No. 11-422-cv

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC.,
Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of New York

Brief 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, and Center for Civil Rights UNC School of Law in Support of Plaintiff-Appellant and Reversal

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April 1, 2011

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, 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, and Center for Civil Rights UNC School of Law state that they are nonprofit organizations that do not issue shares to the public and have no parent companies, subsidiaries, or affiliates that have issued shares to the public in the United States or abroad.

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INTEREST OF AMICI CURIAE

Amici curiae are public interest organizations that share a concern that unduly restrictive decisions concerning standing to sue, such as the decision on appeal in this case, impair the protection of the public against unlawful action by both public officials and private entities. Some of the organizations joining in this brief have an interest in the specific health risks that are at issue in this case. Others are primarily interested in other types of cases, such as environmental or civil rights matters, that could be affected if the reasoning of the district court were affirmed. Amici curiae file this brief with the consent of all parties to this appeal.[*]

Public Citizen, Inc., a national consumer-advocacy organization founded in 1971, appears on behalf of approximately 225,000 members and supporters before Congress, administrative agencies, and courts on a range of issues, promoting enactment and enforcement of laws protecting consumers, workers, and the public. Public Citizen often represents the interests of its members in litigation and as amicus curiae, and issues of standing freqeuently arise in Public Citizen's litigation.

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[*] This brief was not authored in whole or in part by counsel for a party. No party or party's counsel contributed money intended to fund the preparation or submission of this brief, nor did any other person, other than amici curiae, their members, or their counsel.

The Asian American Legal Defense and Education Fund (AALDEF), founded in 1974, is a national organization that protects and promotes the civil rights of Asian Americans. By combining litigation, advocacy, education, and organizing, AALDEF works with Asian American communities across the country to secure human rights. The decision below has the potential to undermine claims for civil rights violations by denying standing to Asian Americans who face real injuries.

The Bronx Health Link, Inc. (TBHL) is a clearinghouse of health information for the community and the members of the health and human service delivery system of the Bronx. Its mission is to improve community health by: identifying community health issues; increasing communication to better serve the community; providing information to providers and community residents on services and resources; and increasing access to available services and programs. TBHL is concerned about any court decision that would limit the rights of Bronx residents to use the courts to seek health and environmental justice.

The Empire State Consumer Project is a public interest group involved in product safety, alternatives to pesticides, and other environmental issues. Among other activities, it has tested consumer

products for toxics such as lead and cadmium since 2007 and is responsible for numerous Consumer Product Safety Commission (CPSC) recalls. The Project successfully petitioned the CPSC to initiate a rulemaking to establish a cadmium standard.

The Equal Justice Society (EJS) is a national organization of scholars, advocates, and citizens that seeks to promote equal opportunity and progressive social change through law, public policy, public education, and research. The primary mission of EJS is to combat the continuing scourge of racial discrimination and inequality in America. Consistent with that mission, EJS works to confront all manifestations of invidious discrimination and second-class citizenship. An integral part of EJS's mission is to ensure that the courts remain accessible to those whose rights have been violated.

Healthy Schools Network is a national environmental health organization dedicated to children's environmental health and ensuring that every child has a healthy school that is clean and in good repair. Through its online Healthy Schools/Healthy Kids Clearinghouse, it delivers direct informational and organizing services to hundreds of parents and personnel concerned about environmental exposures in

schools every year. Because children are unable to prevent their own exposures in schools, and their parents often have trouble finding out what products are in use, the organization has launched a national campaign to require schools to use certified green cleaning products that reduce or eliminate germs without the use of antimicrobials and disinfectants. Although Healthy Schools Network does not itself engage in litigation, its goal of fostering use of healthy cleaning products gives it a significant interest in the outcome of this case.

The Institute for Health and the Environment is a research organization within the University at Albany that has members from the various schools and colleges within the University, and also scientists from other academic and government institutions who share its interest on the general subject of environmental causes of human disease. One major goal of the Institute is to promote interdisciplinary research in the areas of public and environmental health. The Institute as such is not involved in any litigation, although individual members may participate in litigation on their own. The Institute strongly advocates for finding ways to reduce human exposure to environmental chemicals and other threats that are harmful to human health.

