# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND SOUTHERN DIVISION

MARY SCOTT DOE, et al.,	)
Plaintiffs,	) )
v.	) Civil Case No. AW-09-2197
KATHLEEN SEBELIUS, et al.,	) )
Defendants.	)

## **MEMORANDUM OPINION**

Before this Court is a Motion to Dismiss filed on behalf of Defendants, Kathleen Sebelius, in her official capacity as Secretary of the Department of Health and Human Services ("HHS"); and Francis S. Collins, in his official capacity as Director of the National Institutes of Health ("NIH") (collectively referred to as the "Government"). (Doc. No. 6.) Plaintiffs' also filed a Motion for Other Relief Request for a Hearing (Doc. No. 11). Plaintiffs Mary Scott Doe, a human embryo frozen in cyro-preservation within the United States on behalf of herself and those similarly situated; National Organization for Embryonic Law ("NOEL"), a non-profit organization pursuing the legal protection of human life; Nightlight Christian Adoptions, a licensed adoption agency that operates an embryo adoption program; and four married couples who are putative adopters of human embryos bring this complaint seeking declaratory and injunctive relief against the Defendants and costs associated with this lawsuit. The Plaintiffs claim that the final Guidelines issued by the Defendants to implement Executive Order 13505, which provides federal funding for human embryo stem cell research ("hESC"), violates the frozen embryos' constitutional rights to due process, equal protection, and freedom from involuntary servitude under the Fifth, Fourteenth, and Thirteenth Amendments. Plaintiffs also assert that Defendants violated the Administrative Procedure Act by acting arbitrarily and capriciously with respect to certain provisions in the final Guidelines. Plaintiffs further argue that Defendants' actions violate the Dickey-Wicker Amendment. The Court has reviewed the entire record as well as the pleadings with respect to this motion and finds that no hearing is deemed necessary. *See* Local Rule 105.6 (D. Md. 2008). Defendants argue, and this Court agrees, that Plaintiffs lack standing to bring any of these claims. Therefore, the Court need not engage in a detailed analysis of the substantive claims. Accordingly, this Court will **GRANT** Defendants' Motion to Dismiss (Doc. No. 6) and **DENY** Plaintiffs' Motion for Other Relief Request for a Hearing (Doc. No. 11).

#### FACTUAL AND PROCEDURAL BACKGROUND

This case involves primarily the same parties who asserted essentially the same claims in a prior case before this Court, *Doe v. Obama*, AW-09-755, (hereinafter referred to as "*Doe I*"). The Plaintiffs in this case are primarily the same as in *Doe I*, however, unlike in *Doe I*, Nightlight Christian Adoptions has not requested to be removed as a party in this case. Moreover, unlike *Doe I*, President Obama is not named as a Defendant in this case. The Plaintiffs assert, as they did in *Doe I*, that federal funding of human embryo stem cell research violates the embryos' right to due process under the Fifth and Fourteenth Amendment, freedom from slavery and involuntary servitude under the Thirteenth Amendment, and violates the Dickey-Wicker Amendment. The current case challenges the final Guidelines issued by the NIH and HHS to implement Executive Order 13505, which were in draft form when *Doe I* was filed, but does not challenge the Executive Order itself. Moreover, the current case asserts an additional claim that the NIH and HHS's decisions concerning the wording of specific provisions of the final Guidelines are arbitrary and capricious in violation of the Administrative Procedure Act. Therefore, this case is essentially the same as *Doe I* with the exception of a few details.

