

)	
JAMES SHERELY, et al.,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 1:09-cv-1575 RCL
)	
)	
KATHLEEN SEBELIUS, et al.,)	
)	
Defendants.)	
)	
)	

This matter comes before the Court on defendants’ Motion [22] to Dismiss. Plaintiffs brought this suit to enjoin defendants from taking further actions to implement and apply the guidelines promulgated by the National Institute of Health (“NIH”) that provide for public funding of human embryonic stem cell (“hESC”) research. 74 Fed. Reg. 32,170 (July 7, 2009). Defendants’ motion asserts, among other things, that plaintiffs lack standing. This Court agrees with defendants and finds that plaintiffs lack standing. Accordingly, the Court will grant defendants’ Motion to Dismiss.

Plaintiffs are Drs. James L. Sherley and Theresa Deisher, Nightlight Christian Adoptions (“Nightlight”), Embryos, Shayne and Tina Nelson, William and Patricia Flynn, and Christian Medical Association (“CMA”). (Compl.¶¶ 6-12.) Drs. Sherely and Deisher specialize in adult stem cell research and plan to seek NIH funding for adult stem cell research in the future. (*Id.* ¶¶ 6-7.) In addition, Dr. Sherley has one proposal currently pending. (*Id.* ¶ 6.) Nightlight is an

adoption agency that helps individuals adopt human embryos that are being stored in fertilization clinics. (*Id.* ¶ 8.) The Embryos consist of all individual human embryos that were created for reproductive purposes, but are no longer needed for those purposes. (*Id.* ¶ 9.) The Nelsons and Flynns are clients of Nightlight who seek to adopt human embryos in the future. (*Id.* ¶¶ 10-11.) CMA is non-profit association of doctors that strives to improve the ethical standards of health care in the United States and abroad. (*Id.* ¶ 12.) Together, plaintiffs seek to enjoin defendants “from applying the Guidelines [promulgated by NIH] or otherwise funding research involving the destruction of human embryonic stem cells.” (*Id.* ¶ 4.)

On March 9, 2009, President Obama issued Executive Order No. 13,505, 74 Fed. Reg. 10,667. (*Id.* ¶ 30.) This Executive Order removed President Bush’s limitations on hESC research. Exec. Order No. 13,505, §§ 1, 5. In addition, the Order directed NIH to issue new guidelines to allow hESC research to the extent permitted by law. *Id.* §§ 2-3.

After a notice and comment period, NIH issued the final guidelines on July 7, 2009. 74 Fed. Reg. 32,170. Under the guidelines, for an applicant to conduct research on hESC derived from embryos donated on or after the effective date of the guidelines, the applicant must either limit his or her research to cell lines posted on an NIH registry, or submit an assurance of compliance with part A of the Guidelines. *Id.* at 32,174. The requirements of part A of the guidelines ensure that the proposed research involves only hESC that are no longer needed for reproductive purposes and were voluntarily donated to be used for research purposes. *Id.* For an applicant to conduct research on hESC derived from embryos donated before the effective date of the guidelines, the applicant must either show compliance with part A of the guidelines, or submit materials to an advisory committee, which will make recommendations concerning the

eligibility for NIH funding. *Id.* at 32,175.

Plaintiffs allege that the guidelines, by allowing NIH to fund hESC research, will cause them irreparable harm. Specifically, Drs. Sherely and Deisher contend that the new guidelines will “result in increased competition for limited federal funding and will thereby injure [their] ability to successfully compete for . . . NIH stem cell research funds.” (Compl. ¶ 6-7.) Nightlife alleges that the guidelines will cause a decrease in the number of embryos available for adoption. (*Id.* ¶ 8.) The Embryos, through Nightlight, contend that their lives will face a recurring risk of destruction as a result of the guidelines. (*Id.* ¶ 9.) The Nelsons and Flynns maintain that the guidelines will “jeopardize the likelihood that embryos will become available” for them to adopt in the future. (*Id.* ¶¶ 10-11.) Finally, CMA alleges that the guidelines will frustrate its purpose and require it to expend significant resources to combat the ethical problems posed by hESC research. (*Id.* ¶ 12.)

II. DISCUSSION

Defendants move to dismiss plaintiffs’ complaint on the grounds that this Court lacks subject-matter jurisdiction, or, in the alternative, that plaintiffs have failed to state a claim upon which relief could be granted. FED. R. CIV. P. 12(b)(1), (6). The Court finds that it lacks subject-matter jurisdiction because plaintiffs do not have standing. Therefore, the Court need not address defendants’ additional arguments.

