

DO EMBRYOS HAVE CONSTITUTIONAL RIGHTS?: *DOE V. OBAMA*

Scientists can cause stem cells to function as any number of specific types of cell, and therefore, stem cell research has the potential to yield treatments for many diseases.¹ While adult stem cells are somewhat specialized, stem cells derived from embryos, known as human embryonic stem cells (hESCs), are pluripotent, which means they are able to transform into nearly any type of cell in the human body.² Accordingly, hESCs are highly valuable to scientific researchers.³ Generally, embryos that are turned into hESCs are created via in vitro fertilization (IVF) and donated for stem cell research when they are no longer needed for reproductive purposes and are not made available for adoption.⁴ When researchers create a stem cell line from the embryo, the embryo is destroyed.⁵ Thus, the issue of stem cell research has been controversial, both within the scientific field and as a moral issue regarding the role of science in curing disease and preserving life.⁶ While many believe that stem cell research is essential to developing cures for certain illnesses, many others posit that the destruction of a human embryo in the process of creating an hESC is the equivalent of killing human life, and therefore, researchers should pursue non-embryonic sources of stem cell research.⁷ Accordingly, the issue of whether the federal government should fund stem cell research has proven contentious.⁸

The Dickey-Wicker Amendment⁹ was passed by Congress and signed by President Bill Clinton in 1996.¹⁰ The Dickey-Wicker Amendment prohibits the Department of Health and Human Services and the National Institutes of Health (NIH) from using appropriated federal government funds to create human embryos for research, or from conducting research in which human embryos are destroyed or “knowingly subjected to risk of injury or death.”¹¹ The Amendment specifically defines “embryo” to mean “any organism, not protected

-
1. *Sherley v. Sebelius*, 610 F.3d 69, 70 (D.C. Cir. 2010).
 2. *Sherley v. Sebelius*, 644 F.3d 388, 390 (D.C. Cir. 2011). Induced pluripotent adult stem cells were recently developed. *Id.*
 3. *Doe v. Obama*, 631 F.3d 157, 159 (4th Cir. 2011), *cert. denied*, 131 S. Ct. 2938 (2011).
 4. *Id.*
 5. *Id.*
 6. *Id.*
 7. *Doe v. Obama*, 670 F. Supp. 2d 435, 437 (D. Md. 2009), *aff'd*, 631 F.3d 157 (4th Cir. 2011). Former President George W. Bush noted in a statement on August 9, 2001, that diseases that could potentially benefit from stem cell research included “juvenile diabetes . . . Alzheimer’s . . . Parkinson’s . . . and spinal cord injuries.” President George W. Bush, Address to the Nation on Stem Cell Research from Crawford, Texas (Aug. 9, 2001), *available at* <http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>.
 8. *Doe*, 631 F.3d at 159.
 9. Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, Division F, Title V, § 509(a), 123 Stat. 524, 803 (2009).
 10. *See Doe*, 670 F. Supp. 2d at 437.
 11. *Id.* (quoting Omnibus Appropriations Act § 509(a)).

as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”¹²

On August 9, 2001, President George W. Bush, in an attempt to balance the potential benefits of stem cell research with moral and ethical concerns, stated that he would permit federal funding only on stem cell lines from embryos that were already destroyed and derived by private or foreign researchers.¹³ Consequently, on June 20, 2007, President Bush issued Executive Order 13435, which banned federally funded stem cell research on all stem cell lines created after August 9, 2001.¹⁴

President Barack Obama specifically revoked Bush’s Executive Order 13435 on March 9, 2009 with his own Executive Order 13505 and a declaration that “Bush’s August 9 statement [is] no longer effective as a statement of governmental policy.”¹⁵ Executive Order 13505 allowed the NIH to “support and conduct responsible, scientifically worthy human stem cell research to the extent permitted by law.”¹⁶ The NIH subsequently issued draft guidelines on April 23, 2009,¹⁷ and final guidelines on July 7, 2009.¹⁸ The NIH Guidelines explained that researchers could apply for federal funding for new stem cell lines, provided that the lines are derived from unused IVF embryos donated for scientifically meritorious research purposes.¹⁹ The NIH Guidelines also contained specific safeguards that required proper informed consent from the donor to ensure that the donor would not be unduly influenced into donating the embryo for research.²⁰

In January 2011, the Fourth Circuit Court of Appeals decided *Doe v. Obama*.²¹ *Doe* was filed in Maryland district court as a response to Executive Order 13505 and the NIH Guidelines.²² The named plaintiffs were Mary Scott Doe, a human embryo frozen in cryo-preservation in the United States for either research or adoption, on behalf of herself and those similarly situated; the National Organization for Embryonic Law (NOEL); and four married couples, putative future adopters of human embryos.²³ Plaintiffs sought a declaratory

12. Omnibus Appropriations Act § 509(b).

13. *Doe*, 670 F. Supp. 2d at 437 (citing Bush, *supra* note 7).

