

PUBLISHED

**UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

MARY SCOTT DOE, a human embryo "born" in the United States (and subsequently frozen in which state of cryopreservation her life is presently suspended), individually and on behalf of all other frozen human embryos similarly situated; NATIONAL ORGANIZATION FOR EMBRYONIC LAW (NOEL); NIGHTLIGHT CHRISTIAN ADOPTIONS; PETER MURRAY; SUZANNE MURRAY; COURTNEY ATNIP; TIM ATNIP; STEVEN B. JOHNSON; KATE ELIZABETH JOHNSON; CORA BEST; GREGORY BEST,

Plaintiffs-Appellants,

v.

BARACK HUSSEIN OBAMA, in his official capacity as President of the United States; CHARLES E. JOHNSON, in his official capacity as acting secretary of the Department of Health & Human Services; RAYNARD S. KINGTON, in his official capacity as acting director of the National Institutes of Health,

Defendants-Appellees.

No. 10-1104

MARY SCOTT DOE, a human embryo "born" in the United States (and subsequently frozen in which state of cryopreservation her life is suspended), individually and on behalf of all other frozen human embryos similarly situated; NATIONAL ORGANIZATION FOR EMBRYONIC LAW (NOEL); PETER MURRAY; SUZANNE MURRAY; COURTNEY ATNIP; TIM ATNIP; STEVEN B. JOHNSON; KATE ELIZABETH JOHNSON; CORA BEST; GREGORY BEST,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, In her official capacity as Secretary of the Department of Health & Human Services; FRANCIS S. COLLINS, In his official capacity as director of the National Institutes of Health,

Defendants-Appellees.

No. 10-1106

Appeals from the United States District Court
for the District of Maryland, at Greenbelt.
Alexander Williams, Jr., District Judge.
(8:09-cv-00755-AW; 8:09-cv-02197-AW)

Argued: December 7, 2010

Decided: January 21, 2011

Before TRAXLER, Chief Judge, and WILKINSON and
SHEDD, Circuit Judges.

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Chief Judge Traxler and Judge Shedd joined.

COUNSEL

ARGUED: Rudolph Martin Palmer, Jr., Hagerstown, Maryland, for Appellants. Benjamin Seth Kingsley, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** Tony West, Assistant Attorney General, Mark B. Stern, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., Rod J. Rosenstein, United States Attorney, Baltimore, Maryland, for Appellees.

OPINION

WILKINSON, Circuit Judge:

Plaintiffs in this case challenge the federal funding of research involving embryonic stem cells. The district court dismissed the suit for want of standing. We appreciate the sensitivity of the underlying issue and respect the sincerity of arguments on all sides of the question. However, as a matter of law, the principles of standing enunciated by the Supreme Court mandate an affirmance of the judgment.

I.

Human embryonic stem cells (hESCs) are valued by scientific researchers for their ability to transform into any type of

cell in the human body. They are derived from embryos, largely embryos created via in vitro fertilization (IVF) for reproductive purposes and donated for research when no longer needed for that reason. The process of creating hESCs generally results in the destruction of the embryo. Embryos not donated for research can also be made available for adoption.

In addition to technical discussions, the issue of stem cell research has elicited debate on the role of science in alleviating human suffering and the relationship of science to the sanctity of life. Federal funding guidelines have not surprisingly proven controversial. Although hESCs have been available for research since 1998, the National Institutes of Health (NIH) did not fund research involving hESCs until 2001. That funding, however, was restricted to research involving hESCs derived from stem cell lines already in existence. *See* Address to the Nation on Stem Cell Research from Crawford, Tex., 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001); *see also* Exec. Order No. 13435, 72 Fed. Reg. 34591 (June 20, 2007). On March 9, 2009, President Obama issued Executive Order 13505, 74 Fed. Reg. 10667, removing that restriction and expanding federal funding of hESC research. Executive Order 13505 also directed the NIH to issue new guidelines on that research. The NIH responded on July 7, 2009 with final Guidelines for Human Stem Cell Research ("NIH Guidelines"). 74 Fed. Reg. 32170.