A. Legal Standard

Federal courts are courts of limited jurisdiction. When a defendants files a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff must demonstrate by a preponderance of evidence that the court has subject-matter jurisdiction. *Allen*

v. Nicholson, 573 F. Supp. 2d 35, 37 (D.D.C. 2008). The court must accept all the factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *See Jerome Stevens Pharm. v. FDA.*, 402 F.3d 1249, 1253 (D.C. Cir. 2005). Furthermore, the court may consider material outside of the pleadings in its effort to determine whether the court has jurisdiction in the case. *See Herbert v. Nat'l Acad. of Sciences.*, 974 F.2d 192, 197 (D.C. Cir. 1992); *Alliance for Democracy v. FEC*, 362 F. Supp.2d 138, 142 (D.D.C. 2005).

A court lacks subject-matter jurisdiction if the plaintiff fails to establish standing. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) ("The party invoking federal jurisdiction bears the burden of establishing [standing]."). To have constitutional standing, the plaintiff must demonstrate: (1) an injury in fact; (2) causation; and (3) redressability. *Id.* 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 (internal citations and quotations omitted).

"When a plaintiff's asserted injury arises from the Government's regulation of a third party that is not before the court, it becomes 'substantially more difficult' to establish standing." *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 938 (D.C. Cir. 2004) (quoting *Lujan*, 504 U.S. at 562). The court, however, will not dismiss a complaint brought by multiple plaintiffs if one of the plaintiffs has standing. *See Rumsfeld v. Forum for Academic & Inst. Rights, Inc.*, 547 U.S. 47, 53 n.2 (2006) (stating that "the presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement").

B. Plaintiffs Lack Standing

I. CMA

CMA alleges that it will suffer injury because “the Guidelines will frustrate CMA’s purpose and require CMA to devote significant resources to address and counteract the grave ethical problems posed by illegal public funding of embryo research.” (Compl. ¶ 12.)

Frustration of purpose is not a sufficient injury to establish standing. *See Nat’l Taxpayers Union v. United States*, 68 F.3d 1428, 1433 (D.C. Cir. 1995) (stating that allegations that frustrate an organization’s objectives is an “abstract concern that does not impart standing”). Indeed, plaintiffs do not argue in their Opposition that this injury is sufficient for standing purposes. Accordingly, the Court finds that CMA lacks standing.

2. *Nightlight*

Nightlight contends that it will suffer injury because the guidelines will cause a decrease in the number of embryos available for adoption. (Compl. ¶ 8.) This alleged injury does not satisfy the “injury in fact” requirement of standing because it is speculative and dependent upon third party conduct. *See Nat’l Wrestling Coaches Ass’n*, 366 F.3d at 938. The guidelines do not mandate a decrease in the number of embryos available for adoption. Rather, the guidelines allow funding for hESC research on embryos that 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 (emphasis added). Thus, for Nightlight to suffer an injury, potential embryo donors have to choose to donate their embryos for research, and not for adoption.

The choice, however, is not simply whether to donate embryos for research or for adoption. The donors must choose between continuing to store the embryos, discarding them, donating them for research, or giving them to an adoption agency involved in embryonic

adoption. This choice is solely within the discretion of individuals in possession of embryos that are no longer needed for reproductive purposes. By allowing funding for hESC research, the guidelines do not interfere with the discretion of potential donors.

Accordingly, the Court finds that Nightlight lacks standing because its alleged injury is “mere ‘unadorned speculation’ as to the existence of a relationship between the [guidelines] and the third-party conduct.” *Nat’l Wrestling Coaches Ass’n*, 366 F.3d at 938 (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 44 (1976)). Indeed, if Nightlight suffers any injury at all, it will be because of the choices of third parties not before this court, and not because of the guidelines.

3. *Embryos*

Nightlight also seeks to proceed in this complaint on behalf of all embryos created for reproductive purposes that are no longer needed for such purposes. The complaint alleges that the embryos face the risk of imminent injury, *i.e.*, destruction, as result of the NIH guidelines. (Compl. ¶ 9.) The Court finds, however, that the embryos are not “persons” under the law, and therefore do not have standing.

Plaintiffs reliance on *Hatch v. Riggs Nat’l Bank*, 361 F.2d 559, 566 (D.C. Cir. 1966) for the proposition that embryos qualify as persons and should have a guardian ad litem appointed to represent their interest is misplaced. *Hatch* concerned the “interests of unborn and/or otherwise unascertainable beneficiaries of a trust.” *Id.* An unborn’s legal interest in a trust has been recognized for centuries. *See Roe v. Wade*, 410 U.S. 114, 162 (1973) (noting that historically guardians ad litem have been appointed to represent property interest of the unborn that are “contingent upon live birth”). This case, however, does not concern whether an embryo qualifies

as a person in order to enforce a trust. Rather, it concerns whether an embryo qualifies as a person in order to assert a liberty interest. The Supreme Court has stated that “the unborn have never been recognized in the law as persons in the whole sense” and that they have no right to life protected under the Fourteenth Amendment. *Id.* at 158, 162. Accordingly, the Court concludes that the embryos lack standing because they are not persons under the law. *See Doe v. Shalala*, 862 F. Supp. 1421, 1426-27 (D. Md. 1994) (declining to appoint a guardian ad litem for an embryo and dismissing the case as to the embryo because it is not a person under the law).