14. *Id.* (citing Exec. Order No. 13,435, 3 C.F.R. 222 (2007), *revoked by* Exec. Order No. 13,505, 3 C.F.R. 229 (2009)).

15. *Id.* at 437–38 (citing Exec. Order No. 13,505, 3 C.F.R. 229, 230 (2009)). President Obama’s Executive Order 13,505 was titled “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.” *Id.* (citing Exec. Order No. 13,505, 3 C.F.R. 229, 229 (2009)).

16. Exec. Order No. 13,505, 3 C.F.R. 229, 229 (2009).

17. *Doe*, 670 F. Supp. 2d at 438.

18. National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,170 (July 7, 2009) [hereinafter NIH Guidelines].

19. *Doe*, 670 F. Supp. 2d at 438; NIH Guidelines, *supra* note 18, at 32,171.

20. *Doe*, 670 F. Supp. 2d at 438; NIH Guidelines, *supra* note 18, at 32,174–75.

21. *Doe v. Obama*, 631 F.3d 157 (4th Cir. 2011), *cert. denied*, 131 S. Ct. 2938 (2011).

22. *Id.* at 159; 670 F. Supp. 2d at 435, 436–37.

23. *Doe*, 670 F. Supp. 2d at 436.

judgment and an injunction, claiming that Executive Order 13505 violated both the Dickey-Wicker Amendment and the embryos' "constitutional rights to due process, equal protection, and freedom from involuntary servitude under the Fifth, Fourteenth, and Thirteenth Amendments."²⁴ The Maryland district court dismissed the litigation for lack of standing.²⁵

Doe and the putative adoptive parents appealed, and the Fourth Circuit Court of Appeals affirmed the district court.²⁶ The Fourth Circuit cited judicial restraint, and averred that a court is "not at liberty to resolve every grievance over government policy, no matter how significant" due to the Article III limitation that federal courts adjudicate only actual "cases" and "controversies."²⁷ The case-or-controversy constraint encompasses the requirement that a plaintiff must have standing to bring a claim.²⁸ To show standing, the plaintiff must demonstrate three elements. The first is that he or she has suffered an "'injury in fact' that is . . . concrete and particularized and . . . actual or imminent, not conjectural or hypothetical."²⁹ The second requirement is that "the injury is fairly traceable to the challenged action of the defendant."³⁰ The final requirement is that the plaintiff must show that it is likely, not merely speculative, that the injury will be rectified by a decision in the plaintiff's favor.³¹

The court held that the named plaintiff of the class of frozen embryos could not prove a sufficiently "concrete and particularized" injury in fact to establish standing.³² The plaintiffs contended that the frozen embryos suffered an injury in fact because Executive Order 13505 and the NIH Guidelines increased the embryos' risk of being reduced to hESCs.³³ However, this was insufficient under Supreme Court precedent, which requires 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.'"³⁴ The court explained that, without any indication of Doe's "particularized characteristics," there was a question as to whether Doe herself would actually be used for NIH-funded

24. *Id.* at 436–37.

25. *Id.* at 442.

26. *Doe*, 631 F.3d at 159.

27. *Id.* at 160 (quoting *Allen v. Wright*, 468 U.S. 737, 750 (1984)) (internal quotation marks omitted).

28. *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

29. *Id.* (quoting *Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000)).

30. *Id.* (quoting *Friends of the Earth*, 528 U.S. at 180) (internal quotation marks omitted).

31. *Id.* (quoting *Friends of the Earth*, 528 U.S. at 181).

32. *Id.* at 161 (quoting *Friends of the Earth*, 528 U.S. at 180) (internal quotation marks omitted).

33. *Id.* at 160.

