United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Filed On November 21, 2006

No. 04-5350

ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS AND WASHINGTON LEGAL FOUNDATION,
APPELLANTS

v.

ANDREW C. VON ESCHENBACH, M.D., IN HIS OFFICIAL CAPACITY AS ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, AND MICHAEL O. LEAVITT, IN HIS OFFICIAL CAPACITY AS SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 03cv01601)

On Petition for Rehearing

Peter G. Keisler, Assistant Attorney General, U.S. Department of Justice, *Kenneth L. Wainstein*, U.S. Attorney at the time the petition was filed, *Gregory G. Katsas,* Deputy Assistant Attorney General, *Jeffrey Bucholtz,* Principal Deputy Assistant Attorney General, *Michael J. Ryan* and *Rhonda C. Fields*, Assistant U.S. Attorneys, *Mark B. Stern*, *Scott R. McIntosh*, and *I. Glenn Cohen*, Attorneys, U.S. Department of Justice, *Daniel Meron*, General Counsel, Food & Drug Administration, *Eric M. Blumberg*, Deputy Chief Counsel for Litigation, and *Karen E. Schifter*, Associate Chief Counsel, were on the petition for rehearing and rehearing en banc and supplemental brief on standing for appellees.

J. Scott Ballenger, *David A. Price*, *Daniel J. Popeo*, and *Richard A. Samp* were on the response to the petition for rehearing and rehearing en banc and supplemental brief on standing for appellants.

Before: GINSBURG, *Chief Judge*, and ROGERS and GRIFFITH, *Circuit Judges*.

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

Opinion concurring in part and dissenting in part filed by *Circuit Judge* GRIFFITH.

ROGERS, *Circuit Judge*: On May 2, 2006, the court held that the district court erred in dismissing a complaint filed by the Abigail Alliance for Better Access to Developmental Drugs ("the Alliance"). We concluded that the district court's dismissal for failure to state a claim pursuant to FED. R. CIV. P. 12(b)(6) was premature because the Alliance had stated a liberty interest protected by the Due Process Clause. We remanded the case to the district court to address whether the challenged policy of the Food and Drug Administration ("FDA") was

narrowly tailored to address a compelling governmental interest. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 484-86 (D.C. Cir. 2006).

The FDA filed a petition for rehearing and rehearing en banc, challenging the merits of our original disposition and, for the first time, raising the issue of Article III standing. We requested supplemental briefing to develop the jurisdictional basis for the Alliance's claims. We now deny the petition for rehearing.

I.

Article III standing is a fundamental prerequisite to any exercise of our jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). A showing of standing requires, at the "irreducible constitutional minimum," *id.*, that the litigant has suffered a concrete and particularized injury that is actual or imminent, traceable to the challenged act, and redressable by the court. *See Allen v. Wright*, 468 U.S. 737, 750-51 (1984); *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37-38 (1976). An organization can have standing on its own behalf, *see Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378-79 (1982); *Warth v. Seldin*, 422 U.S. 490, 511 (1975), or on behalf of its members, *see United Food & Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 553 (1996); *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977). At each stage of trial, the party invoking the court's jurisdiction must establish the predicates for standing "with the manner and degree of evidence required at" that stage of trial. *Defenders of Wildlife*, 504 U.S. at 561. At the motion to dismiss stage, "general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we 'presum[e] that general allegations embrace those specific facts that are necessary to support the claim.'" *Id.* (quoting *Lujan v.*

Nat'l Wildlife Fed'n, 497 U.S. 871, 889 (1990)).

The Alliance maintains that it has made an adequate showing of standing, both as an organization and as a representative of its members. To remedy any possible shortcomings in its original complaint, the Alliance has filed an unopposed motion for leave to amend its complaint in order to add additional allegations as to standing. *See* 28 U.S.C. § 1653; FED. R. CIV. P. 15(a). We grant the Alliance's motion. Upon consideration of the amended complaint, we hold that the Alliance has made allegations both as to organizational standing and as to representational standing that are sufficient to survive a motion to dismiss.

A.

The Alliance contends that the actions of the FDA have caused the Alliance as an organization to suffer cognizable injuries that will continue without this court's intervention. "There is no question that an association may have standing in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy." *Warth*, 422 U.S. at 511.