This case stems from the same factual background as *Doe I*, and the Court incorporates by reference the facts articulated therein. Subsequent to filing the complaint in Doe I, "the NIH requested written comments on the draft Guidelines" to be sent to the NIH by May 26, 2009. (Doc. No. 10 at 13.) Plaintiffs NOEL and Nightlight Christian Adoptions submitted comments concerning two aspects of the draft Guidelines and reiterated their position that the Guidelines violated the constitutional rights of human embryos and also violated the Dickey-Wicker Amendment. Plaintiffs sought clarification that paragraph II.B.1 of the proposed Guidelines, which provided that donors should be explained all options for disposition of embryos no longer needed for reproductive purposes, includes an explanation of the option to donate the embryos for adoption. Similarly, the Plaintiffs suggested that Paragraph II.B.7.b., which requires that potential donors understand alternative options relating to the disposition of their unused embryos, "should clarify that the language 'alternative options' includes the option of human embryo adoption . . . ." (Doc. No. 10 at 15.) Plaintiffs also submitted comments concerning Paragraph II.B.7.d. of the draft Guidelines, which provided that donors be informed of what happens to embryos in the derivation process of obtaining stem cells for research, and requested that the language explicitly inform donors that "the embryo will be killed or destroyed" by this process and "will never be able to develop into a fully formed individual and fulfill his or her destiny." (Doc. No. 10 at 15.)

The NIH issued final Guidelines on July 7, 2009, governing the "expenditure of [its] funds for research using human embryonic stem cells (hESCs)." National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170, 32174 (July 7, 2009). The Guidelines state that they are based on the following principles: "(1) Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover

new ways to prevent and/or treat illness; and (2) individuals donating embryos for research purposes should do so freely, with voluntary and informed consent." *Id.* The Guidelines further indicate that the NIH received over 49,000 comments on the draft guidelines and provides NIH's responses to those comments. *Id.* at 32170

In response to Plaintiffs' concern that donors be informed of adoption of embryos as an option for disposition of unused embryos, NIH responded that

The Guidelines require that all the options available in the health care facility where treatment was sought pertaining to the use of embryos no longer needed for reproductive purposes were explained to the potential donor(s). Since not all [in vitro fertilization ("IVF")] clinics offer the same services, the healthcare facility is only required to explain the options available to the donor(s) at that particular facility.

74 Fed. Reg. at 32173. Thus, the final Guidelines only require that donors be informed of options available at the IVF clinic where the donor received treatment and not "all options" as provided in the proposed Guidelines. Moreover, in response to concerns that the informed consent forms explicitly state that embryos are destroyed in the derivation process to obtain human stem cells for research, the NIH stated:

In the process of developing guidelines, the NIH reviewed a variety of consent forms that have been used in responsible derivations. Several had extensive descriptions of the process and the research to be done, going well beyond the minimum expected, yet they did not use these exact words. Given the wide variety and diversity of forms, as well as the various policy, statutory and regulatory obligations individual institutions face, the NIH declines to provide exact wording for consent forms, and instead endorses a robust informed consent process where all necessary details are explained and understood in an ongoing, trusting relationship between the clinic and the donor(s).

*Id.* Therefore, the NIH declined to incorporate the Plaintiffs' comments in the final version of the Guidelines, which the Plaintiffs argue is an arbitrary and capricious decision in violation of the Administrative Procedure Act.

As in *Doe I*, Plaintiffs ask this Court to enjoin the implementation of the Guidelines and declare that they violate embryos' rights to due process and freedom from involuntary servitude, and to declare that the Guidelines violate the Dickey-Wicker Amendment. In this case, Plaintiffs also seek a declaration that the Guidelines violate the Administrative Procedure Act because the Guidelines are arbitrary and capricious.

## STANDARD OF REVIEW

Pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, federal courts must dismiss claims where the court lacks subject-matter jurisdiction. Although courts are permitted to consider materials outside of the pleadings to determine whether it can exercise subject-matter jurisdiction, the court must generally accept as true all factual allegations pled in the complaint. *Albright v. Oliver*, 510 U.S. 266, 268 (1994). However, as reiterated in *Ashcroft v. Iqbal*, "although for the purposes of a motion to dismiss [the court] must take all the factual allegations in the complaint as true, [the court is] 'not bound to accept as true legal conclusions couched as factual allegations." 129 S. Ct. 1937, 1950 (2009).

