United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 2, 2011 Decided March 13, 2012

No. 11-5035

COALITION FOR MERCURY-FREE DRUGS (COMED, INC.), A NON-PROFIT ORGANIZATION, ET AL.,
APPELLANTS

v.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, AND MARGARET HAMBURG, COMMISSIONER OF FOOD AND DRUGS,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:09-cv-00015)

Robert E. Reeves argued the cause for appellants. With him on the briefs was *James S. Turner*.

Henry C. Whitaker, Attorney, U.S. Department of Justice, argued the cause for appellees. On the brief were *Tony West*, Assistant Attorney General, *Ronald C. Machen, Jr.*, U.S. Attorney, and *Douglas N. Letter* and *Catherine Y. Hancock*, Attorneys. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Aaron Colangelo and *Vivian H.W. Wang* were on the brief for *amicus curiae* Natural Resources Defense Council in support of neither party.

Before: ROGERS and KAVANAUGH, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* KAVANAUGH.

KAVANAUGH, *Circuit Judge*: The Coalition for Mercury-Free Drugs opposes the use of vaccines that contain thimerosal, a mercury-based preservative. The Coalition believes that vaccines containing mercury harm young children and pregnant women. The Coalition and several of its members sued to suspend Food and Drug Administration approval of thimerosal-preserved vaccines. The District Court dismissed plaintiffs' suit for lack of standing.

We recognize plaintiffs' genuine concern about thimerosal-preserved vaccines. But plaintiffs are not required to receive thimerosal-preserved vaccines; they can readily obtain thimerosal-*free* vaccines. They do not have standing to challenge FDA's decision to allow *other people* to receive thimerosal-preserved vaccines. Plaintiffs may, of course, advocate that the Legislative and Executive Branches ban all thimerosal-preserved vaccines. But because plaintiffs are suffering no cognizable injury as a result of FDA's decision to allow thimerosal-preserved vaccines, their lawsuit is not a proper subject for the Judiciary. We affirm the judgment of the District Court.

I

A

Vaccine manufacturers often distribute vaccines in vials containing multiple doses. Under federal law, multiple-dose vials must contain a preservative so as to prevent bacterial and fungal contamination. *See* 21 C.F.R. § 610.15(a). Preservatives are important because injection with a contaminated vaccine can be fatal. *See* FDA, THIMEROSAL IN VACCINES, *available at* http://www.fda.gov.

Thimerosal is a mercury-based compound that FDA has found to be safe and effective as a vaccine preservative. *See* 42 U.S.C. § 262(a)(2)(C)(i); FDA Response to Coalition Citizen Petition at 4-5. FDA has explained that "thimerosal has been the subject of several studies . . . and has a long record of safe and effective use preventing bacterial and fungal contamination of vaccines, with no ill effects established other than minor local reactions at the site of injection." FDA, THIMEROSAL IN VACCINES.

Despite FDA's approval, some members of the public have expressed concern about thimerosal-preserved vaccines. And in 1999, "as a precautionary measure," the Public Health Service (an entity within HHS) established the goal of removing thimerosal from early childhood vaccines. FDA Response to Coalition Citizen Petition at 18.[1] Since 2001,

[1] At the time, the CDC reiterated that "there are no data or evidence of any harm caused by the level of exposure that some children may have encountered in following the existing immunization schedule." CDC, *Notice to Readers: Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*, MORBIDITY AND MORTALITY WEEKLY REPORT (July 9, 1999), *available at*

most vaccines routinely recommended for children younger than six or for pregnant women have contained no thimerosal or only trace amounts. The significant exception is the flu vaccine: Thimerosal-preserved flu vaccines are necessary to ensure sufficient supply at a reasonable price. Therefore, flu vaccines with thimerosal remain on the market and are approved not just for adults but also for young children and pregnant women.

B

The Coalition for Mercury-Free Drugs and its members believe vaccines containing thimerosal are unsafe. They are especially concerned about the possible effects of thimerosal-preserved vaccines on young children and pregnant women. Exposure to thimerosal, plaintiffs believe, can cause miscarriages, autism, and other developmental disorders.