The National Campaign to Restore Civil Rights (NCRCR) is a non-partisan movement of more than one hundred civil rights and social justice organizations and individuals working to ensure that our courts protect and preserve equal justice, fairness, and opportunity. NCRCR is interested in this case because of its concern for protecting access to the courts. A decision upholding the district court's dismissal of this case may have far-reaching effects and affect many of the Campaign's partner organizations, including racial justice, immigrants', and disability rights organizations, and advocates working on housing, the environment, access to health care, education, employment, the rights of the aging, women's rights, and the rights of people who are LGBTQ. The district court's reasoning has the potential to curtail civil rights and social justice advocates' and organizations' ability to challenge policies, laws, and actions (or inactions) that cause injury and violate their and their stakeholders' rights.

New York City Environmental Justice Alliance is a non-profit citywide network founded in 1991 linking grassroots organizations from low-income communities of color in their struggle for environmental justice. It coalesces member organizations around common issues to

advocate for improved environmental conditions and against inequitable burdens by coordinating campaigns to affect city and state policies.

The New York Committee for Occupational Safety and Health (NYCOSH) is a coalition of 200 local unions and 300 individuals dedicated to fighting for every worker's right to a safe and healthful workplace. NYCOSH has a 32-year history of providing quality safety and health training, materials, and technical assistance to working people, employers, community-based organizations, and government agencies in the New York metropolitan area. NYCOSH is committed to ensuring that all workers have access to legal remedies when their rights have been violated.

New York Lawyers for the Public Interest (NYLPI) is an organization that advances equality and civil rights, with a focus on health justice, disability rights, and environmental justice, through the power of community lawyering and partnerships with the private bar. Through community lawyering, NYLPI puts its legal, policy, and community organizing expertise at the service of New York City communities and individuals. NYLPI's partnership with the private bar strengthens its advocacy and connects community groups and non-profits

with critical legal assistance. Litigating civil rights issues is critical to advancing its mission. If upheld, the ruling below would reduce NYLPI's ability to challenge civil rights violations on behalf of the community members and organizations it represents.

The UNC Center for Civil Rights is a legal organization that uses action-oriented advocacy, including litigation, to make America's promise of justice, opportunity, and prosperity a reality for all people. Using a range of advocacy strategies that also includes community education, research, and public policy efforts, the Center is recognized nationally as one of the principal, university-based hubs of civil rights advocacy in the South. The Center's core program areas are *Educational Advancement and Fair Opportunities* and *Community Inclusion and Development.* In both these areas, the Center often represents community-based grassroots organizations advocating on behalf of their members. Issues of standing are not uncommon in matters where the Center represents client communities attempting to address the range of impacts of the legacy of exclusion and segregation (including substandard housing, school assignment patterns, environmental justice, access to services, and political rights).

SUMMARY OF ARGUMENT

Does a person who is exposed to a threat of injury but can incur some expense or take some other inconvenient or unwanted action to avoid the injury suffer an "injury in fact" sufficient to create Article III standing? That question is squarely posed by the district court's decision in this case, which dismissed NRDC's challenge to the FDA's failure to carry out its duty to take timely action addressing the risks posed by antibacterial compounds used in soaps and hand sanitizers solely because NRDC members exposed to these substances at their workplaces could avoid injury by buying their own soap and bringing it to work with them.

The district court's decision reflects a fundamental misconception of the law of standing and the nature of the injury-in-fact requirement that lies at its heart. Article III standing requires, as an "irreducible constitutional minimum," that a plaintiff suffer or be threatened with an imminent "injury in fact" to a "judicially cognizable interest," that the injury be "fairly traceable" to the conduct challenged in the lawsuit, and that the injury be "redressable" by the relief potentially available in the lawsuit. *Bennett v. Spear*, 520 U.S. 154, 167 (1997). The injury need not, however, be wholly unavoidable or incapable of being mitigated. As the

Supreme Court explained in *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 129 (2007), a case or controversy still exists when a plaintiff has "eliminated the threat of imminent harm" by changing her behavior in some undesired way. The reason is that, as this Court recognized most recently in *Amnesty International USA v. Clapper*, __ F.3d __, 2011 WL 941524, at *9 (2d Cir. Mar. 21, 2011), having to incur a cost to avoid a threatened injury is itself an injury for standing purposes. In other words, even if a plaintiff has the ability to choose the lesser of two evils, she has still suffered an injury in fact.