Two sets of plaintiffs in these consolidated cases challenge Executive Order 13505 and the NIH Guidelines. Plaintiff Mary Scott Doe represents a putative class of all frozen embryos held throughout the United States for either research or adoption purposes. The other plaintiffs are several parents who have children that were adopted as frozen embryos and who are considering adopting embryos again. Together, plaintiffs argue that the new hESC policies violate the Thirteenth and Fourteenth Amendments, the Administrative Procedure Act, and the Dickey-Wicker Amendment, Pub. L. No. 111-8,

div. F, Title V, § 509(a)(2), 123 Stat. 524, 803, a restriction on NIH funding which bars the use of federal funds for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." The district court dismissed both lawsuits for lack of standing. Plaintiffs now appeal.

II.

We are not at liberty to resolve every grievance over government policy, no matter how significant, for "Article III of the Constitution confines the federal courts to adjudicating actual 'cases' and 'controversies.'" *Allen v. Wright*, 468 U.S. 737, 750 (1984). The Supreme Court has made clear that "standing is an essential and unchanging part" of that case-or-controversy requirement, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992), one that "state[s] fundamental limits on federal judicial power in our system of government," *Allen*, 468 U.S. at 750. To satisfy that constitutional requirement, a plaintiff must demonstrate:

(1) it has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180-81 (2000). We review de novo the district court's decision to dismiss for lack of standing. *Bishop v. Bartlett*, 575 F.3d 419, 423 (4th Cir. 2009).

III.

Plaintiffs first assert that the class of all human embryos currently held at IVF clinics throughout the country, including

named plaintiff Mary Scott Doe, have standing to assert their constitutional and statutory rights.

A.

Plaintiffs contend that the class of frozen embryos is threatened with injury sufficient for standing because Executive Order 13505 and the NIH Guidelines increase the embryos' risk of being reduced to embryonic stem cells. By itself, this contention is insufficient. The Supreme Court has made clear that "named plaintiffs who represent a class 'must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.'" *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n.20 (1976) (quoting *Warth v. Seldin*, 422 U.S. 490, 501 (1975)). Without a sufficient allegation of harm to the named plaintiff in particular, plaintiffs cannot meet their burden of establishing standing.

We cannot identify a particularized harm because the complaint does not identify any of the named plaintiff's particularized characteristics. Instead, it leaves us only with questions such as whether the embryo will ever be used for research and whether that research will be funded by the NIH. We have no idea under what terms the named plaintiff embryo was donated or stored or what its status even is. In the absence of answers, the chosen appellation of Mary Scott Doe could equally designate any member of an amorphous frozen embryo class. Indeed, the complaint even states that Mary Scott Doe may be one of the embryos donated for adoption.*

*Plaintiffs reversed course in a subsequent motion before this court, arguing that the named plaintiff is actually a construct "representing the next human embryo to be vivisected in the nation at any given moment of time." *Motion for Preventive Injunction* at 10. Even if such hypothetical litigants could have standing, this one cannot lest *Simon's* instruction that "named plaintiffs who represent a class must allege and show that they personally have been injured," be rendered a nullity. 426 U.S. at 40 n.20 (internal quotation omitted).

JA 15. Because the class of frozen embryos includes several subsets, we have no way of knowing whether "the claims or defenses of the representative part[y] are typical of the claims or defenses of the class," Fed. R. Civ. P. 23(a)(3), which is to say whether the named plaintiff is threatened with the harm plaintiffs impute to the class as a whole.

While plaintiffs attempt to bypass the requirement of particularized harm by asserting that all frozen embryos are threatened with harm, this is not a sound contention. The NIH Guidelines permit funding for research involving only stem cells from embryos "donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32174. Plaintiffs offer no reason to think, for example, that embryos already donated for adoption are at any risk for the injury allegedly caused by the Guidelines. Moreover, the complaint provides no basis to conclude that the named plaintiff in particular will be part of the subset that suffers any injury at all, much less an injury due to the challenged government policy. Because the injury-in-fact test requires "that the party seeking review be himself among the injured," *Sierra Club v. Morton*, 405 U.S. 727, 735 (1972), we cannot conclude that these plaintiffs have alleged a "concrete and particularized" harm, *Friends of the Earth*, 528 U.S. at 180.

