RECORD NO. 03-2554

United States Court of Appeals

for the

Fourth Circuit

MARY DOE, a human embryo "born" in the United States (and Subsequently frozen in which state of cyro-preservation her life is presently suspended), individually and on behalf of all other frozen human embryos similarly situated,

Plaintiff-Appellant,

– v. –

TOMMY G. THOMPSON, in his official capacity as Secretary of Health and Human Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. HAROLD VARMUS, in his official capacity as Director of the National Institutes of Health; and NATIONAL INSTITUTES OF HEALTH,

Defendants-Respondents.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BRIEF OF PLAINTIFF-APPELLANT

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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT
Richmond, VA

No. 03-2254 Doe v. Thompson, Secretary of Health and Human Services

DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER ENTITIES WITH A DIRECT FINANCIAL INTEREST IN LITIGATION

ONLY ONE FORM NEED BE COMPLETED FOR A PARTY EVEN IF THE PARTY IS REPRESENTED BY MORE THAN ONE ATTORNEY. DISCLOSURES MUST BE FILED ON BEHALF OF INDIVIDUAL PARTIES AS WELL AS CORPORATE PARTIES. DISCLOSURES ARE REQUIRED FROM AMICUS CURIAE ONLY IF AMICUS IS A CORPORATION. COUNSEL HAS A CONTINUING DUTY TO UPDATE THIS INFORMATION. PLEASE FILE AN ORIGINAL AND THREE COPIES OF THIS FORM.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Mary Doe, et al. who is appellants ,
(name of party/amicus) (appellant/appellee/amicus)

makes the following disclosure:

1. Is party/amicus a publicly held corporation or other publicly held entity? ( ) YES (X) NO

2. Does party/amicus have any parent corporations?
( ) YES (X) NO
If yes, identify all parent corporations, including grandparent and great-grandparent corporations:

3. Is 10 percent or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity?
( ) YES (X) NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(b))

( ) YES (X) NO

If yes, identify entity and nature of interest:

5. Is the party a trade association?

( ) YES (X) NO

If yes, identify all members of the association, their parent corporations, and any publicly held companies that own 10 percent or more of a member's stock:

6. If case arises out of a bankruptcy proceeding, identify any trustee and the members of any creditor's committee:

_____ _____

(Signature) (date)

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JURISDICTIONAL STATEMENT

The District Court had subject matter jurisdiction over this action for declaratory and injunctive relief, brought under the Declaratory Judgment Act, 28 U.S.C. § 551 et seq., and seeking a declaration regarding the federal constitutional rights of Plaintiff-Appellant Mary Doe under the Fourteenth Amendment to the United States Constitution, under 28 U.S.C. § 1331. The Court of Appeals has jurisdiction over this appeal, taken from a final order of the District Court entered August 5, 2003, denying Plaintiffs' Petition for Reconsideration of the District Court's Final Order of Judgment entered July 3, 2003, which dismissed the case as moot and directed the Clerk to close the case, under 28 U.S.C. § 1291. Plaintiff-Appellant timely filed her Notice of Appeal on October 3, 2003.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Did the District Court err as a matter of law in dismissing the case as moot, where the current Bush Administration policy allows federal funding of stem cell research on a limited number of lines of stem cells extracted from human embryos prior to a specified date and time, and where it is not absolutely clear that the Federal Government will not fund additional human embryo/stem cell research in the future ?

2. Does Plaintiff-Appellant Mary Doe, a human embryo, have standing to sue?

STATEMENT OF THE CASE

On or about August 10, 1999, Plaintiff-Appellant Mary Doe commenced this declaratory judgment action by filing her Complaint in the United States District Court for the District of Maryland. (A3, A11.) The Complaint named, as party defendants, the Secretary of Health and Human Services, the Department of Health and Human Services, the Director of the National Institutes of Health, and the National Institutes of Health. (A11.)