The district court's contrary view—that the possibility of spending money or taking some other unwanted action to avoid injury means that a plaintiff lacks standing—would have far-reaching negative consequences. In environmental cases, it would eliminate or curtail one of the most common and clearly accepted means of showing standing—namely, demonstrating that members of a group use a location threatened with contamination or some other form of damage for recreational or aesthetic purposes. *See, e.g.*, *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167 (2000). Under the district court's analysis, such a demonstration would not suffice because the group's

members could avoid injury simply by choosing to go elsewhere. Similarly, the district court's reasoning would impose potential new obstacles to standing in consumer safety, civil rights, and First Amendment cases, as well as in actions brought by businesses challenging government regulation, as plaintiffs in many such cases have the ability to avoid or minimize an injury by incurring expenses or changing their behavior in some other undesirable way.

Moreover, the district court's reasoning fails to recognize that the very point of the law NRDC seeks to enforce here—in common with many other laws and regulations that plaintiffs seek to enforce through litigation—is to protect people from having to use self-help measures to avoid injury. Similarly, environmental laws and laws prohibiting discrimination are designed so that people do not have to go out of their way to avoid harmful contamination or invidious discrimination. And the First Amendment is intended to spare speakers the choice between punishment for protected speech and self-censorship. But if standing law is distorted so that persons who can avoid the direct impacts of unlawful conduct by changing their own behavior in undesired ways are denied the ability to bring legal actions challenging that unlawful conduct, the

substantive protections afforded them by law will be significantly impaired. That result is by no means compelled by Article III's case-or-controversy requirement.

ARGUMENT

Contrary to the District Court's View, Having to Incur Expense to Avoid the Threat of Injury Is Itself an Injury in Fact Giving Rise to Article III Standing.

A. *Amnesty International* Establishes That NRDC's Members Would Suffer Injury If They Incurred Expenses to Buy Triclosan- and Triclocarban-Free Soap.

Without questioning that the workplace exposure of NRDC members to soaps containing triclosan and triclocarban would itself constitute a sufficient injury in fact to afford them Article III standing to challenge the FDA's failure to fulfill its regulatory responsibility to determine the safety and efficacy of those drugs, the district court denied standing solely because those members could avoid the risk of exposure by purchasing their own triclosan- and triclocarban-free soaps and bringing them to work in place of those supplied by their employers. Observing that soap is not expensive, the district court stated that the ability of NRDC members to avoid injurious exposure by taking the self-help measure of substituting their own soaps for those supplied at their

workplaces was entirely dispositive of their claim that they faced an injury as a result of the FDA's failure to carry out its duties with respect to the regulation of antibacterial soaps.

The district court got the matter exactly backward by failing to realize that being placed in the position of having to incur an expense—even a small one—to avoid an injury *is itself an injury* sufficient to confer standing under Article III. As this Court has very recently explained, the basic injury-in-fact requirement of standing is met when a plaintiff is "affected … in some concrete way" by a challenged government action. *Amnesty Int'l*, 2011 WL 941524, at *9. A plaintiff may demonstrate such a "cognizable injury in fact" attributable to a government action "by showing that he has altered or ceased conduct as a reasonable response to the challenged [action]." *Id.* at *17. A change in behavior aimed at avoiding a reasonably likely threat of injury created by the government's conduct is precisely the kind of alteration in conduct that constitutes such a "reasonable response." *See id.* at *11-*20. And where the change in behavior to avoid the reasonably feared injury requires the plaintiff to incur monetary costs—the classic and indeed "most mundane form of injury in fact," *id*. at *10—there can be "little doubt that the plaintiffs

have satisfied the injury-in-fact requirement." *Id*. In short, where plaintiffs have a reasonable fear of injury, and they "incur[] … professional and economic costs as a direct result of that reasonable fear, their present injuries in fact clearly satisfy the requirements for standing." *Id*. at *11. Thus, in *Amnesty International*, the plaintiffs had standing to challenge the federal government's wiretapping program because, to avoid the reasonable possibility that their legitimate, confidential communications might be intercepted, they changed their behavior and took costly and inconvenient measures to avoid government eavesdropping.

The same principles leave no doubt that the course of action the district court said NRDC members could take to *avoid* injury would itself amount to a legally cognizable injury in fact. First, there can be no doubt that buying soap not containing triclosan or triclocarban would, in *Amnesty International*'s terms, be a reasonable response to a reasonable fear of injury. The FDA could hardly suggest otherwise, given that its own "Consumer Update" about triclosan tells consumers that, in light of evidence raising questions about triclosan's safety and the absence of evidence that it offers any health benefits, "[c]onsumers concerned about

using hand and body soaps with triclosan should wash with regular soap and water." http://www.fda.gov/forconsumers/consumerupdates/ucm 205999.htm (visited Mar. 30, 2011).

