousness is categorically not actual or imminent, relying in part on *Baur v. Veneman*,[13] which held that an enhanced risk of disease transmission where the plaintiff alleges exposure to potentially harmful products may satisfy the injury-in-fact requirement in the context of food and drug safety suits.[14]

The court held that the NRDC had established a "credible threat of harm," as required under *Baur*, rather than merely a conjectural threat, because the evidence showed that triclosan may be harmful, that the FDA was unable to determine whether it was or was not harmful, and the FDA's failure to regulate allows triclosan to enter the market without its safety being confirmed. The court stated that under *Baur*, injury may be based on at least two possibilities: (1) "uncontested exposure to a potentially harmful substance," as in this case, and (2) "potential exposure to an undisputedly dangerous contaminant," as in *Baur*.[15]

The court also concluded that a plaintiff asserting standing based on "enhanced risk" is not required to submit quantitative evidence of the "precise risk," and that such a requirement is better addressed in the merits determination.[16] The specific facts presented in the expert declaration and, significantly, the FDA's own acknowledged concerns with respect to triclosan, were sufficient to demonstrate a credible threat for purposes of standing.

The court also decided whether the "potential avoidability" of triclosan exposure at the workplace, by purchasing triclosan-free soap or by further "advocating with employers" to supply triclosan-free soap, rendered the

exposure "self-inflicted" so as to vitiate the causal link between the FDA's delay and the NRDC member's triclosan exposure.[17] The court held that neither of these possibilities broke the chain of causation for purposes of standing; an injury is only self-inflicted so as to defeat causation if "the injury is so completely due to the plaintiff's own fault as to break the causal chain."[18]

First, the court stated that incurring the expense of buying triclosan-free soap would itself constitute an injury-in-fact, because even a small financial loss is an injury for standing purposes. Second, Owens' failure to take affirmative action to advocate with her employer did not render her exposure self-inflicted because the FDA's alleged unreasonable delay "remains a contributing factor" to her exposure—but for the FDA's alleged inaction, the soaps would not be available on the market.[19]

**Triclocarban.** The NRDC's theory of harm with respect to triclocarban was that the FDA's delay in finalizing triclocarban's monograph leads to widespread adoption of the drug for use in antibacterial soaps, that users of the soaps breed antibiotic-resistant bacteria, and that the NRDC members may become infected with those bacteria and be unable to cure themselves of the infection.[20] The court rejected the notion that this satisfied the injury-in-fact requirement, stating that the NRDC provided "no evidence" that its members were directly exposed to triclocarban, and the existence of a chemical that "may contribute to the development of antimicrobial—or antibiotic-resistant bacteria" was too "contingent" and "far-off," and therefore not sufficiently actual or imminent.[21]

The court explained that "in order for those [antibiotic-resistant bacteria] to harm plaintiffs, there must be an intermediate step in which triclocarban causes those bacteria to become resistant to antibiotics," and thus the claim "seems less like a present injury and more like a threatened injury."[22]

The NRDC also argued that the court need not specifically address its standing with respect to triclocarban if the court determined that it had standing with respect to triclosan, since the FDA regulates the two drugs by means of the same monograph. The court rejected this argument, noting that 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," and "a plaintiff must demonstrate standing for each claim."[23] The court explained that NRDC's standing with respect to regulation of triclosan does not entitle it to seek regulation of other antimicrobial drug products if the FDA chooses to sever its regulation of the substances.

The court thus vacated the district court's decision and remanded the case for further proceedings.

The Second Circuit concluded that a plaintiff asserting standing based on "enhanced risk" is not required to submit quantitative evidence of the "precise risk," and that such a requirement is better addressed in the merits determination.

## Conclusion

In its decision, the Second Circuit clarified what is required to establish injury-in-fact in the context of consumer food and drug suits when the effects of exposure to a particular drug are still undetermined. In doing so, the court relied in part on a case from the environmental context, signaling that injury based on "increased health-related uncertainty" may apply more broadly.[24] The court indicated that it will allow suits to compel the FDA to act pursuant to its statutory authority: should the NRDC succeed on the merits, the FDA will likely have to finalize its monograph, potentially excluding triclosan and triclocarban—drugs found in many hand soaps—from the market.

The court also declined to limit standing to plaintiffs who could not avoid potential injury, and held that even a small financial loss constitutes an injury for purposes of Article III standing. On the other hand, the court required a clear showing that particular persons are being exposed to direct potential harm. A claim based on the threat of generalized harm to members of a group from a drug—particularly where the potential harm requires an intermediate step to expose itself—will generally be insufficient to support standing.

1. *Natural Res. Def. Council v. U.S. Food and Drug Admin.*, No. 11-422-cv, 2013 WL 100677 (2d Cir. March 15, 2013).
2. Judge Cogan of the U.S. District Court for the Eastern District of New York, sitting by designation.
3. 2013 WL 100677 at *2 (citing 5 U.S.C. §§702, 706(1)).
4. Id. at *1 (citing 21 C.F.R. §330.10; 37 Fed. Reg. 9464 (May 11, 1972)).
5. Id. at *2 (citing FDA Compliance Policy Guide §450.200; 68 Fed. Reg. 75585, 75590-91 (Dec. 31, 2003)).
6. The court's opinion noted that both tentative monographs "would have excluded triclosan." Id. at *2. Appellants' brief stated that "[h]ad the agency finalized its regulation, either classification would have required the removal" of both products from the market. Brief of plaintiff-appellant at *4, *Natural Res. Def. Council v. U.S. Food and Drug Admin.*, No. 11-422-cv, 2011 WL 1230081 (2d Cir. March 25, 2011).
7. The court concluded that the Owens Declaration was sufficient to establish NRDC's standing, and thus did not discuss the second member declaration. 2013 WL 100677, at *3.
8. Id. at *4.
9. The district court orally granted the FDA's motion for summary judgment on Jan. 19, 2011 and thereafter issued a summary order dismissing the NRDC's complaint "for the reasons stated on the record." Brief of Plaintiff-Appellant at *2; Order Granting Defendants' Motion for Summary Judgment, No. 10-cv-05690-AKH, Dkt. 22 (S.D.N.Y. Jan. 20, 2011).
10. In addition, a number of public interest organizations filed a joint Amicus brief that focused on the district court's specific holding and argued that affirming its decision that a plaintiff who can avoid direct injury lacks standing would have far-reaching effects on established standing doctrines. Brief for Amici Curiae at *15-16, *Natural Res. Def. Council v. U.S. Food and Drug Admin.*, No. 11-422-cv, 2011 WL 1357503 (2d Cir. April 1, 2011).
11. 2013 WL 100677 at *7, 10.
12. 504 U.S. 555 (1992).
13. 352 F.3d 625 (2d Cir. 2003).
14. Id. at 628, 634.
15. 2013 WL 100677 at *9.
16. Id. at *10.
17. Id. at *6.
18. Id. at *11 (citing *St. Pierre v. Dyer*, 208 F.3d 394, 401 (2d Cir. 2000)).
19. Id. at *11.
20. Brief of Plaintiff-Appellant at *23-25.
21. 2013 WL 100677 at *11-12.
22. Id. at *12.
23. Id. at *12.
24. Id. at *9 (citing *New York Public Interest Research Group v. Whitman*, 321 F.3d 316 (2d Cir. 2003)).