The Complaint sought a declaratory judgment that (1) the plaintiff Mary Doe, a human embryo, is a "person" entitled to the protection of the due process and equal protection clauses of the Fourteenth Amendment, (2) the recommendations of the National Bioethics Advisory Commission fail to recognize Mary Doe's "equal humanity and personhood and therefore, violate her rights to equal protection and the due process of law," and (3) that human embryo experimentation that "results in the certain and sudden death of Mary Doe" violates her Fourteenth Amendment rights to equal protection and due process of law. The Complaint further sought the issuance of an injunction against the Defendants, "ordering them to cease and desist any and all plans to undertake human embryo (stem cell) experimentation." (A24.)

On or about January 5, 2000, the Defendants moved to dismiss, or, in the alternative, for summary judgment. (A4, A26.)

On or about October 25, 2002, the Defendants moved to dismiss the case as moot. (A8, A47.)

On July 3, 2003, the District Court entered a Final Order of Judgment dismissing the case as moot and directing the Clerk to close the case. (A50.) On August 5, 2003, the District Court entered an Order denying Plaintiffs' Petition for Reconsideration of Case Closure. (A55, A60.)

On October 3, 2003, Appellant Mary Doe timely filed her Notice of Appeal. (A61.)

STATEMENT OF FACTS

Plaintiff-Appellant Mary Doe is human embryo "born", i.e., produced or brought into life, in the United States, by in vitro fertilization. (A13.) Her life was thereafter suspended by the freezing of the embryo in liquid nitrogen, a process known as cryo-preservation. (A13.) The modern science of in vitro fertilization allows Mary Doe to be unfrozen and thereby returned to the warmth of life, after storage for months or years in a frozen state, and then to be implanted in the womb of an adopting mother as a "child in vitro." (A13.)

Prior to the Clinton Administration, all presidential administrations that had addressed the issue had banned human embryo experimentation. (A20.) In response to attempts by the Clinton Administration to begin human embryo experimentation, the United States Congress, as part of certain stop-gap spending bills, added the proviso that no federal funds were to be used for human embryo experimentation. (A20.)

In November 1998, President Clinton charged the National Bioethics Advisory Commission ("NBAC"), a Presidential Advisory Commission appointed

under the Federal Advisory Committee Act (FACA), 5 U.S.C. , App. 2, § 1 et seq., with reviewing the issues associated with human stem cell[1] research, including balancing all ethical and medical issues. (A32.) On July 13-14, 1999, NBAC issued a Draft Report, which concluded that federally funded scientists should be allowed to use "donated" human embryos for bio-medical research. (A33.) The final NBAC report, which was issued in September 1999, recommended that federal funding should be made available for the use and extraction of stem cells from both cadaveric fetal tissue and "donated" embryos remaining after infertility treatments, and further recommended that the relevant statutes and regulations be amended to permit federal funding of such research. (A33.)

The Department of Health and Human Services (DHHS) took the position that "stem cell research" did not fall within the Congressional ban against the use of federal funds for human embryo experimentation. (A20-21.) Specifically, DHHS was prohibited by appropriations law from using any appropriated funds "for the creation of a human embryo or embryos for research purposes; or research

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[1]Stem cells are a unique cell type found in animals, that are capable of continually reproducing themselves to renew tissue throughout an individual's life. Embryonic stem cells are found in early-stage, animal embryos. Human stem cells can be extracted from, among other sources, human fetal tissue following an elective abortion and from "excess" human embryos that are created by in vitro fertilization for couples being treated for infertility. (*See* A20, A32-33.)

in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. § 46.208(a)(2) [the DHHS human subject protection regulations] and section 498(b) of the Public Health Service Act (42 U.S.C. § 289f(b)." (A34, quoting Public Law 106-113, § 510). DHHS nevertheless concluded that, because stem cells are not embryos, this provision did not prohibit the use of federal funds for research using human stem cells that had been extracted from embryos–thereby destroying the embryos–using non-federal funding. (A34.)