Although, as the district court stated, soap may be cheap, it is not free—unlike the triclosan- and triclocarban-containing soaps provided at the workplaces of NRDC's members. Thus, the district court's recommendation that NRDC's members avoid injury by bringing their own soap to the office would require a change in their behavior entailing that "most mundane of injuries in fact: the expenditure of funds." *Amnesty Int'l*, 2011 WL 941524, at *10. That the injury may not be a large one is irrelevant, because the injury in fact necessary to support standing "need not be large, an identifiable trifle will suffice." *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002) (citation omitted).

To be sure, NRDC in this case (unlike the plaintiffs in *Amnesty International*) did not premise its claim of standing on its members' having actually incurred the cost of buying their own soap, but on their exposure to triclosan- and triclocarban-containing soaps at their workplaces. *Amnesty International* is, nonetheless, directly relevant because the district court's ruling was premised on the existence of an

alternative course of action open to the plaintiffs that, in the court's view, would not expose them to any cognizable injury at all. That the alternative would, if chosen, itself constitute an injury fatally undermines the district court's reasoning. As this Court recognized in *Amnesty International*, when a plaintiff faces a "Hobson's choice" between two injurious courses of action, he is "affected … in such a way as to give him standing" whichever choice he makes. 2011 WL 941524, at *18. Put differently, a plaintiff who faces a sufficiently imminent and concrete threat of injury cannot be denied standing on the ground that she could have chosen *to be injured in another way*.

B. Affirming the District Court's Decision That a Plaintiff Who Can Avoid Direct Injury Lacks Standing Would Have Far-Reaching Effects on Established Standing Doctrines.

The district court's decision is inconsistent not only with this Court's decision in *Amnesty International*, but also with a host of decisions in a variety of areas of law finding that injury satisfying Article III's case-or-controversy requirement is present in cases where plaintiffs could take actions that (if the district court's view in this case were accepted) would avoid their injuries.

Perhaps the most obvious examples are environmental cases, where plaintiffs typically premise their standing to object to the contamination or destruction of an environmentally sensitive area by establishing that they make use of it for recreational or aesthetic purposes, and now face the choice of either exposing themselves to harm by continuing to do so or ceasing to use the area. For example, in *Friends of the Earth, Inc. v. Laidlaw Environmental Services*, the injury on which the Supreme Court's recognition of the plaintiff's standing rested was that the plaintiff organization had members who had *curtailed* their use of the North Tyger River because of the defendant's discharge of pollutants into it. That is, the organization's members had chosen *not* to fish or swim in the river, to canoe on it, or to hike, camp, or picnic near it, in order to avoid exposure to noxious and hazardous pollutants. 528 U.S. at 181-83. Similarly, this Court and other courts of appeals regularly recognize that environmental plaintiffs who make use of recreational areas threatened with pollutants (or who cease to do so to avoid the pollutants) suffer injuries sufficient to support standing. *See, e.g., Building & Constr. Trades Council v. Downtown Dev., Inc.*, 448 F.3d 138, 146 (2d Cir. 2006); *Maine People's Alliance v. Mallinckrodt, Inc.*, 471

F.3d 277 (1st Cir. 2006); *American Canoe Ass'n v. City of Louisa Water & Sewer Comm'n*, 389 F.3d 536 (6th Cir. 2004); *American Canoe Ass'n v. Murphy Farms, Inc.*, 326 F.3d 505 (4th Cir. 2003); *Piney Run Pres. Ass'n v. County Comm'rs*, 268 F.3d 255 (4th Cir. 2001); *Ecological Rights Found. v. Pacific Lumber Co.*, 230 F.3d 1141 (9th Cir. 2000); *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149 (4th Cir. 2000).

Under the district court's reasoning, the fact that the plaintiffs in such cases had ceased fishing, boating, or swimming in contaminated waters to avoid injury—or even the possibility that they could do so (and indeed might even save some money if they did)—would mean that they *lacked* standing and could not gain access to court. Because a plaintiff who asserted a recreational or aesthetic interest in making use of some threatened location could *always* go somewhere else or take up some different form of recreation, the district court's view would cut off a basis for standing that the Supreme Court has consistently held to be available in environmental cases. *See, e.g., Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1149 (2009) ("[I]f [environmental] harm in fact affects the

recreational or even the mere esthetic interests of the plaintiff, that will suffice.").