4. *The Nelsons and Flynns*

The Nelsons and Flynns, who each have had a child through the adoption of an embryo from Nightlight, allege that they are seeking to adopt additional human embryos. (Compl. ¶¶ 10-11.) They contend the guidelines injure them by “jeopardiz[ing] the likelihood that embryos will become available in a timely manner for adoption and implantation.” (*Id.*)

The Court finds that the Nelsons and Flynns have not alleged a concrete and imminent injury. As discussed with Nightlight, the allegation that fewer embryos will be available for adoption is speculative and dependent upon third parties. *See Nat’l Wrestling Coaches Ass’n*, 366 F.3d at 938. Moreover, the guidelines do not regulate embryonic adoption, and neither the Nelsons nor the Flynns allege that the guidelines have erected any barriers to their efforts to adopt an embryo. Accordingly, the Nelsons and Flynns do not have standing.

5. *Drs. Sherley and Deisher*

Drs. Sherley and Deisher allege that the guidelines “will result in increased competition for limited federal funding and will thereby injure [their] ability to compete successfully for . . . NIH stem cell research funds.” (Compl. ¶¶ 6, 7.) The Court finds that increased competition for

funding is an insufficient injury to impart standing.

Drs. Sherley and Deisher contend that they have standing under the “competitor standing” doctrine. Under the competitor standing doctrine, a plaintiff “suffer[s] constitutional injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition.” *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998). The plaintiff does not have to wait to suffer a specific injury, provided that the “challenged agency action authorizes allegedly illegal transactions that will almost surely cause [the plaintiff] to lose business.” *El Paso Natural Gas Co. v. FERC*, 50 F.3d 23, 27 (D.C. Cir. 1995).

The competitor standing doctrine is not applicable to the facts of this case. The Supreme Court has held that the competitor standing doctrine applies only “when the particular statutory provision [or regulation] invoked . . . reflect[s] a legislative purpose to protect a competitive interest.” *Hardin v. Ky. Util. Co.*, 390 U.S. 1, 6 (1968). Here, Drs. Sherley and Deisher have not demonstrated that they have a protected competitive interest in receiving NIH funding. Their only protected interest is their opportunity to compete with other applicants for limited NIH funding. *See CC Distributors Inc. v. United States*, 883 F.2d 146, 150 (D.C. Cir. 1989) (stating that “a plaintiff suffers a constitutionally cognizable injury by the loss of an opportunity to pursue a benefit”). The guidelines neither prevent nor hinder either doctor’s opportunity to compete for funding. Indeed, Drs. Sherley and Deisher’s proposals for adult stem cell research can receive funding if they survive the two-tier review process that *all* applications undergo. (Rockey Decl. ¶ 8.)

In addition, the cases relied upon by Drs. Sherley and Deisher are readily distinguishable. In those cases, the competitor standing doctrine applied where the petitioners were active

participants in the strictly regulated economic markets of energy, communication, and banking. *See, e.g., La. Energy & Power Auth.*, 141 F.3d at 365 (challenging a FERC ruling that would increase competition in a local market); *U.S. Telecom Ass’n v. FCC*, 295 F.3d 1326, 1330-31 (D.C. Cir. 2002) (challenging an FCC ruling that would enable a competitor to charge lower prices); *Investment Co. Inst v. FDIC*, 815 F.2d 1540, 1542-43 (D.C. Cir. 1987) (challenging an FDIC ruling that would allow banks that are not members of the Federal Reserve System to engage in the securities business). Drs. Sherley and Deisher, however, are not participants in strictly regulated economic markets. They are applicants for research grants. Unlike in an economic market, an increase in competition for funding does not mean that all other applicants are harmed. *See, e.g., Idaho Power Co. v. FERC*, 312 F.3d 454, 41 (D.C. Cir. 2002) (noting that the basic laws of economics assume that increased competition will cause a drop in prices or sales for existing competitors). As stated above, Drs. Sherley and Deisher may still receive funding.

Last, even if the competitive standing doctrine did apply, Drs. Sherley and Deisher would not have standing because the guidelines will not “almost surely cause [Drs. Sherley and Deisher] to lose” funding. *El Paso Natural Gas Co.*, 50 F.3d at 27. The application process to receive NIH funding is extremely competitive. Only about 22% of applications receive NIH funding. (Rockey Decl. ¶ 14.) Thus, even if the guidelines did not exist, Drs. Sherley and Deisher are not assured of receiving funding for adult stem cell research.

Accordingly, the Court concludes that the competitor standing doctrine does not apply and that Drs. Sherley and Deisher lack standing.

IV. CONCLUSION

For the reasons set forth above, the Court finds that plaintiffs lack standing and will grant defendants' Motion [22] to Dismiss. A separate order shall issue this date.

Signed by Royce C. Lamberth, Chief Judge, on October 27, 2009.