On December 2, 1999, the National Institutes of Health ("NIH") issued draft Guidelines for Research Involving Human Pluripotent Stem Cells. *See* DHHS, "Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells", 64 Fed. Reg. 67576 (Dec. 2, 1999). The Draft NIH Guidelines applied to applications for NIH funding of research involving utilization of embryonic stem cells extracted from human embryos without DHHS funding, as well as to applications for NIH funding of research involving the derivation and/or utilization of embryonic stem cells from fetal tissue. *Id.* at 67577. Research to be funded by NIH under the guidelines was to involve stem cells extracted from either fetal tissue or from "donated" human embryos created

by in vitro fertilization "in excess of clinical need", that had not been not implanted in a woman's uterus, and had not reached the stage when the first major tissue type is formed. *Id.* at 67577-78.

When the Bush administration came into office in early 2001, it announced its intention to review the Government's stem cell research policy. On August 9, 2001, President George W. Bush announced that federal funds may be awarded for research using human embryonic stem cells if the following criteria are met:

> [1] The derivative [i.e., the extraction] process (which begins with the destruction of the embryo) was initiated prior to 9:00 p.m. EDT on August 9, 2001.
>
> [2] The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed.
>
> [3] Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements.

(A52-53.)

The District Court found that, "[f]rom all that appears, the National Institutes of Health (NIH), the real party-defendant in interest, has been in compliance with [the Bush Administration] policy." (A52.) The District Court, without making any

determination as to the possibility or likelihood of a further change in the Government's policy regarding stem cell research, agreed with the Government's argument that "the current policy and the fact of NIH's compliance have mooted the original suit brought by Plaintiffs" and that therefore "closure of the case is appropriate." (A52-53.)

SUMMARY OF THE ARGUMENT

The District Court's decision to dismiss on the grounds of mootness, due the Bush Administration's voluntary cessation of the Clinton Administration's stem cell research policy, fails to acknowledge that there is at least a reasonable possibility that the Government will at some time in the future resume federal funding of stem cell research that requires the extraction of additional stem cells from human embryos, resulting in their inevitable destruction. Because the Government failed to carry its heavy burden to show that it is "absolutely clear" that this wrongful behavior could not reasonably be expected to recur, the case is not moot. The District Court further erred in refusing to apply the "capable of repetition, yet evading review" exception to the mootness doctrine. The Government could repeatedly make new announcements of federal funding of stem cell research, limited to the use of stem cells extracted just prior to each

announcement, thereby evading review, but resulting in the steady destruction of human embryos. Finally, the District Court failed to realize that (a) the Bush Administration's stem cell research policy still presents a "live" controversy, since it continues to provide federal funding for research on stem cells derived from human embryos, and (b) that Mary Doe still has a vital, legally cognizable interest in halting such federal funding, as it will inevitably reduce the supply of stem cells available for stem cell research using non-federal funds and eventually require the extraction of stem cells from additional human embryos, thus threatening Mary Doe and the other human embryos she seeks to represent with destruction.

In addition, Mary Doe has standing to sue as a living, human embryo *ex utero*. Although the abortion cases, including *Roe v. Wade*, 410 U.S. 113 (1973) have held that a fetus or human embryo *in utero* is not a "person" protected by the Fourteenth Amendment, those cases turned on the competing, constitutional rights of the mother, on whom the fetus is dependent for being birthed. By contrast, conferring standing on living, human embryos *ex utero* does not involve any competition with the rights of either of the embryo's parents, but rather serves to provide much needed protection for these developing human lives.

STANDARD OF REVIEW

Questions of mootness are reviewed de novo, *Christian Coalition of Alabama v. Cole*, ___ F.3d ___, 2004 WL 34832 (11th Cir. Jan. 8, 2004) (No. 03-11305); *Wade v. Kirkland*, 118 F.3d 667, 669 (9th Cir. 1997) ("Mootness is a question of law reviewed de novo"); *Comer v. Cisneros*, 37 F.3d 775, 787 (2d Cir. 1994) (same), under a plenary standard of review. *31 Foster Children v. Bush*, 329 F.3d 1255, 1263 (11th Cir. 2003), *cert. denied*, ___ U.S. ___, 124 S.Ct. 483 (2003); *Rucchio v. United Transp. Union, Local 60*, 181 F.3d 376, 382 (3d Cir. 1999), *cert. denied,* 528 U.S. 1154 (2000). As the Third Circuit has noted, the plenary standard of review is appropriate because the "mootness doctrine relates to the courts' constitutional authority to hear a case; the court must dismiss a case as moot if there is no Article III case or controversy." *Rucchio v. United Transp. Union, Local 60*, 181 F.3d at 382 n. 8.