B.

There is an additional difficulty with the embryo plaintiffs' claim of standing. "[T]he 'case or controversy' limitation of Art. III still requires that a federal court act only to redress injury that 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." *Simon*, 426 U.S. at 41-42. Here, the NIH Guidelines restrict funding to research involving stem cells "[t]hat were created using in vitro fertilization for reproductive purposes and were no lon-

ger needed for this purpose" and "[t]hat were donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32174. Thus, the independent decision of biological parents to donate embryos for research is an intervening cause of the injury that plaintiffs assert on behalf of the embryos.

The conclusion that the injury asserted is not fairly traceable to Executive Order 13505 or the NIH Guidelines follows from the Supreme Court's pronouncements. In *Allen*, the Court addressed an allegation that the Internal Revenue Service (IRS) failed to ensure that racially discriminatory private schools were denied tax-exempt status. Though the plaintiffs had suffered a cognizable injury in the form of a reduced ability to attend a racially integrated school, the conclusion that "withdrawal of a tax exemption from any particular school would lead the school to change its policies" or that "any given parent of a child attending such a private school would decide to transfer the child to a public school as a result" was "entirely speculative." 468 U.S. at 758.

Likewise in *Simon*, the Court found it "purely speculative" to conclude that nonprofit hospitals would provide expanded care to indigent patients if their tax-exempt status were threatened. 426 U.S. at 42-43. *Allen* and *Simon* illustrate a fundamental tenet of standing doctrine: where a third party such as a private school or hospital makes the independent decision that causes an injury, that injury is not fairly traceable to the government. Here, the mere fact that the government permits private donors to choose to donate their embryos for research does not therefore make that decision fairly traceable to Executive Order 13505 or the NIH Guidelines.

Plaintiffs recognize the role of the biological parents' decision, but nevertheless maintain that the decision is not truly independent. In their view, "the decisions of genetic parents of embryos whether or not to donate their unused embryos for

experimentation will be powerfully influenced" by the additional funding available under the new policy. *Brief of Appellants* at 43. But this argument cannot salvage plaintiffs' claim that any injury is fairly traceable to the challenged policies.

The NIH Guidelines already acknowledge the possibility that researcher demand for embryos driven by additional funding could influence the decision of biological parents to donate their embryos for research, and address that concern with several strict conditions. First, the Guidelines require that "[n]o payments, cash or in kind, [be] offered for the donated embryos." 74 Fed. Reg. at 32174. Second, they demand that "[p]olicies and/or procedures [be] in place at the health care facility where the embryos [are] donated that neither consenting nor refusing to donate embryos for research would affect the quality of care provided to potential donor(s)." *Id.* Third, the Guidelines require a "clear separation" between the decisions to create embryos and to donate them, a separation requiring that "[d]ecisions related to the creation of human embryos for reproductive purposes [be] made free from the influence of researchers proposing to derive or utilize hESCs in research." *Id.* Where government policy not only allows the biological parents to choose what to do with their embryos, but also safeguards the independence of their decision with strict conditions, the connection between injury and policy is a "purely speculative" one. *Simon*, 426 U.S. at 42.

IV.

Plaintiffs also assert that the parents who "are actively considering adopting" human embryos have standing to challenge Executive Order 13505 and the NIH Guidelines. Assuming, without deciding, that these parents are proper parties to bring claims on behalf of the embryos, the parents themselves still must show the "irreducible constitutional minimum" of an injury in fact that is "'fairly . . . trace[able] to the challenged action of the defendant'" and that will likely be "'redressed by

a favorable decision.'" *Lujan*, 504 U.S. at 560-61 (alterations in original) (quoting *Simon*, 426 U.S. at 38, 41).