The Alliance's amended complaint alleges:

> Defendants' conduct has frustrated Abigail Alliance's efforts to assist its members and the public in accessing potentially life-saving drugs and its other activities, including counseling, referral, advocacy, and educational services. The challenged regulations have caused a drain on Abigail Alliance's resources and time because the organization has had to divert significant time and resources from these activities toward helping its members and the public address the unduly burdensome requirements that the FDA

imposes on experimental treatments.

Am. Compl. ¶ 6.

The Supreme Court addressed a similar claim to organizational standing in *Havens Realty*. In that case, the Court found allegations of standing sufficient to withstand a motion to dismiss where an organization that provided counseling and referral services for home-seekers claimed that the defendants' actions led it "'to devote significant resources to identify and counteract the defendant's [*sic*] racially discriminatory steering practices.'" 455 U.S. at 379 (quoting plaintiff's complaint); *see also Metro. Wash. Airports Auth. v. Citizens for the Abatement of Aircraft Noise, Inc.*, 501 U.S. 252, 264-65 (1991).

This court has applied *Havens Realty* to justify organizational standing in a wide range of circumstances. *See, e.g.*, *Fair Employment Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276 (D.C. Cir. 1994); *Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 799 (D.C. Cir. 1987); *Action Alliance of Senior Citizens v. Heckler*, 789 F.2d 931, 936-39 (D.C. Cir. 1986). The court has distinguished organizations that allege that their activities have been impeded from those that merely allege that their mission has been compromised. *See Nat'l Treasury Employees Union v. United States*, 101 F.3d 1423, 1429-30 (D.C. Cir. 1996). The Alliance has met this threshold by alleging that it actively engages in "counseling, referral, advocacy, and educational services." Am. Compl. ¶ 6; *see also Competitive Enter. Inst. v. NHTSA*, 901 F.2d 107, 122 (D.C. Cir. 1990); *Action Alliance*, 789 F.2d at 938 & n.7. Moreover, the Alliance alleges that this injury is directly attributable to FDA policies. Am. Compl. ¶ 6; Decl. of Frank Burroughs ¶¶ 4-5; *see Rainbow/PUSH Coalition v. FCC*, 396 F.3d 1235, 1240-42 (D.C. Cir. 2005).

The FDA presents no arguments—and we find none—that counsel against finding that the Alliance's allegations of organizational standing are sufficient. Although the FDA suggests that holding the Alliance has standing would allow "public interest organizations to bring legal challenges at will to any and all regulations (and statutes) that they dislike," Appellees' Supp. Br. Regarding Article III Standing at 3, our holding does not relax the standing requirements. For standing to be based upon injury to the organization's activities there must still be a direct conflict between the defendant's conduct and the organization's mission. *See Nat'l Treasury Employees Union*, 101 F.3d at 1430. Furthermore, an organization is not injured by expending resources to challenge the regulation itself; we do not recognize such self-inflicted harm. *See, e.g.*, *Fair Employment*, 28 F.3d at 1276-77.

B.

The Alliance also alleges standing on behalf of its members. The standard for representational standing is well-established:

> [A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

United Food & Commercial Workers, 517 U.S. at 553 (quoting *Hunt*, 432 U.S. at 343). The only question here is whether a member of the Alliance would have standing to sue in his or her own right.

In the amended complaint, the Alliance alleges that its members include "terminally ill individuals whose best chance

of survival is to obtain access to certain drugs with a record of clinical success in pre-approval testing, but which have not yet been approved by the FDA for marketing." Am. Compl. ¶ 7. The Alliance further alleges that these members had been unable to gain access to clinical trial programs and that any request to the FDA for entry into an expanded access program is futile in light of its current regulations. *Id.*; *see also* Decl. of Steven Walker ¶¶ 4-16.

The amended complaint and accompanying affidavits reference seven members of the Alliance. Am. Compl. ¶ 22 (Abigail Burroughs); *id.* ¶ 23 (David Baxter); *id.* ¶ 24 (Alita Randazzo); *id.* ¶ 25 (Joel Oppenheim); Decl. of Victoria Jean Doran ¶¶ 2, 6-7 (Patrick Joseph Smid, Jr.); Decl. of Carole Steele ¶¶ 2, 6-8 (James Michael Steele); Decl. of Shari Kahane ¶¶ 1-2 (herself). Burroughs, Baxter, and Randazzo had already died when the complaint was filed. As a result, they cannot be the source of our jurisdiction, *see Friends of the Earth*, 528 U.S. at 191.