The question whether a party has standing is likewise a question of law that is reviewed by this Court de novo. *Piney Run Preservation Ass'n v. County Commissioners of Carroll County, Md.*, 268 F.3d 255, 262 (4th Cir. 2001), *cert. denied*, 535 U.S. 1077 (2002); *Marshall v. Meadows*, 105 F.3d 904, 905-06 (4th Cir. 1997).

ARGUMENT

I. THE CASE WAS NOT MOOTED BY THE BUSH ADMINISTRATION'S ADOPTION OF A DIFFERENT POLICY REGARDING HUMAN EMBRYO/STEM CELL RESEARCH.

Mootness is primarily a function of the Article III "case or controversy" limitation on the jurisdiction of the Federal courts. *American Legion Post 7 of Durham, North Carolina v. City of Durham*, 239 F.3d 601, 605 (4th Cir. 2001). A case is moot when the issues presented are not longer "live" or the parties lack a legally cognizable interest in the outcome. *City of Erie v. Pap's A.M.,* 529 U.S. 277, 287 (2000). To survive an assertion that a claim is moot, a party must have suffered an actual injury that can be redressed by a favorable judicial decision. *Iron Arrow Honor Society v. Heckler*, 464 U.S. 67, 70 (1983).

The District Court's decision to dismiss the case as moot should be reversed for three reasons. First, the Government's voluntary cessation of the illegal conduct, i.e., confining the federal funding of stem cell research to stem cells already extracted from human embryos, does not moot this case as the Government has failed to show that it is "absolutely clear" that neither the Bush Administration nor a new administration will resume federal funding of stem cell research in the future that will require the extraction of additional stem cells from human embryos, thus resulting in their destruction. Second, the matter is one "capable of repetition,

yet evading review," since the Government could repeatedly choose to fund additional stem cell research that is restricted to the use of stem cells extracted just prior to each announcement of such additional federal funding, thereby precluding challenges by surviving, living human embryos. Finally, the matter still presents a "live" controversy, since the Bush Administration policy involves the federal funding of stem cell research using existing lines of stem cells that were already extracted from "excess," "donated" human embryos, thereby destroying such embryos, and since Mary Doe has a legally cognizable interest in the outcome given that such federal funding of stem cell research will inevitably decrease the available, limited supply of previously extracted stem cells for stem cell research, including such research funded by non-federal resources, and thereby increase the risk that Mary Doe and the other human embryos she seeks to represent will be destroyed to provide additional stem cells for research purposes.

A. Voluntary Cessation Of Illegal Conduct Does Not Moot A Federal Case Unless It Is Absolutely Clear That The Allegedly Wrongful Behavior Could Not Reasonably Be Expected To Recur.

It is by now well established that "[v]oluntary cessation of challenged conduct moots a case . . . only if it is '*absolutely* clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Ararand Constructors, Inc.*

v. Slater, 528 U.S. 216, 222 (2000) (quoting *United States v. Concentrated Phosphate Export Ass'n, Inc.*, 393 U.S. 199, 203 (1968)) (emphasis the Court's). Moreover, "the 'heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again *lies with the party asserting mootness*.'" *Id.* (quoting *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000)) (emphasis the Court's).

Thus, the Government, not Mary Doe, carries the burden of demonstrating that the case is moot. The Government therefore has the "heavy burden" of demonstrating that the challenged policy of funding stem cell research using stem cells to be extracted in the future from "excess" or "donated" human embryos cannot reasonably be expected to start up again.

Because the Government "cannot satisfy this burden," *Ararand Constructors, Inc. v. Slater*, 528 U.S. at 222 , the District Court erred in dismissing the case as moot. The Government has not demonstrated that there is "absolutely" no reasonable possibility that the Bush Administration will change its policy regarding stem cell research at some point in the future. Given the pressures that have been brought to bear in the past in favor of permitting expansive federal funding of stem cell research, there is at least a reasonable possibility that the Bush Administration may change its current policy to allow further federal funding of

stem cell research using additional stem cells "derived" or extracted from "excess" or "donated" human embryos.