In August 2007, the Coalition submitted a "Citizen Petition" to FDA. The petition asked FDA to ban use of thimerosal-preserved vaccines for young children and pregnant women. The Coalition claimed that pharmaceutical products containing thimerosal "lack the appropriate safety studies." Coalition Citizen Petition at 2. According to the Coalition, "substantial inferential evidence, and a growing body of toxicological human exposure and animal data" show that small amounts of thimerosal "can cause neurological and other tissue damage." *Id.*

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http://www.cdc.gov; *cf.* Paul A. Offit, *Thimerosal & Vaccines – A Cautionary Tale*, 357 NEW ENG. J. MED. 1278, 1279 (2007) (criticizing Joint Statement's "precautionary" approach on the ground that ensuing alarm led parents to avoid vaccinations and take other serious risks to avoid "disproved" risk of thimerosal-preserved vaccines).

FDA denied the Coalition's petition. The agency stated that it had "applied sound scientific judgment in evaluating the products at issue" and had "repeatedly found that the vaccines and other products currently being marketed that contain thimerosal as a preservative are safe within the meaning of the" applicable statutes. FDA Response to Coalition Citizen Petition at 4. FDA cited numerous scientific studies supporting the safety of the vaccines and rebutted the evidence offered in the Coalition's petition. *Id.* at 4-16.

The Coalition and several of its members then filed this action in U.S. District Court. The complaint alleged that FDA, by allowing thimerosal-preserved vaccines, violated its statutory duty to ensure the safety of vaccines. Complaint at 25-26. Plaintiffs asked for a court order requiring FDA to prohibit the administration of vaccines containing more than a trace level of thimerosal to young children and pregnant women. Plaintiffs also sought to force FDA to remove thimerosal-preserved vaccines from the market. Complaint at 29-30.

The Government moved to dismiss for lack of standing and failure to state a claim. The District Court granted the motion to dismiss on the ground that the Coalition and the individual plaintiffs lacked standing to bring the suit. *See Coalition for Mercury-Free Drugs v. Sebelius*, 725 F. Supp. 2d 1, 5 (D.D.C. 2010).

II

The doctrine of standing derives from Article III of the Constitution, which limits the jurisdiction of the federal courts to "Cases" and "Controversies." U.S. CONST. art. III, § 2; *Arizona Christian School Tuition Org. v. Winn*, 131 S. Ct. 1436, 1441-42 (2011). Standing helps differentiate "those disputes which are appropriately resolved through the judicial

process" from policy disputes that are appropriately addressed by the elected branches. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)); *see also Allen v. Wright*, 468 U.S. 737, 752 (1984) (standing rests on "a single basic idea": the separation of powers).

Permitting "courts to oversee legislative or executive action" without regard to the plaintiff's personal stake in the litigation would "significantly alter the allocation of power away from a democratic form of government." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009) (citation and ellipsis omitted); *see also Winn*, 131 S. Ct. at 1442. Standing protects democratic government by requiring citizens to express their generalized dissatisfaction with government policy through the Constitution's representative institutions, not the courts. *See Public Citizen v. NHTSA*, 489 F.3d 1279, 1289 (D.C. Cir. 2007) (standing "helps ensure that the Judicial Branch does not perform functions assigned to the Legislative or Executive Branch"). The requirement of Article III standing thus helps preserve the Constitution's separation of powers and demarcates "the proper – and properly limited – role of the courts in a democratic society." *Warth v. Seldin*, 422 U.S. 490, 498 (1975).

If the plaintiff does not have standing, a dispute does not present a justiciable case or controversy. The "judicial Power" conferred by Article III "exists only to redress or otherwise to protect against injury to the complaining party," not to review the legality of governmental conduct in a vacuum. *Id.* at 499; *see also Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 487 (1982) (federal courts are not "ombudsmen of the general welfare"); *Marbury v. Madison*, 5 U.S. 137, 170 (1803) (the "province of the court is, solely, to decide on the

rights of individuals"). The doctrine of standing thus requires a plaintiff to demonstrate "a personal stake in the outcome of the controversy" in order to "justify exercise of the court's remedial powers on his behalf." *Warth*, 422 U.S. at 498-99 (citation omitted).

The "irreducible constitutional minimum of standing contains three elements": (1) the plaintiff must have suffered an "injury in fact – an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent," not abstract, generalized, remote, or speculative; (2) there must be a "causal connection" between the injury and the challenged action of the defendant; and (3) it must be "likely," not merely "speculative," that the relief sought will redress the injury. *Lujan*, 504 U.S. at 560-61 (internal quotation marks and citations omitted).

