IN THE UNITED STATES COURT OF APPEALS
FOR THE D.C. CIRCUIT

JAMES L. SHERLEY, *et al.*,

Appellees,

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services, *et al.*,

Appellants.

No. 10-5287
[Civil Action No. 1:09-cv-, 1575 (RCL) (D.D.C.)]

DEFENDANTS' EMERGENCY MOTION TO STAY PRELIMINARY INJUNCTION PENDING APPEAL AND REQUEST FOR IMMEDIATE ADMINISTRATIVE STAY

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INTRODUCTION AND SUMMARY

Defendants, the Secretary of Health and Human Services, et al., respectfully ask the Court to stay pending appeal the district court's preliminary injunction of August 23, 2010. The order enjoins the National Institutes of Health ("NIH") "from implementing, applying, or taking any action whatsoever pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." Add. 1 (Order 1). The order is at odds with the express intent of Congress in enacting the funding restriction at issue, and with the longstanding interpretation of that restriction by NIH, of which Congress was fully aware. To avoid immediate loss of ongoing medical research aimed at curing the most devastating illnesses afflicting Americans, we also ask that the Court issue an administrative stay pending its consideration of this motion. The district court denied the government's motion for a stay pending appeal on September 7, 2010.

The preliminary injunction rests on the district court's erroneous legal conclusion that NIH Guidelines violate an appropriations restriction known as the Dickey-Wicker Amendment. Congress first enacted the Dickey-Wicker Amendment in 1996 and has included the same language in subsequent appropriations bills without substantive change. In its current form, it prohibits the use of federal funds for "(1) the creation of a human embryo or embryos for research purposes; or (2) research in

which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death * * * ." Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81.

NIH has consistently interpreted this provision throughout the past decade to distinguish between funding for research that involves the creation or destruction of embryos (which is prohibited) and funding for research that involves the use of stem cell lines derived from embryos. *See* Add. 95 (65 Fed. Reg. 51,975 (Aug. 25, 2000)); Add. 89 (74 Fed. Reg. 32,170, 32,173 (July 7, 2009)); *see also* Add. 12-13 (discussing NIH's interpretation). In repeatedly reenacting the same statutory language, Congress has been well aware of the agency's interpretation of the funding restriction. Indeed, the relevant Committee Report for the 2010 appropriations bill, which was enacted after issuance of the current NIH Guidelines, noted that the bill "should not be construed to limit Federal support for research involving human embryonic stem cells carried out in accordance with policy outlined by the President." H.R. Rep. No. 111-220, at 273 (July 22, 2009); *see also* S. Rep. No. 111-66, at 121-22 (Aug. 4, 2009) (welcoming the Guidelines and noting the "congressional intent to expedite this important area of research"); H.R. Rep. No. 111-366, at 982 (Dec. 8, 2009) ("In implementing this conference agreement, the Departments and agencies should be guided by the language and instructions set forth in House Report 111-220 and Senate Report 111-66 accompanying the bill, H.R. 3293.").

The district court set aside this longstanding agency interpretation that had been repeatedly ratified by Congress, and erased the distinction between, on the one hand, funding the derivation of stem cell lines and, on the other hand, funding research using stem cell lines already derived from human embryos. In the court's view, because embryonic stem cells "must be derived from an embryo," embryonic stem cell research "is clearly research in which an embryo is destroyed." Add. 13 (Aug. 23 Op.). That view necessarily precludes federal funding for any and all embryonic stem cell research.

The order stops NIH funding for embryonic stem cell research in its tracks, and precludes NIH from acting on embryonic stem cell grant applications that have already been fully reviewed and from considering dozens of other applications in various stages of the review process. Absent a stay, it will likely take as long as 6 to 8 months to re-initiate the peer review process for grant applications. Add. 54, ¶ 18 (Decl. of Francis S. Collins, Director of NIH). Disruption of ongoing research will result in irreparable setbacks and, in many cases, may destroy a project altogether.