Nor has the Government demonstrated that there is "absolutely" no reasonable possibility that President George W. Bush will be defeated for re-election and that a different, Democratic administration will assume office in 2005. To the contrary, there is at least a reasonable possibility that the Democratic nominee for the 2004 Presidential Election will be elected and that a new, Democratic administration will assume office in 2005, an administration that may well be more sympathetic to and revive the policies of the Clinton Administration regarding federal funding of stem cell research.

As the Supreme Court has noted, "[t]he plain lesson of [our precedents] is that there are circumstances in which the prospect that a defendant will engage in (or resume) harmful conduct may be too speculative to support standing, *but not too speculative to overcome mootness*." *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. at 190 (emphasis added). "[U]nder the circumstances of this case, it is impossible to conclude that [the Government] ha[s] borne [its] burden of establishing that it is 'absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Adarand Constructors, Inc. v. Slater*, 528 U.S. at 224 (quoting *Friends of Earth, Inc. v.*

Laidlaw Environmental Services (TOC), Inc., 528 U.S. at 189.)

As the Government did not carry its heavy burden to show that it is absolutely clear that the challenged conduct cannot reasonably be expected to start up again, and as the District Court made no determination that the Government had so met its burden, the District Court clearly erred in dismissing the case as moot.

B. The Matter Is One "Capable Of Repetition, Yet Evading Review."

The "capable of repetition, yet evading review" exception to the mootness doctrine was first enunciated in *Southern Pacific Terminal v. ICC*, 219 U.S. 498 (1911), and "has been applied to numerous fact situations[.]" *Leonard v. Hammond*, 804 F.2d 838, 842 (4th Cir. 1986). Two elements are required to employ this exception: "(1) the challenged action [is] in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there [is] a reasonable expectation that the same complaining party would be subjected to the same action again." *Id.* (quoting *Weinstein v. Bradford*, 423 U.S. 147, 149 (1975)).

In view of the facts and circumstances of this case, it is clear that the "capable of repetition, yet evading review" exception applies. The controversy involved is extremely "short run." *Leonard v. Hammond*, 804 F.2d at 843. Because stem cells can be extracted from an embryo (thus destroying the embryo)

in a matter of minutes if not seconds, the Government could always choose to fund stem cell research using only stem cells that were extracted from embryos just prior to, or just after, the date and time of the announcement of the funding policy, thus making it virtually impossible to bring a timely lawsuit to litigate the policy and enjoin the destruction of human embryos. Furthermore, while the plaintiff Mary Doe and the other human embryos she seeks to represent are free at the moment from the imminent threat of destruction, there is a substantial risk of them again being subjected to such threat of destruction if either (a) the Bush Administration changes its policy to permit federal funding of stem cell research on additional stem cells taken from "excess" or "donated" human embryos, or (b) there is a change of administrations as a result of the 2004 Presidential Election, resulting in a revival of the Clinton Administration (or similar) policies.

In short, as it clearly presents a controversy that is "capable of repetition, yet evading review," the District Court erred in dismissing the instant action for declaratory and injunctive relief as being moot.

C. The Matter Is Not Moot As Mary Doe Still Retains A Legally Cognizable Interest In The Outcome.

The District Court further erred in dismissing the case as moot, since Mary Doe and the other human embryos she seeks to represent still retain a legally

cognizable interest in the outcome of this case. By allowing federal funding of stem cell research using the limited supply of stem cells extracted from human embryos prior to 9:00 p.m. on August 9, 2001, the Government has threatened deplete the available supply of human embryo stem cells, thereby making it more likely that additional human embryos, such as Mary Doe, will have to be destroyed in order to extract enough stem cells for privately funded and other non-federally funded research. Thus, as the Government's current policy still poses an imminent threat of destruction to Mary Doe and other human embryos, Mary Doe has suffered an actual injury that can be redressed by a favorable judicial decision.