It is understandably difficult for the Alliance to produce the affidavits typically used to establish standing. Because of the nature of their predicaments, many of those Alliance members who were members on July 28, 2003, when the complaint was filed, have succumbed to their terminal illnesses. However, the allegations in the complaint supplemented by the affidavits supplied by the Alliance establish that "at least one member . . . has standing to pursue this challenge," *Am. Library Ass'n v. FCC*, 406 F.3d 689, 696 (D.C. Cir. 2005).

Joel Oppenheim was a member of the Alliance when the initial complaint was filed. He suffered injury-in-fact that was traceable to the FDA and redressable by judicial action. Oppenheim was diagnosed with multiple myeloma in 1995. The disease became active in 1999. Am. Compl. ¶ 25. He was

treated with dexamethadrone ("dex") and thalidomide, the latter of which was FDA-approved only to treat leprosy but was still available to Oppenheim under FDA policies as an off-label use. *Id.*; *see Abigail Alliance*, 445 F.3d at 483. As his condition worsened, his oncologists recommended that he seek access to Revamid or PS-341 Velcade, two medications that were not yet FDA-approved but were available in clinical trials. Am. Compl. ¶ 26. Oppenheim "was unable to obtain a place in the Revamid trials or Velcade trials because [of] his prior treatment with dex." *Id.* As a result, he was kept on thalidomide "for a period much longer than his physician thought advisable," Decl. of Steven Walker ¶ 21, and was forced to undergo "a dangerous and damaging" autologous bone marrow transplant that "had been made necessary by his lack of access to Velcade or Revamid," Am. Compl. ¶¶ 27-28. As Oppenheim's cancer continued to worsen, he continued to seek access to Velcade trials but continued to be rejected. *Id.* ¶ 28. In desperation, he stopped taking any medication in order to make himself eligible to enter a trial. *Id.* He finally was admitted to a trial of Revamid just before the initial complaint was filed. *Id.* However, the years of delay had severely diminished Oppenheim's chances of responding to the medication because cancers like Oppenheim's mutate as the disease progresses and his excessive exposure to thalidomide likely made him resistant to the chemically-similar Revamid. Decl. of Steven Walker ¶ 21. Oppenheim died before Revamid was approved by the FDA earlier this year. *Id.* ¶ 22.

Oppenheim's injury is clear. When he had no other medically-feasible options, he was denied access to a medication that had saved others' lives. That he was ultimately able to join a clinical trial—and subjected to the harsh limitations on his medical care that accompany such trials—well after the medication's period of likely effectiveness had come and gone does not make him less injured. The FDA challenges whether

this result was caused by its actions and whether judicial action can redress injuries like Oppenheim's. We hold that the Alliance has made the requisite showings.

For standing to be proper, it must be that the injury "fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court." *E. Ky. Welfare Rights Org.*, 426 U.S. at 41-42. The FDA claims that Alliance members like Oppenheim have not properly sought individual-use approval and that their inability to access investigational new drugs that have survived Phase I clinical trials thus cannot be attributed to the FDA.

The Alliance responds that its terminally-ill members cannot be required to apply for individual-use approval from the agency when the FDA procedures they challenge are "effectively inoperative," Decl. of Steven Walker ¶ 5, and make success virtually impossible. Taking the sworn statements supplied by the Alliance as true, requests for individual use "are in all material and regulatory aspects clinical trials that effectively cannot be requested or initiated by any patient or any physician." *Id.* The net result is that for this approach to succeed, a sponsor must have a preexisting program approved by the FDA, an Institutional Review Board must grant its approval, and the patient must meet the restrictive eligibility requirements of the sort that failed Oppenheim time and again. *Id.* ¶ 6. The FDA controls these programs so that they are "almost never available until the months prior to FDA approval." *Id.* ¶ 8. Furthermore, the FDA has an acknowledged "private stance on expanded access" that, unsurprisingly, pharmaceutical companies awaiting approval are unwilling to violate. *Id.* ¶ 15; *see also* Decl. of Shari Kahane ¶ 15.

The Alliance's amended complaint and accompanying

affidavits make clear that many hurdles impeding Alliance members from accessing post-Phase I investigational new drugs have been erected by the FDA. This is sufficient to establish causation.