A.

The parents do not allege that they have already suffered an injury. Instead, they claim that they face the threat of a future injury, namely that implementation of Executive Order 13505 will "reduce the number of *in vitro* human embryos available for adoption" such that they will be unable to adopt. *Brief of Appellants* at 53. However, they do not allege facts from which we can infer that such an injury would be "actual or imminent." *Lujan*, 504 U.S. at 564.

In *Lujan*, the Supreme Court addressed an analogous injury. There two plaintiffs challenged a regulation that interpreted a provision of the Endangered Species Act not to apply to foreign nations. The plaintiffs claimed to have standing because they had visited other countries to observe endangered species and intended to do so again in the future. *Id.* at 563-64. The Supreme Court found these indefinite plans insufficient to confer standing: "Such 'some day' intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the 'actual or imminent' injury that our cases require." *Id.* at 564.

Lujan's requirement that plaintiffs have some concrete plan constrains us here. The entirety of plaintiffs' allegation in the complaint is that some of the parents "continue to consider the adoption of and/or seek to adopt additional *in vitro* human embryos." JA 43. Although "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice," *Lujan*, 504 U.S. at 561, plaintiffs are not excused from the constitutional prerequisite of alleging an injury that "is 'certainly impending,'" *id.* at 565 n.2 (emphasis in original) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). The imminence requirement is "stretched beyond the

breaking point when, as here, the plaintiff alleges only an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Id.* Thus the Supreme Court has "insisted that the injury proceed with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all." *Id.* The plaintiff parents here did not allege that they have already tried and failed to adopt embryos, nor do they allege any concrete plans for future adoption, so the possibility that they will never suffer the alleged injury looms too large.

B.

Moreover, like the class of frozen embryos, the plaintiff parents cannot establish that the claimed injury is fairly traceable to Executive Order 13505 or the NIH Guidelines. As the district court correctly noted, "it is the donor's choice which could potentially reduce the number of human embryos for adoption and not the Defendants' conduct which 'causes' Plaintiffs' alleged injury." JA 324. The parents' claim of standing thus falters for largely the same reasons identified in part III.B. *supra*.

V.

Our conclusion that plaintiffs cannot establish standing in this case is a narrow one, for we do not suggest that no party would ever have standing to assert similar claims. The bar of standing must not be set too high, lest many regulatory actions escape review contrary to the intent of Congress. *See* Administrative Procedure Act, 5 U.S.C. § 702 ("A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.").

A complaint that provided more concrete information about the identity of the named plaintiff embryo or the plaintiff par-

ents' plans for adoption would at least address more directly what the Supreme Court has identified as serious constitutional concerns. A sister circuit has concluded that certain scientists who compete directly with hESC researchers for NIH funding have "competitor standing" to bring related claims. *See Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010). The *Sherley* plaintiffs were doctors that "specialize in adult stem cell research," *id.* at 71, and in order to compete with embryonic stem cell researchers for NIH funding, they would "have to invest more time and resources to craft a successful grant application," *id.* at 74. That injury—an increased risk that a government agency would choose not to fund the doctors' research—is not alleged here. *See id.* at 72.

We express no opinion on the standing issue in *Sherley* or any other case not presently before this court, but simply note that such cases are different from the one that is before us. In the absence of a showing that the Supreme Court's requirements for standing have been met in this particular case, the complaint presents what is essentially a policy dispute over the administration's approach to stem cell research. We do not doubt for a moment the sincerity of those who oppose, as well as those who support, the revised NIH funding guidelines. But depth of conviction, while admirable, cannot serve to displace the courts' own deep attachment to the law. "Recognition of standing in such circumstances would transform the federal courts" into more political organs, less differentiated from the workings of the political branches whose actions we are now requested to review. *See Allen*, 468 U.S. at 756. Because "[c]onstitutional limits on the role of the federal courts preclude such a transformation," *id.*, we affirm the judgment of the district court.

AFFIRMED