Here, the standing of the Coalition and the individual members named as plaintiffs turns on the same question: whether any individual member of the Coalition has alleged facts sufficient to show Article III standing – namely, an injury caused by FDA's allowing thimerosal-preserved vaccines and redressable by a court order that FDA no longer permit such vaccines. *See Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002) ("The issue before the court, then, is whether at least one member of the Sierra Club has standing under Article III.").[2]

[2] An association such as the Coalition has standing to sue on behalf of its members if: "(1) at least one of its members would have standing to sue in his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires that an individual member of the association participate in the lawsuit." *Sierra Club*, 292 F.3d at 898 (citing *Hunt v. Wash. State Apple*

Plaintiffs allege three kinds of injuries as the basis for their Article III standing: 1) physical injuries caused by mercury in vaccines, 2) reputational injuries to members who are medical professionals, and 3) difficulty in obtaining thimerosal-free vaccines. We address each in turn.

A

Plaintiffs attribute several past injuries – including miscarriages, autism, and other neurological harms to children – to exposure of young children and pregnant women to thimerosal in vaccines. As the District Court correctly explained, however, a plaintiff who seeks prospective injunctive relief cannot establish standing based on past harm alone. Even if a plaintiff has suffered past harm from the kind of conduct the suit seeks to enjoin, the plaintiff must "establish a real and immediate threat" that the harm-producing conduct will recur. *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983).

Apparently recognizing that settled legal principle, plaintiffs allege a fear of *future* exposure to mercury from thimerosal-preserved vaccines. For a plaintiff seeking injunctive relief, however, the harm feared must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (internal quotation marks omitted); *see also Lyons*, 461 U.S. at 102 (threat of injury must be "real and immediate"); *Whitmore*, 495 U.S. at 158 ("threatened injury must be certainly impending to constitute injury in fact") (internal quotation marks omitted). But Coalition members do not claim that *they* intend to receive thimerosal-preserved vaccines in the future. On the contrary, they say that they will refuse thimerosal-preserved

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Advertising Comm'n, 432 U.S. 333, 342-43 (1977)). Only the first element is at issue here.

vaccines. Moreover, they acknowledge that thimerosal-free versions of all essential vaccines, including the flu vaccine, are available on the market. *See* Pls.' Mem. of Law in Opp'n to Defs.' Mot. to Dismiss at 4 ("every prophylactic vaccine and biological drug product routinely recommended for population-wide administration to protect the public health is admittedly available in a form that has no added mercury compound").

In light of plaintiffs' avowed intention to refuse thimerosal-preserved vaccines, plaintiffs cannot show that they face a "certainly impending," or even likely, risk of future physical injury from thimerosal in vaccines.

To be sure, plaintiffs point out that vaccination is often compulsory for children whose parents seek to enroll them in public schools. *See, e.g.*, Declaration of Seth Sykes at 2. But thimerosal-free versions of required vaccines are available, as plaintiffs have conceded, so parents concerned about the effects of thimerosal can obtain thimerosal-free vaccines for their school-age children.

Plaintiffs also suggest that doctors, nurses, and pharmacists do not pay sufficient attention to whether the flu vaccines they administer contain thimerosal. *See, e.g.*, Declaration of Lisa Sykes at 5-7; Declaration of Jennifer Kate Krekeler at 5-6; Declaration of Lisa Jean Pleggenkuhle Grummer at 2-3; Declaration of Theresa Colleen Farris at 1-2. But Coalition members are aware of the difference between thimerosal-preserved and thimerosal-free vaccines and therefore can ask their doctors, nurses, and pharmacists to ensure that they receive only thimerosal-free vaccines.

To establish standing, plaintiffs must allege likely future injury to Coalition members, not to other members of the public. Plaintiffs have not done so.

B

The Coalition also asserts injury to the reputations of its members who are medical professionals. Specifically, it claims that "member physicians and researchers have suffered injury to their reputation due to the damage done to the profession by the increasing evidence that the FDA has not been ensuring that vaccines" are safe. Coalition Br. at 35. Coalition member Dr. Mark Geier states that he "was placed in the impossible position as a physician to either risk giving my patients a vaccine, which contained Thimerosal . . . or refuse to administer a 'swine' influenza vaccine." Supp. Declaration of Mark Geier at 3.[3]

The short answer to this argument is that FDA is not forcing Dr. Geier to administer thimerosal-preserved vaccines, nor is it forcing any patient to receive such vaccines. So any reputational injury allegedly suffered by Dr. Geier is not legally attributable to FDA.