The two plaintiff scientists, by contrast, identify no imminent irreparable harm to themselves that would result from a stay. Indeed, they identify no irreparable harm that has occurred in the 10 months since their suit was originally dismissed for lack of standing. In a prior opinion, this Court concluded that the two scientists, who engage in research using adult stem cells, have standing to challenge the allocation of funds to

other stem cell research based on possible competitive injury. *See* Add. 74 (D.C. Cir., June 25, 2010). A stay pending appeal will not impair that asserted interest. Dr. Deisher has never applied for research funding from NIH and states only that she is "in the process of applying" for funding. Add. 56, ¶ 24; 59, ¶ 4 (Decl. of Dr. Deisher). And Dr. Sherley has received $425,500 in NIH grant funds since implementation of the Guidelines. Add. 55-56, ¶ 23 (Decl. of Dr. Sherley). The speculative interest of competitive injury by those who have not sought to compete previously or have successfully competed cannot outweigh the disruption or ruin of research into promising treatments for the most debilitating illnesses and injuries.

In sum, because the injunction rests on legal error and will result in significant, irreparable injury, we ask that the Court stay the ruling pending appeal and issue an administrative stay pending consideration of this motion.

STATEMENT

I. Stem Cell Research.

Three kinds of stem cells are available for research – human embryonic stem cells, adult stem cells, and induced pluripotent stem cells. *See* National Academies, *Understanding Stem Cells: An Overview of the Science and the Issues from the National Academies* 2, *available at* http://dels.nas.edu/bls/stemcells/basics.shtml. Most embryonic stem cells - and all those eligible for use in federally funded projects - are produced from stem cell lines derived from embryos that were created in an *in vitro* fertilization clinic

for reproductive purposes. In many cases, more embryos are created than are necessary to meet an individual or couple's reproductive goals or some embryos may be unsuitable for transfer. Those individuals or couples may choose to donate their remaining embryos for stem cell research.

Embryonic stem cells are pluripotent, meaning that they are able to transform into any of the approximately 200 types of cells in the human body. Adult stem cells are not pluripotent and can only differentiate into a restricted set of specialized cells. Induced pluripotent stem cells, a recent innovation, are adult cells that are reprogrammed to assume a state similar to embryonic stem cells.

Each of these types of cells has its own capabilities and limitations and presents its own research possibilities and challenges, and NIH is committed to funding research on each type of stem cell line. *See* Add. 48-49, ¶ 7; 55, ¶ 22. For FY 2010, NIH has provided approximately $380 million in funding to non-embryonic (adult and pluripotent) stem cell research; for FY 2010 to date, NIH has provided $131 million to funding human embryonic stem cell research. Add. 55, ¶ 22.

II. Regulatory Background.

A. Beginning in 1996, Congress has restricted appropriations in language known as the Dickey-Wicker Amendment. The language, which has not been substantively altered since its first enactment, prohibits NIH from funding "research

in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." *See* Pub. L. No. 111-117, Div. D, § 509(a).

This language has always been understood to bar funding for extracting stem cells from embryos to create embryonic stem cell lines, but not for research using stem cell lines. As noted, embryonic stem cell lines eligible for use in federally funded projects are created using cells extracted from embryos that were created in an *in vitro* fertilization clinic and donated for research purposes by individuals or couples when there was no longer a need for them for reproductive purposes.

A stem cell line is typically created by growing the cells extracted from a four- or five-day-old embryo in a laboratory culture dish where, with appropriate care, the cells begin to divide. Embryonic stem cells that have continued to divide for a prolonged period without differentiating, and are genetically identical to the original cells, are referred to as an embryonic stem cell line. With appropriate care, embryonic stem cell lines continue to divide and produce additional identical embryonic stem cells indefinitely. NIH does not fund the creation of stem cell lines.