The FDA challenges redressability on the grounds that, even if its regulations were changed, it is merely speculation that drug manufacturers would sell their investigational medications to members of the Alliance. Its reliance on *National Wrestling Coaches Ass'n v. Department of Education*, 366 F.3d 930 (D.C. Cir. 2004), is misplaced. In that case, wrestling coaches were found to lack standing because, in order for their injuries to be redressed, a wrestling program would have to be reinstated, possibly at the expense of another men's athletic program, and no school had indicated an inclination to do so. *See id.* at 936-40. Here, it would be in the drug companies' pecuniary interests to expand access to experimental drugs and thereby develop a market, particularly if the FDA allows them to charge market prices. This makes the question of redressability a hardly-speculative exercise in naked capitalism, and our skepticism from *National Wrestling Coaches Ass'n* need not transfer. The FDA also maintains that elimination of the regulation would not change the FDA's alleged hostility to access or the drug companies' fear of reprisal, but the agency's perceived hostility to access will no doubt diminish if it rescinds the regulation that sets up the barrier to compassionate use programs in the first place.

That Oppenheim died before the lawsuit was resolved does not divest the federal courts of jurisdiction. If the Alliance establishes a "continuing interest" that survives Oppenheim's death, *Friends of the Earth*, 528 U.S. at 191-92; *see Sosna v. Iowa*, 419 U.S. 393, 402 (1975), then the court may continue to hear the case. The affidavit of Alliance member Shari Kahane makes this showing.

Kahane suffers from metastasized breast cancer and has exhausted standard treatments for her condition. Decl. of Shari Kahane ¶¶ 3, 11-12. Her declaration addresses injury-in-fact, causation, and redressability. *See Am. Library Ass'n*, 406 F.3d at 696. The injury-in-fact is Kahane's inability to obtain potentially life-saving treatments. Her injury is traceable to FDA policies because, notwithstanding the likely failure, she has sought access to "compassionate use" programs of experimental drugs and has been told that FDA regulations "are preventing [drug companies] from providing [her] with access." Decl. of Shari Kahane ¶ 15. This injury would be redressable by judicial action, according to Kahane, because "manufacturers of those medications have indicated that they would be likely to make those medications available to cancer patients outside of their clinical trials if . . . [the] FDA did not make it so difficult to establish 'compassionate use programs' and if manufacturers were permitted to charge market prices for their medications." *Id.*

Even if the Alliance could not supply a particular terminally-ill member, at each moment, who has exhausted all conventional treatments but has not died, this is a classic case of a situation "capable of repetition, yet evading review." *S. Pac. Terminal Co. v. ICC*, 219 U.S. 498, 515 (1911). By the very nature of its membership, the Alliance has a reasonable expectation that its members will continue to suffer the same short-lived injuries that this doctrine addresses. *Cf. Weinstein v. Bradford*, 423 U.S. 147, 149 (1975) (per curiam); *Sosna*, 419 U.S. at 402.

Having satisfied all of the requirements, the Alliance has adequately pleaded representational standing.[1]

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[1] Because we hold that the Alliance has standing premised on the specific grounds of organizational and representational standing,

II.

On the merits, we remain convinced that "the Alliance's claim . . . falls squarely within the realm of rights the Supreme Court has held are 'implicit in the concept of ordered liberty'" that enjoy special protection from the Due Process Clause. *Abigail Alliance*, 445 F.3d at 483-84 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).

The narrowly-defined liberty interest that is articulated in *Abigail Alliance*, *id.* at 472, is consistent with the treatment of such rights by the Supreme Court, which has said:

> In a long line of cases, we have held that, in addition to the specific freedoms protected by the Bill of Rights, the "liberty" specially protected by the Due Process Clause includes the rights to marry, *Loving v. Virginia*, 388 U.S. 1 (1967); to have children, *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942); to direct the education and upbringing of one's children, *Meyer v. Nebraska*, 262 U.S. 390 (1923); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925); to marital privacy, *Griswold v. Connecticut*, 381 U.S. 479 (1965); to use contraception, *ibid.*; *Eisenstadt v. Baird*, 405 U.S. 438 (1972); to bodily integrity, *Rochin v. California*, 342 U.S. 165 (1952), and to abortion, [*Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992)]. We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment. *Cruzan* [*v. Dir., Mo. Dep't of Health*, 497

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we do not reach the Alliance's broader claim that, notwithstanding its members' inability to *obtain* life-saving medication, they suffer injury-in-fact merely by facing a barrier to access.

U.S. 261 (1990)].

Washington v. Glucksberg, 521 U.S. 702, 720 (1997). We see no reason to retreat from the analysis set forth in *Abigail Alliance*. Alliance members who are terminally ill and who lack government-approved treatment options have a due process interest in self-determination that protects their pursuit of promising new medications to save their lives.