To summarize, the Government has failed to carry its heavy burden to show that it is "absolutely clear" that the challenged conduct cannot reasonably be expected to recur, the matter is one "capable of repetition, yet evading review," and Mary Doe still retains a legally cognizable interest in the outcome of this matter due to the Government's current policy of allowing federal funding of human embryo/stem cell research. For all of these reasons, the District Court erred in dismissing the case on mootness grounds.

II. MARY DOE, A HUMAN EMBRYO, HAS STANDING TO SUE.

Although the District Court dismissed the action on grounds of mootness, the

Government will likely argue, as an alternative ground for upholding the District Court's dismissal of the case, that Mary Doe lacks standing to bring the action. The Government will also likely rely, as it did below, on the District Court's prior ruling in *Doe v. Shalala*, 862 F. Supp. 1421, 1426 (D. Md. 1994) (Messitte, J.) that Mary Doe, an embryo *ex utero*, lacks standing to sue.

"'The being that is now you or me is the same being that was once an adolescent, and before that a toddler, and before that an infant, and before that a fetus, *and before that an embryo*. *To have destroyed the being that is you or me at any of these stages would have been to destroy you or me*.'" Sameul B. Casey & Nathan A. Adams, "Specially Respecting The Living Human Embryo By Adhering To Standard Human Subject Experimentation Rules," 2 *Yale J. Health Policy, Law & Ethics* 111 (2001) (quoting Robert George, "Stem Cell Research: A Debate; Don't Destroy Human Life," *Wall Street Journal*, July 30, 2001, at A18) (emphasis added). Mary Doe, a developing human life, should be accorded standing in order to assert her right to be free from destruction at the hands of medical researchers.

In the only prior federal decision to address this issue, *Doe v. Shalala*, the plaintiffs, including Mary Doe, a human embryo, filed a class action suit on behalf of more than 20,000 embryos stored in various IVF labs across the United States. Plaintiffs asserted that the National Institutes of Health Human Embryo Research

Panel ("the Panel") was not "fairly balanced" within the meaning of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 § 5(b)(2). They alleged that at least ten (10) members of the Panel were "current or former NIH grantees who [had] firmly endorsed the principle and many of the protocols of extended and unfettered human embryo research." 862 F. Supp. at 1426. Arguing that the Panel's bias and likely favorable recommendations on the funding of embryo research would cause them irreparable harm, the plaintiffs sought a preliminary injunction to halt further Panel deliberation and publication of a Report. *Id.*

The District Court dismissed the suit for lack of standing, saying:

> [P]hilosophical and religious considerations aside, the Supreme Court has made it clear that the word "person," as used in the Fourteenth Amendment, does not include the unborn. *Roe v. Wade*, 410 U.S. 113, 158 . . . (1973). It has thus been held that embryos are not persons with legally protectable interests within the meaning of Fed.R.Civ.P. 17(c) such that appointments of *guardians ad litem* are warranted or required. *See Roe v. Casey*, 464 F. Supp. 483 (E.D. Pa. 1978), *aff'd,* 623 F.2d 829 (3d Cir. 1980). The Court sees no distinction between fetuses *in utero* or *ex utero*.

Id.

The District Court in *Doe v. Shalala* "did not consider whether the embryos [*ex utero*, including Mary Doe,] deserved different treatment–or legal opportunities–as the subjects of scientific research" than a unborn child in a mother's womb, as it "believed such questions had already been answered by *Roe*

[*v. Wade*, 410 U.S. 113 (1973)] and [*Roe v.*] *Casey* [, 464 F. Supp. 483 (E.D. Pa. 1978), *aff'd*, 623 F.2d 829 (3d Cir. 1980).]" Christine L. Feiler, "Human Embryo Experimentation: Regulation and Relative Rights," 66 *Fordham L. Rev.* 2435, 2445 (1998). *Roe* and *Casey*, however, were abortion cases, involving the fetus or embryo *in utero*, and the holdings in those cases were greatly influenced by the competing interests and constitutional rights of the mother:

> The abortion cases were decided in a normative adversarial context: The woman's right to control her own body was pitted against the fetus's proposed right to be born. *Roe* and its successors make clear that a woman's liberty interests in reproductive autonomy and bodily integrity often outweigh the State's interest in protecting unborn life.