NIH has consistently recognized, however, that research using stem cells is not "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." *See* Add. 97 (65 Fed. Reg. at 51,976 (Aug. 25, 2000)). As the current Guidelines explain, funding "of the derivation of stem cells from human embryos is prohibited" but NIH has "consistently interpreted

[the Amendment] as not applicable to research using [embryonic stem cell lines], because [embryonic stem cells] are not embryos as defined by" the Amendment. Add. 93 (Fed. Reg. at 32,173 (July 7, 2009)). The researchers using stem cell lines are rarely those who derived the stem cells in the first instance.

B. On March 9, 2009, President Obama issued Executive Order No. 13,505. *See* Add. 86. The order provided that NIH "may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." Add. 87, § 2. The President directed NIH to review existing guidelines on human stem cell research, and to "issue new NIH guidance on such research that is consistent with this order." *Id.* § 3.

The executive order also withdrew two directives that had been issued in the prior administration: (1) a presidential statement of August 9, 2001, and (2) Executive Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007). Add. 88, § 5. In these directives, President Bush had announced his policy of permitting federal funding of some research using embryonic stem cells, but limiting funding to research involving stem cells produced by lines that were created by private or foreign researchers from "embryos that have already been destroyed." *See* Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001); *see also* Executive Order No. 13,435, 72 Fed. Reg. 34,591.

NIH issued the final Guidelines on July 7, 2009, through notice-and-comment rulemaking. Add. 89. The Guidelines require that research involve only embryonic stem cells produced by lines that "have been derived from human embryos" that "were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose" and "were donated by individuals * * * who gave voluntary written consent for the human embryos to be used for research purposes." Add. 93.

III. Prior Proceedings.

A. Plaintiffs Dr. James L. Sherley and Dr. Theresa Deisher are scientists who perform research using adult stem cells. The suit originally included several other plaintiffs, including an agency facilitating the adoption of frozen embryos, three of its clients, the Christian Medical Association, and embryos created using *in vitro* fertilization and no longer needed for reproduction. The district court dismissed claims by all plaintiffs for lack of standing. The ruling was appealed only with respect to the two scientists. This Court held that the two scientists fell within the "competitor standing" doctrine, under which "'plaintiffs may establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate potential to compete with [their] own sales.'" Add. 80 (citation omitted). The Court reasoned that the increase in grant applications for embryonic cell research resulting from the Guidelines would

"intensif[y] the competition for a share in a fixed amount of money." Add. 83.[1] The Court declined plaintiffs' invitation to reach the merits of their claims and remanded to the district court. *Ibid.*

B. On August 23, without receiving any additional filings from the parties to address developments that had taken place during the 10 months during which there had been no stay in place, the district court issued a preliminary injunction. The order enjoins defendants from "implementing, applying, or taking any action whatsoever pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." Add. 1 (Aug. 23 Order).

The district court denied the government's motion for a stay pending appeal on September 7. Add. 19.

ARGUMENT

In considering whether to grant a stay pending appeal, the Court is guided by the four factors set out in *Washington Metro. Area Transit Comm'n* v. *Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977). The government's likelihood of success on the merits as well as the balance of harms strongly militate in favor of a stay in this case.

[1] The government respectfully disagrees with the panel's holding. We recognize, however, that the ruling is binding on other panels.

I. The Government Has A Strong Likelihood Of Success On The Merits.

A. Congress has included the Dickey-Wicker Amendment in NIH's annual appropriations bill without substantive change since 1996, despite policy shifts in federal funding for stem cell research. As enacted in the FY 2010 appropriations bill, the amendment restricts funds for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death."

At no point in the 14 years since the Amendment was first enacted has NIH interpreted this language to bar embryonic stem cell research. Instead, it has consistently interpreted the Amendment to prohibit federal funding of the derivation of a stem cell line. *See* Add. 97 (65 Fed. Reg. at 51,976 (Aug. 25, 2000)) (research using embryonic stem cells is not "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death").