On rehearing the FDA attempts to construe the Alliance's due process claim as seeking "a right of access to unapproved experimental drugs." Appellees' Petition for Panel Rehearing and Rehearing En Banc at 6 [hereinafter "Petition"]. In so doing, the FDA confuses the means of enforcing the right with the right itself. As the court recognized, the Alliance seeks to enforce "the right of terminally ill patients to make an informed decision that may prolong life." *Abigail Alliance*, 445 F.3d at 477. As their lives hang in the balance, they ask "that the decision to assume . . . known or unknown risks be left to the terminally ill patient and not to the FDA." *Id.* at 478. So described, this right to self-determination is so fundamental that it is no wonder that no federal law has needed to articulate its precise boundaries. A unanimous declaration sent to England's King George III more than two centuries ago noted that the "unalienable Rights" of "Life, Liberty and the pursuit of Happiness" were "self-evident." THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776). Justice Cardozo found no difficulty applying this principle in the celebrated case of *Schloendorff v. Society of the New York Hospital*, 105 N.E. 92 (N.Y. 1914), *overruled on other grounds by Bing v. Thunig*, 143 N.E. 2d 3 (N.Y. 1957), where he noted that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body." *Id*. at 93. The Supreme Court has reinforced the manifest clarity of this cardinal right: "It cannot be disputed that the Due Process Clause protects an

interest in life as well as an interest in refusing life-saving medical treatment." *Cruzan*, 497 U.S. at 281.

Moreover, in taking issue with the history of drug regulation confirmed by no less than an FDA historian, *see Abigail Alliance*, 455 F.3d at 482 n.13, and others, *see, e.g.*, EDWARD KREMERS & GEORGE URDANG, HISTORY OF PHARMACY 271-79 (2d ed. 1951), the FDA ignores the crucial distinction between regulation for *safety* and regulation for *efficacy*. *See Abigail Alliance*, 445 F.3d at 483. The FDA's acknowledgment that it has been "[d]eveloping policies for treatment uses of investigational drugs . . . for more than twenty years," Petition at 13, only underscores the newness of the federal government's endeavors to restrict the ability of the terminally ill to determine their own best course.

It bears repeating that the recognition of a liberty interest does not end this case. As the Supreme Court acknowledged in addressing a due process challenge to state-mandated inoculation for smallpox, even "the inherent right of every freeman to care for his own body and health in such way as to him seems best" is not "absolute," *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905). In assessing that liberty interest, which is strikingly similar to the interest this court addressed, the Supreme Court in *Jacobson* observed that it "has more than once recognized it as a fundamental principle that 'persons and property are subjected to all kinds of restraints and burdens,'" *id.* (quoting *R.R. Co. v. Husen*, 95 U.S. 465, 471 (1878)), and that liberty could be compromised when "'essential to the safety, health, peace, good order and morals of the community,'" *id.* (quoting *Crowley v. Christensen*, 137 U.S. 86, 89 (1890)). Neither in our opinion nor now do we prejudge whether the FDA policy challenged here outweighs the Alliance members' interests in self-determination; we require further inquiry by the district court on remand as to the FDA's countervailing interests.

See Abigail Alliance, 455 F.3d at 407. At that time, concerns expressed by the FDA about the implications for federal drug regulation, *see* Petition at 2, 4, 7, 14-15, can be addressed on the basis of fulsome briefing not previously provided.

Accordingly, we deny the petition for rehearing. Although the Alliance reminds the court that it has an additional basis for its claims, *see* Appellants' Response to Petition for Rehearing and Rehearing En Banc at 10-12; *Abigail Alliance*, 445 F.3d at 476, based on the demands of "personal dignity and autonomy" when human life depends upon medical decision-making, *Casey*, 505 U.S. at 851, it suffices for the court to hold that the Alliance has Article III standing and to reaffirm the analysis in *Abigail Alliance*, 445 F.3d 470, without reaching the Alliance's other grounds for its claim. The Alliance's other grounds are properly preserved.

GRIFFITH, *Circuit Judge*, concurring in part, dissenting in part: Although I agree that Abigail Alliance has made a sufficient showing of standing at this stage in the proceedings, for the reasons set forth in my dissent, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470, 486-500 (D.C. Cir. 2006), I would vote to grant the petition for rehearing.