Feiler, 66 *Fordham L. Rev.* at 2445-46 (footnotes omitted).

By contrast, "the discussion of the embryo's status [as the subject of scientific research or experimentation] must necessarily stand on a different legal footing than that of the discussion of fetal abortion." Dan L. Burk, "Patenting Transgenic Human Embryos: A Nonuse Cost Perspective," 30 *Hous. L. Rev.* 1597, 1652 (1993). "[E]ven strong pro-abortion proponents acknowledge that *Roe v. Wade* has no necessary bearing upon the *ex utero* living human embryo where maternal and fetal rights are not in opposition." Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 118-19.

The standing issue presented by this case, like that presented in *Doe v. Shala*,

is therefore "fundamentally different from . . .[that presented in the cases involving] abortion [such as *Roe* and *Casey*] . . . because individual reproductive autonomy is not implicated." Feiler, *Fordham L. Rev.* at 2446. As one of the most notable proponents of the right to abortion has admitted, "[b]ut for its biological dependence on the woman, it is at least arguable that the fetus could be regarded as a holder of rights under the due process clause of the fifth and fourteenth amendments, as well as the equal protection clause of the latter." Laurence H. Tribe, "The Abortion Funding Conundrum: Inalienable Rights, Affirmative Duties, and the Dilemma of Dependence," 99 *Harv. L. Rev.* 330, 340 (1985). The human embryo *ex utero* enjoys such independence, *see* Feiler, 66 *Fordham L. Rev.* at 2446 ("The research embryo is an independent entity whose existence does not require a woman to sacrifice her constitutionally protected autonomy."); Burk, 30 Hous. L. Rev. at 1653 ("[U]nlike a fetus, the embryo can exist independently outside the womb; . . . [c]onsequently, the autonomy of the mother need not enter into the discussion of embryo status at all[.]"), and should therefore be accorded both standing and protection as a "person" under the due process and equal protection clauses of the Fourteenth Amendment.

Standing should also be accorded Mary Doe for the following compelling reasons. First, the embryo "is an instance of human life", Feiler, 66 *Fordham L.*

Rev. at 2450, i.e., as it is both "living and genetically unique" and "human and capable of developing into an adult." Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 111. In short, "embryos are developing human lives." Feiler, 66 *Fordham L. Rev.* at 2453. Second, "[e]mbryos are the most immature and utterly incapacitated human entities," Feiler, 66 *Fordham L. Rev.* at 2452, and they "are incapable of giving consent to their . . . use in experimental procedures." *Id.* Finally, "derivation of human stem cells from embryos terminates them." Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 111. Researchers must inevitably destroy embryos in order to gain the knowledge that they want. Feiler, 66 *Fordham L. Rev.* at 2453.

Thus, human embryos, such as Mary Doe, deserve and need extensive protection from "the inevitable risk and ultimate harm of manipulation and destruction at the hands of researchers." Feiler, 66 *Fordham L. Rev.* at 2452. Absent the conferral of standing to seek judicial relief, Mary Doe and the other embryos she seeks to represent will have no assurance such protection will ever be extended. Furthermore, if such standing is denied, "the utilitarian fog into which medical researchers [performing human embryo stem cell research] will travel in the years to come will surely take American medical researchers down the darkened and dead-ended roads previously traveled from Buchenwald to Tuskegee." *Cf.*

Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 112 (footnotes omitted).

For all of the above reasons, Mary Doe submits that she and her fellow human embryos *ex utero* should be accorded standing to pursue the instant litigation.

CONCLUSION

In view of the arguments made and authorities cited above, Plaintiff-Appellant Mary Doe respectfully requests that the District Court's Final Order and Judgment, entered July 3, 2003, dismissing the case as moot and directing the Clerk to close the case should be reversed, and the matter remanded for a trial on the merits.

Respectfully submitted,

_____
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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 03-2554 **Caption:** DOE v. TOMPSON

CERTIFICATE OF COMPLIANCE UNDER FED. R. APP. P. 32(A)(7)

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