Similarly, the district court's view would be fatal to standing in nearly every case challenging the inadequacy of health, safety, or other regulations affecting consumer products, as consumers could be told by courts that they were not injured as long as they had the ability to seek out and purchase safer products already on the market (even if, as in this case, that involved incurring some incremental expense or other difficulty). *But see Center for Auto Safety v. NHTSA*, 793 F.2d 1322 (D.C. Cir. 1986) (recognizing standing of consumer groups to challenge inadequacy of automobile fuel efficiency standards); *Public Citizen v. Foreman*, 631 F.2d 969 (D.C. Cir. 1980) (recognizing standing of consumer groups to challenge inadequacy of regulation of food products containing nitrites).

The district court's reasoning is also at odds with the well-established principle that plaintiffs in First Amendment cases suffer injury in fact not only when the government takes action against them for engaging in protected speech, but also when they change their behavior to avoid a genuine threat of such direct consequences. Thus, the

Supreme Court found a justiciable controversy in *Steffel v. Thompson*, 415 U.S. 452 (1974), where the plaintiff alleged that he had decided to stop distributing handbills at a shopping mall in order to avoid prosecution. As the Court explained, "it is not necessary that petitioner first expose himself to actual arrest or prosecution to be entitled to challenge a statute that he claims deters the exercise of his constitutional rights." *Id.* at 459. And the Court held in *Meese v. Keene*, 481 U.S. 465 (1987), that a plaintiff suffered injury in fact when he chose *not* to show films branded as propaganda by the government in order to *avoid* the reputational injuries that would follow if he were associated with such propaganda. Recognizing that the plaintiff could have taken some steps to minimize injury to his reputation if he had shown the films, the Court pointedly commented that "the need to take such affirmative steps to avoid the risk of harm to his reputation constitutes a cognizable injury." *Id.* at 475.

The courts of appeals also regularly hold that plaintiffs who change their conduct to avoid a realistic threat of sanctions have standing to raise First Amendment challenges to the laws that pose the threat. *See, e.g., Eldred v. Reno*, 239 F.3d 372, 375 (D.C. Cir. 2001) (plaintiffs had

standing to challenge copyright statute because they were injured by *compliance* with its restrictions on exploitation of copyrighted works), *aff'd sub nom. Eldred v. Ashcroft*, 537 U.S. 186 (2003); *Brister v. Faulkner*, 214 F.3d 675, 679-81 (5th Cir. 2000); *Wilson v. State Bar*, 132 F.3d 1422, 1428 (11th Cir. 1998); *Jacobs v. Florida Bar*, 50 F.3d 901, 904-05 (11th Cir. 1995); *Int'l Soc'y for Krishna Consciousness v. Eaves*, 601 F.2d 809, 817-19 (5th Cir. 1979). As the First Circuit has put it, a threat of sanctions if a plaintiff exercises First Amendment rights "poses a classic dilemma for an affected party: either to engage in the expressive activity, thus courting prosecution, or to succumb to the threat, thus forgoing free expression. Either injury is justiciable." *New Hampshire Right to Life Political Action Comm. v. Gardner*, 99 F.3d 8, 14 (1st Cir. 1996). On the reasoning of the district court in this case, however, the possibility that a plaintiff could choose a course of action that would minimize her injury would be a basis for denying standing.

The district court's reasoning would also jeopardize well-established bases for standing in civil rights cases. For example, the Supreme Court held in *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), that civil rights "testers" and the organizations employing them

have Article III standing to raise Fair Housing Act claims when real estate agents deny them their right to truthful information about the availability of housing—even when the testers have no actual interest in seeking housing and in fact *expect* to receive false information. *See id.* at 373-74. The district court's reasoning in this case is inconsistent with the Supreme Court's holding in *Havens Realty* because the plaintiffs there could easily have avoided injury by not engaging in testing.