C

In their final and most forceful argument for standing, plaintiffs say that FDA's approval of thimerosal-*preserved*

[3] The Coalition also submitted a declaration by researcher Dr. Janet Kern. Dr. Kern is not a named plaintiff, and her name does not appear on the membership roll placed in the record by the Coalition. In any event, her declaration contains no concrete, particularized allegation that would alter our analysis here. *See* Declaration of Janet Kern at 2, 4 ("The Secretary's slow and incompetent actions related to Thimerosal are creating the potential for a public health crisis due to distrust of the health care system. . . . Forcing the FDA to do its job will begin to restore public confidence in the medical community including myself.").

vaccines has made it more difficult and costly for Coalition members to find and obtain thimerosal-*free* vaccines.

This Court has permitted consumers of a product to challenge agency action that prevented the consumers from purchasing a desired product. In *Consumer Federation of America v. FCC*, for example, this Court held that a consumer group had standing to challenge the FCC's approval of the AT&T-Comcast merger. 348 F.3d 1009, 1012 (D.C. Cir. 2003). In that case, a member of the consumer group alleged that the merger would prevent him from subscribing to Comcast's high-speed internet service while retaining the ability to choose his own internet service provider. *Id.* The Court stated that the "inability of consumers to buy a desired product may constitute injury-in-fact even if they could ameliorate the injury by purchasing some alternative product." *Id.* (internal quotation marks omitted); *see also Chamber of Commerce v. SEC*, 412 F.3d 133, 136-38 (D.C. Cir. 2005) (lost opportunity to purchase shares in mutual funds with less than 75% independent directors); *Competitive Enterprise Inst. v. NHTSA*, 901 F.2d 107, 112-13 (D.C. Cir. 1990) (lost opportunity to purchase larger vehicles); *Center for Auto Safety v. NHTSA*, 793 F.2d 1322, 1332-34 (D.C. Cir. 1986) (lost opportunity to purchase more fuel-efficient vehicles).

But here, plaintiffs do not allege that FDA's approval of thimerosal-preserved vaccines prevents them from purchasing thimerosal-free vaccines altogether. Rather, plaintiffs concede that mercury-free versions are available.

Under our precedents, that does not end the analysis, however, for plaintiffs also contend that FDA's approval of thimerosal-preserved vaccines makes thimerosal-free alternatives *difficult to obtain*, because clinics and doctors do

not consistently carry them. *See* Pls.' Mem. of Law in Opp'n to Defs.' Mot. to Dismiss at 13-15. That asserted injury bears some marginal resemblance to the injury alleged in *Public Citizen v. Foreman*, 631 F.2d 969 (D.C. Cir. 1980). In *Foreman*, a consumer advocacy group and two of its members challenged FDA's approval of the use of nitrites as a preservative in cured bacon. *See id.* at 973-74. The plaintiffs did not claim that nitrite-free bacon was completely unavailable on the market, but they did "allege that the nitrite-free bacon they seek is *not readily available at a reasonable price*." *Id.* at 974 n.12 (emphasis added). The Court held that the plaintiffs had standing. It reasoned that although "this injury may not be overly burdensome . . . , it is an injury nonetheless." *Id.*

Here, however, plaintiffs' complaint and declarations do not allege that mercury-free vaccines are "not readily available." On the contrary, the declarations acknowledge that thimerosal-free vaccines are readily available. For example, the declaration submitted by Coalition member Lisa Sykes describes her visit to a CVS pharmacy in Richmond, Virginia, where a nurse practitioner "explained that she had two types of flu vaccine, with and without Thimerosal, if I was worried about that." Declaration of Lisa Sykes at 4. Similarly, Dr. Mark Geier's declaration reports that a Safeway pharmacy in Silver Spring, Maryland, maintained "a significant stock" of both thimerosal-preserved and thimerosal-free vaccines. Declaration of Mark Geier at 3-5; *see also* Declaration of Larry Hanus at 3 (Walgreens pharmacy offered to order thimerosal-free vaccine overnight); Declaration of Melissa Renee Troutman at 3 (pharmacy offered to order thimerosal-free vaccine, which "would take about a week" to arrive).