Plaintiffs bringing claims in federal court must meet the requirements of standing in order for the court to exercise subject-matter jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 559, 560 (1992) (stating that "the core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III.") The "[s]tanding doctrine functions to ensure . . . that the scarce resources of the federal courts are devoted to those disputes in which the parties have a concrete stake" in the alleged claim. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 191 (2000). Further, when considering whether a party has standing to bring an action, the focus for the Court is on the party asserting the claim and "not on the issue the party wishes to have adjudicated." *Flast v. Cohen*, 392 U.S. 83, 99 (1968). Plaintiffs bear the burden of establishing the three elements of Article III standing which are: (1) injury in fact; (2) causation; and (3) redressability. *Lujan*, 504 U.S. at 561-62. An injury in fact is "an invasion of a *legally protected* interest which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical." *Id.* at 560 (emphasis added). Most notably, "the frustration of a party's generalized interest in the proper application of the law is not by itself an injury in fact for purposes of standing." *Delta Commercial Fisheries Ass'n v. Gulf of Me. Fishery Mgmt. Council*, 364 F.3d 269, 273 (5th Cir. 2004). Moreover, to show the causation element, the plaintiff must show that the suffered injury is "fairly traceable to the defendant" and not the result of the independent acts of a third-party who is not a party in the case. *Friends of the Earth, Inc.*, 528 U.S. at 180-81. Lastly, the plaintiff must demonstrate that there is a "substantial likelihood" that the alleged harm will be remedied if the Court grants the relief sought. *Id.* at 181.

In addition to establishing the constitutional requirements of standing, plaintiffs must also demonstrate that their claims can survive prudential limitations to the federal court's exercise of jurisdiction. *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 11-12 (2004). The Supreme Court has recognized three additional limitations to establishing standing, namely that (1) the plaintiffs' injury must be in the zone of interest the statue at issue is intended to protect; (2) plaintiffs cannot assert the claims of others unless they stand in close relationship to the third party; and (3) plaintiffs cannot air general grievances shared by a large class of persons. *See id.* "Without such limitations—closely related to [Article] III concerns but essentially matters of judicial self-governance—the courts would be called upon to decide abstract questions of wide public significance even though other governmental institutions may be more competent to address the questions and even though judicial intervention may be unnecessary to protect individual rights." *Warth v. Seldin,* 422 U.S. 490, 500 (1975). In any event, "neither the

Administrative Procedure Act, nor any congressional enactment, can lower the threshold requirements of standing under [Article] III." *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State*, 454 U.S. 464, 487 n.24 (1982).

The Defendants argue that even if the Court were to find that Plaintiffs meet the requirements of standing, their claims should be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim upon which relief could be granted. Because this Court agrees with Defendants, and finds that all Plaintiffs lack standing, the Court dismisses the compliant without addressing the merits of the substantive claims.

#### I. Plaintiffs Lack Standing to Assert the Claims Raised in the Complaint.

As discussed above, the same Plaintiffs brought essentially the same claims against the proposed NIH Guidelines in Doe I, and add a claim that the Guidelines violate the Administrative Procedure Act. The Court finds no substantial difference between the arguments asserted in *Doe I* and those set-forth in this case concerning the Plaintiffs' standing to assert their claims. In *Doe I*, this Court held that embryos do not have legally protected interests and thus do not have standing to pursue any of their constitutional claims. Likewise, NOEL and potential adopters of embryos cannot assert third party standing to sue on behalf of the embryos because the embryos do not possess standing in their own right. Furthermore, the Court explained that NOEL has not alleged a sufficient injury to establish standing, merely because its mission conflicts with the Defendants' conduct. Buchanan v. Consol. Stores Corp., 125 F. Supp. 2d 730, 737-38 (D. Md. 2001). Moreover, the Court explained that the potential adopters' alleged injury that federal funding of human embryo stem cell research would necessarily result in decreasing the number of embryos available for adoption, was not traceable to the Defendants issuance and implementation of Executive Order 13505, because the choice to donate embryos to research as opposed to other options, such as adoption, resided solely with third parties not before the Court.