Similarly, a civil rights organization that asserts standing to challenge an allegedly unlawful government policy on the ground that the policy affects the organization by causing it to divert its resources to countering the policy rather than putting them to other preferred uses could be told that it lacks standing because it could always avoid the injury just by choosing not to spend its resources in that manner. *But see Nnebe v. Daus*, __ F.3d __, 2011 WL 1086569, at *6-*8 (2d Cir. Mar. 25, 2011) (recognizing organizational standing based on diversion of resources). Indeed, even plaintiffs challenging such egregious discrimination as the notorious case of the Louisiana justice of the peace who refused to perform interracial marriages could be told they had no standing if they could have "avoided" injury by seeking out another

justice of the peace who would not discriminate. *See Humphrey v. Bardwell*, Civ. Action No. 09-6997 (E.D. La. filed Oct. 20, 2009).

Moreover, the effects of the district court's reasoning would not be confined to public interest litigation—business plaintiffs, too, would be affected by the court's concept that the possibility of avoiding one harm by subjecting oneself to another lesser one obviates standing. In *Medimmune v. Genentech*, for example, the Supreme Court held that a plaintiff had standing to challenge the validity of a patent even though it had avoided the threatened injury of a lawsuit for patent infringement by paying royalties to the patent-holder. *See* 549 U.S. at 129. The Supreme Court emphasized that Article III's requirements are satisfied when a plaintiff "eliminate[s] the imminent threat of harm" by changing its behavior in some undesired way, *id.*, because the "dilemma" faced by a plaintiff presented with a choice of either suffering injury or incurring unwanted costs or taking some other inconvenient or undesired action to avoid that injury provides the necessary basis for a justiciable controversy. *Id*.

Indeed, that very "dilemma" forms the basis for standing and ripeness in most cases where regulated entities bring pre-enforcement

challenges based on allegations that they must either face the injury of government enforcement action or avoid it by costly compliance with regulatory demands. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 152 (1967); *see also, e.g., Cellco P'ship v. FCC*, 357 F.3d 88, 100 (D.C. Cir. 2004) ("As an entity continuously burdened by the costs of complying … with what it contends are 'unnecessary' regulations …, Verizon Wireless' injuries are concrete and actual, traceable to the Commission's alleged failure to meet the statutory deadline, and redressable by a ruling adopting Verizon Wireless' interpretation [of the statute]."); *City of Waukesha v. EPA*, 320 F.3d 228, 234 (D.C. Cir. 2003) ("The administrative record shows that the City of Waukesha would face substantial costs if it was required to comply with the [challenged] regulations. This is sufficient for injury-in-fact."); *Ass'n of Am. R.Rs. v. Dep't of Transp.*, 38 F.3d 582, 585-86 (D.C. Cir. 1994) (cost of compliance with two sets of regulations sufficient to support standing).

In sum, the district court's reasoning is inconsistent with a vast body of Article III standing precedents, and its acceptance would have broad and unforeseeable consequences in a wide range of cases. Choking off standing for the reason asserted by the district court would also

subvert the protections provided by the substantive law at issue in this case, as well as the laws implicated in the other types of cases to which the district court's reasoning might extend. The statute at issue here, for example, is supposed to spare consumers the need to seek out and differentiate safe and effective over-the-counter drugs from unsafe and ineffective ones. Asserting that plaintiffs who have been denied the protection the agency is supposed to provide them can avoid injury simply by changing their behavior and making personal expenditures or engaging in other inconvenient self-help measures is directly contrary to that overarching statutory goal. Thus, by denying NRDC its day in court because its members could go out of their way to protect themselves from harms the agency is supposed to protect them against, the district court's decision not only distorts the law of standing, but also undermines the substantive objectives Congress chose when it tasked the FDA to regulate over-the-counter drugs.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment of the district court and remand for further proceedings on the merits.

Respectfully submitted,

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April 1, 2011

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)(C)

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I certify that the foregoing brief complies with the type-volume, type-face, and type-style requirements of Rules 32(a)(7)(B), 29(d), 32(a)(5), and 32(a)(6) because it is proportionally-spaced, is set in a plain, roman 14-point type-face (Century Schoolbook BT), and, as calculated by my word processing software (Microsoft Office Word 2007), contains 4,813 words.

April 1, 2011

/s/ Allison M. Zieve
Allison M. Zieve

CERTIFICATE OF SERVICE

I hereby certify that on April 1, 2011, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. I certify that all parties required to be served have been served by the appellate CM/ECF system.

April 1, 2011

/s/ Allison M. Zieve
Allison M. Zieve