To be sure, other Coalition members describe visits to individual pharmacies and clinics that did not have thimerosal-free formulations on hand. *See, e.g.*, Declaration of Sarah W. Cooleen at 3 ("I asked him if you could order a thimerosal free shot. He said they couldn't just order one shot and I should check with other Kroger stores."). But the unavailability of thimerosal-free vaccines at a few individual outlets does not come close to establishing that they are "not readily available."[4]

Nor do plaintiffs allege that thimerosal-free vaccines are unreasonably priced as a result of FDA's decision to allow thimerosal-preserved vaccines. *Cf. Foreman*, 631 F.2d at 974 n.12. Some of the declarations do suggest that thimerosal-free vaccines cost more than thimerosal-preserved vaccines. *See, e.g.*, Declaration of Lisa Sykes at 7 ("The vaccine with the preservative cost less than the one without it."); Declaration of Melissa Renee Troutman at 3 (pharmacist stating that pharmacy could order thimerosal-free vaccine, but "it does cost more"); Declaration of Erin Grace Lewis at 3 (pharmacy owner stating that pharmacy did not order thimerosal-free vaccines "because they are more expensive" than vaccines containing trace amounts of thimerosal). *But*

[4] The Coalition's brief states, without further detail or citation, that Coalition member Linda Weinmaster "was not able to get vaccines completely free of Thimerosal for swine flu or seasonal flu" for her son Adam in the 2009-2010 flu season "despite her desire to do so," and that "she anticipates this may be a problem again this fall and winter." Coalition Br. at 19. We find no statement to that effect in plaintiffs' complaint or in either of Mrs. Weinmaster's declarations that were before the District Court. In any event, that isolated statement, without any description of the efforts Mrs. Weinmaster undertook to obtain a thimerosal-free flu vaccine, does not indicate that such vaccines are "not readily available." *Foreman*, 631 F.2d at 974 n.12.

see Declaration of Larry Hanus at 3 (no difference in price at Wal-Mart pharmacy).

But even if vaccine providers generally charge a higher price for thimerosal-free vaccines, the mere existence of a price differential would not establish that thimerosal-free vaccines are "not readily available at a *reasonable* price." *Foreman*, 631 F.2d at 974 n.12 (emphasis added). The price might be higher for the simple reason that things packaged individually (like thimerosal-free vaccines, which are packaged in single doses) generally cost more than the same things packaged in bulk (like thimerosal-preserved vaccines, which are packaged in multi-dose vials). *See* 21 C.F.R. § 610.15(a) ("[p]roducts in multiple-dose containers shall contain a preservative"); FDA, THIMEROSAL IN VACCINES tbl.1 (approved thimerosal-free influenza vaccines are packaged in single doses).

And the price differential might be sufficiently small as to have little effect on the vaccine's affordability for the average person. In any event, plaintiffs' declarations claim only that there was some price differential at a few individual outlets. The question under this aspect of *Foreman* is whether thimerosal-free vaccines are unreasonably priced. Plaintiffs have not alleged facts demonstrating as much. And we decline to stretch *Foreman* to hold that any alleged discrepancy in price between a preferred product and a more widely available one, no matter how small, confers Article III standing to seek an order banning the more widely available product.[5]

[5] At oral argument, the Government suggested that the plaintiffs' desired relief – a court order banning thimerosal-preserved vaccines – would result in a sudden, drastic reduction in the overall availability of flu vaccine. Presumably, a side effect of that contraction would be a significant *increase* in the price of the

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We recognize plaintiffs' concerns about thimerosal. But plaintiffs have not alleged that Coalition members face likely future injury caused by FDA's refusal to ban thimerosal-preserved vaccines. The Constitution therefore requires that they direct their objections to the Executive and Legislative Branches, not to the Judiciary.

We affirm the District Court's judgment dismissing plaintiffs' suit for lack of standing.

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limited stock of thimerosal-free vaccines. Therefore, according to the Government, a court order would not redress plaintiffs' claimed injury. Because we hold that plaintiffs have not alleged a cognizable injury-in-fact under *Foreman*, we need not reach that separate argument advanced by the Government for lack of redressability.