34. *Id.* (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n.20 (1976)) (internal quotation marks omitted).

research and not for privately funded research or adoption.³⁵ Therefore, plaintiffs could not show “that the party seeking review be himself among the injured,” as required for injury in fact.³⁶

The Fourth Circuit further held that the injury to Doe could not fairly be traced to the defendant’s challenged actions.³⁷ NIH Guidelines restricted federal funding to research for hESCs “created using in vitro fertilization for reproductive purposes and no longer needed for this purpose” and subsequently “donated by individuals who sought reproductive treatment” and gave informed consent for the embryos to be used for research.³⁸ Therefore, the court determined that the choice of the biological parents to donate the embryos was an intervening cause of the asserted injury.³⁹ Although the plaintiffs alleged that the new policy would be extremely persuasive in the biological parents’ decision to donate the embryos to research, the Fourth Circuit held that this was insufficient to establish that the injury was fairly traceable to Executive Order 13505 or the NIH Guidelines.⁴⁰ Furthermore, the NIH Guidelines addressed the possibility of undue influence by prohibiting payments for the embryos, requiring policies and procedures to ensure that the quality of health care is equal, regardless of the donors’ choice, and necessitating a “clear separation” between the decision to create the embryo and the decision to donate the embryo to research.⁴¹ Thus, the Fourth Circuit determined that the relationship between the injury and the challenged Executive Order and NIH Guidelines was “purely speculative” because the biological parents were given a choice, protected by certain safeguards to ensure that there was no undue influence, as to whether to donate the embryos.⁴²

The Fourth Circuit held that, regardless of its determination that the alleged injury was not fairly traceable to Executive Order 13505 or the NIH Guidelines, the putative adoptive parents failed to show injury in fact.⁴³ The putative adoptive parents alleged that they were considering adopting in vitro human embryos and that defendants’ actions would “reduce the number of IVF-derived embryos available for adoption.”⁴⁴ The court concluded that plaintiffs did not

35. *Id.*

36. *Id.* at 161 (quoting *Sierra Club v. Morton*, 405 U.S. 727, 735 (1972)) (internal quotation marks omitted).

37. *Id.*

38. *Id.* (quoting National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,174 (July 7, 2009)) (internal quotation marks omitted).

39. *Id.*

40. *Id.* at 162 (quoting Brief of Appellants at 43, *Doe v. Obama*, 631 F.3d 157 (4th Cir. 2011) (Nos. 10-1104, 10-1106), 2010 WL 1048986, at *43).

41. *Id.* (quoting National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. at 32,174) (internal quotation marks omitted).

42. *Id.* (quoting *Simon v. Ky. Welfare Rights Org.*, 426 U.S. 26, 42 (1976)) (internal quotation marks omitted).

43. *Id.* at 163.

44. *Id.* at 162 (quoting Brief of Appellants, *supra* note 40, at 53) (internal quotation marks omitted).

allege sufficient facts to establish that the injury was “actual or imminent.”⁴⁵ The Fourth Circuit averred that “‘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.”⁴⁶ When a future injury is alleged, the plaintiff must show that there is “a high degree of immediacy” to establish standing.⁴⁷ The Fourth Circuit implied that if the plaintiffs had tried and failed to adopt embryos, or had concrete plans for future adoption, they could have been able to establish a sufficiently imminent injury.⁴⁸ The court also noted that, like Doe and the class of frozen embryos, the putative adoptive parents could not establish that the injury was connected to the Executive Order or the NIH Guidelines.⁴⁹

The Fourth Circuit affirmed the district court’s dismissal of the case for lack of standing, but noted that its holding was a narrow one.⁵⁰ The court explained that “[a] complaint that provided more concrete information about the identity of the named plaintiff embryo or the plaintiff parents’ plans for adoption would at least address more directly what the Supreme Court has identified as serious constitutional concerns.”⁵¹ The court concluded by noting that the constitutional constraints on the role of the federal courts precluded it from hearing a case that would transform it into a “political organ.”⁵²

Notably, the Fourth Circuit never addressed whether embryos can be plaintiffs at all. The court did explicitly leave open the door for a revised complaint that could meet the standing requirement.⁵³ However, the court’s implication that a complaint could be sufficient if the named embryo had more particularized characteristics to show that the embryo would be used for NIH-funded research sets an impossibly high standard. Although not explicit on the issue, this decision generally comports with those of the majority of courts, which have adopted the view that an embryo is not a legal person and therefore, cannot bring a lawsuit.⁵⁴

While the Fourth Circuit was hearing *Doe v. Obama*, a similar challenge to Executive Order 13505 and the NIH Guidelines was making its way through the District of Columbia courts. In *Sherley v. Sebelius*,⁵⁵ Dr. James Sherley

45. *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 (1992)) (internal quotation marks omitted).