Finally, the Court explained that the potential adopters of embryos could not overcome the prudential limitations of standing and could not seek to challenge the Dickey-Wicker Amendment merely because they are taxpayers who morally oppose human embryo stem cell research. Therefore, for the same reasons articulated in *Doe I*, the Court finds that the Plaintiffs in *Doe I* do not have standing to pursue these claims in the current case.

The Court did not address the standing of Nightlight Christian Adoptions in Doe I, because Nightlight requested that it be dropped as party in that case. Nightlight has not made such a request in the pending matter and the Court will take the opportunity to address its standing. Like the potential adoptive parents of embryos, Nightlight's alleged injury is that the final Guidelines will cause a decrease in the number of embryos available for adoption. However, Nightlight essentially raised the same alleged injury against the issuance of the final Guidelines in Sherely v. Sebelius, which the District Court for the District of Columbia found did not satisfy the requirements of Article III standing because "it is speculative and dependent upon third party conduct." No. 1:09CV1575(RCL), 2009 WL 3429349, at \*3 (D.D.C. Oct. 27, 2009). In Sherely, the court stated that the choice was not simply "whether to donate embryos for research or for adoption" but also between "continuing to store the embryos or discarding them." Id. Moreover, the court found the choice "[was] solely within the discretion of individuals in possession of embryos that are no longer needed for reproductive purposes" and that "by allowing funding for hESCs research, the guidelines do not interfere with the discretion of the potential donors." Id.

Nightlight attempts to distinguish the holding of *Sherely* from its allegations in this case. Nightlight argues that the Guidelines "are leaving donors in the dark" by not requiring healthcare facilities to inform the potential donors of all options for disposition of unused embryos, including adoption, and by not requiring explicit language in consent forms that donation of embryos to research will "kill" the embryos. (Doc. No. 10 at 46.) However, at best this alleged injury is suffered by the potential donors, not Nightlight, and the prudential limitations to standing prevent third party suits, unless the party bringing the suit can establish a sufficiently close relationship to the third party. *Elk Grove Unified Sch. Dist.*, 542 U.S. at 11-12. There is no allegation in the complaint, or in the opposition to the motion to dismiss, that would support a finding that Nightlight has a sufficiently close relationship with potential donors to bring suit on their behalf.

Nightlight also argues that the "Defendants' actions in lifting restrictions on human embryonic stem cell experimentation" has a direct impact on the potential donors decision and essentially "puts federally funded experimenters and researchers in direct competition with embryo adoption agencies." (Doc. No. 10 at 47.) This allegation is substantially no different than the injury Nightlight claimed in Sherely, and as explained by the District Court for the District of Columbia, such injury is "mere 'unadorned speculation' as to the existence of a relationship between the [guidelines] and the third party conduct." Sherely, at \*3 (internal citations omitted). Moreover, the Court notes that nothing in the Guidelines appear to alter the options the clinics offer to its patients or the decisions of the potential donors prior to the issuance of the Guidelines. Instead the decision of how to dispose of embryos, and what options are made available to donors, remains within the independent discretion of the potential donors and the facilities where they are treated. Nightlight merely speculates that the Guidelines will have some affect on these third parties decisions, which is not sufficient to establish Article III standing. Therefore, like the Plaintiffs in the Doe I, and as found in Sherely, Nightlight also lacks standing to assert the claims alleged in the complaint, and accordingly the Court must dismiss this case for lack of jurisdiction. Moreover, the addition of an Administrative Procedure Act claim does not change the Court's decision because none of the Plaintiffs can demonstrate Article III standing.

# **CONCLUSION**

For the foregoing reasons, the Court holds that all Plaintiffs lack standing to assert the rights and claims alleged in the complaint. Therefore, the Court **GRANTS** Defendants' Motion to Dismiss (Doc. No. 6) and **DENIES** Plaintiffs' Motion for Other Relief Request for a Hearing (Doc. No. 11). A separate order shall follow this Memorandum Opinion.

December 11, 2009 Date /s/

Alexander Williams, Jr. United States District Court Judge