46. *Id.* at 163 (emphasis in original) (quoting *Lujan*, 504 U.S. at 564) (internal quotation marks omitted).

47. *Id.* (quoting *Lujan*, 504 U.S. at 565, n.2) (internal quotation marks omitted).

48. *See id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.* at 164.

53. *Id.* at 163.

54. *See, e.g., Roe v. Wade*, 410 U.S. 113, 158 (1973) (the word “person as used in the Fourteenth Amendment does not include the unborn”); *Doe v. Shalala*, 862 F. Supp. 1421, 1426 (D. Md. 1994) (“[E]mbryos are not persons with legally protectable interests.”).

55. 776 F. Supp. 2d 1 (D.D.C. 2011).

and Dr. Theresa Deisher, researchers working on an alternative to hESCs, brought a lawsuit claiming that under the new NIH Guidelines, they would face increased competition for funding from hESC researchers, and that the NIH Guidelines violated the Dickey-Wicker Amendment.⁵⁶ Originally, the case was dismissed by the U.S. District Court of the District of Columbia for lack of standing.⁵⁷ However, the District of Columbia Circuit Court of Appeals reversed this determination, holding that doctors seeking NIH funding had competitor standing in this matter to bring a claim concerning the new NIH Guidelines on stem cell research.⁵⁸ The court held that the plaintiff researchers successfully showed competitor standing by showing an actual or imminent increase in competition, almost certain to cause an injury in fact.⁵⁹ It is also notable that the only issue addressed by the court as to standing was the issue of whether there was injury in fact, because, unlike the *Doe* court, the district court for the District of Columbia found it was “clear the alleged injury [was] traceable to the Guidelines and redressable by the court.”⁶⁰ On remand, the district court granted the plaintiffs’ motion for a preliminary injunction, prohibiting hESC research funding for the duration of the trial court’s litigation.⁶¹ The district court explained that the Dickey-Wicker Amendment is unambiguous in prohibiting federal funding of any research in which an embryo is destroyed.⁶² The district court further stated that research involving destruction of embryos and research using already destroyed embryos were indistinguishable because the research “necessarily depends on the destruction of a human embryo.”⁶³ However, on April 29, 2011, the U.S. Court of Appeals for the District of Columbia held that the federal funding of embryonic stem cell research is permissible and not a violation of the Dickey-Wicker Amendment.⁶⁴

Although *Sherley* held that hESC research under the NIH Guidelines was not violative of the Dickey-Wicker Amendment, *Sherley* did not address the potential violations of the embryos’ constitutional rights under the Fifth, Thirteenth, and Fourteenth Amendments claimed in *Doe*. Furthermore, *Sherley* explicitly held as to standing that the injury was fairly traceable to the defendants’ actions, directly contradicting the standing analysis applied in *Doe*.

56. *Id.* at 8, 9 (quoting *Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010)).

57. *Id.* at 4.

58. *Sherley*, 610 F.3d at 74, 75. The court of appeals affirmed dismissal for lack of standing as to plaintiffs Embryos, Nightlight Christian Adoptions, putative adoptive parents, and Christian Medical Association. *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 66 (D.D.C. 2010) (citing *Sherley*, 610 F.3d at 71), *vacated*, 644 F.3d 388, 390 (D.C. Cir. 2011).

59. *Sherley*, 610 F.3d at 74.

60. *Id.* at 72.

61. *Sherley*, 704 F. Supp. 2d at 73.

62. *Id.* at 70–71.

63. *Id.* at 71.

64. *Sherley v. Sebelius*, 644 F.3d 388, 390 (D.C. Cir. 2011).

On July 25, 2011, the *Doe v. Obama* petition for rehearing was denied by the United States Supreme Court.⁶⁵ However, because of the contentious nature of hESC research and the failure of the Fourth Circuit to explicitly exclude embryos as plaintiffs with standing, the door remains open for future cases challenging Executive Order 13505 and the NIH Guidelines. Ultimately, the questions of whether the NIH Guidelines and the Executive Order violate the constitutional rights of a frozen embryo under the Fifth, Thirteenth, and Fourteenth Amendment, and more broadly, whether a frozen embryo could ever bring a claim alleging infringement of constitutional rights, remain unanswered.

Sara I. Salehi

65. *Doe v. Obama*, 131 S. Ct. 2938 (2011).