Although President Bush limited federal funding to projects that used stem cells produced by lines created prior to the announcement of his policy, that policy rested on the premise that research using embryonic stem cells is not "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." Congress explicitly recognized in reenacting the Dickey-Wicker language for FY 2002 that the Bush policy was consistent with the Amendment, which does not categorically prohibit funding of all research using embryonic stem cells. *See*

H.R. Rep. No. 107-229, at 180 (Oct. 9, 2001); *see also* S. Rep. No. 107-84, at 18 (Oct. 11, 2001).

After President Obama revoked the orders issued by President Bush, NIH issued the Guidelines challenged here. Like their predecessors, these Guidelines do not authorize funding for the extraction of embryonic stem cells or the creation of embryonic stem cell lines. They provide, moreover, that research using embryonic stem cells will be eligible for federal funding only if the stem cells were produced by stem cell lines that "have been derived from human embryos" that "were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose" and "were donated by individuals * * * who gave voluntary written consent for the human embryos to be used for research purposes." Add. 94.

When Congress included the Dickey-Wicker Amendment in the FY 2010 appropriations bill, it was fully aware of the NIH Guidelines. The relevant Committee Report, like Committee Reports issued during the Bush administration, declared that the Amendment's "language should not be construed to limit Federal support for research involving human embryonic stem cells carried out in accordance with policy outlined by the President." H.R. Rep. No. 111-220, at 223 (July 22, 2009); *see also* S. Rep. No. 111-66, at 121 (Aug. 4, 2009) ("The Committee is pleased that stem cell research was included as a special emphasis area in the NIH Challenge Grant program * * * . The Committee also welcomes the recent release of guidelines for the use of

human embryonic stem cells [hESC] with NIH funds * * * ."); H.R. Rep. No. 111-366, at 982 (Dec. 8, 2009) ("In implementing this conference agreement, the Departments and agencies should be guided by the language and instructions set forth in House Report 111-220 and Senate Report 111-66 accompanying the bill, H.R. 3293.").

Even absent such clear statements of legislative intent, the reenactment of legislative language with knowledge of the existing Executive Branch interpretation would counsel hesitation in setting that interpretation aside. This Court has noted that "Congress is presumed to preserve, not abrogate, the background understandings against which it legislates." *United States* v. *Wilson*, 290 F.3d 347, 356 (D.C. Cir. 2002); *see also Lorillard* v. *Pons*, 434 U.S. 575, 580-58 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."); *N.L.R.B.* v. *Bell Aerospace Co.*, 416 U.S. 267, 274-75 (1974) ("[A] court may accord great weight to the longstanding interpretation placed on a statute by an agency charged with its administration. This is especially so where Congress has re-enacted the statute without pertinent change.").

B. In invalidating the NIH Guidelines, the district court concluded that it would not "defer[] to the NIH's interpretation" of the Dickey-Wicker Amendment because, in the court's view, that interpretation was not "'based on a permissible construction of the statute.'" Add. 10-11 (quoting *Chevron U.S.A., Inc.,* v. *Natural*

Resources Defense Counsel, Inc., 467 U.S. 837, 843 (1984)). As noted, the Amendment restricts funds for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." This plain language, on its face, does not apply to research that uses embryonic stem cells from previously derived stem cell lines, which is not research in which embryos are destroyed.

The district court nonetheless concluded that "'Congress had directly spoken to the precise question at issue.'" Add. 10-12 (quoting *Chevron*, 467 U.S. at 842). The court declared that "the term 'research' as used in the Dickey-Wicker Amendment has only one meaning, *i.e.*, 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.'" Add. 11 (quoting 45 C.F.R. § 46.102(d)).[2] In the court's view, this definition compels the conclusion that "[d]espite defendants' attempt to separate the derivation of [embryonic stem cells] from research on the [embryonic stem cells], the two cannot be separated." Add. 13.

To say that research is a "systematic investigation" does not mean that each research project includes the projects and actions that preceded it– including projects performed by different scientists. At a minimum, the court's interpretation does not

[2] The definition cited by the district court is contained in the Human Subject Protection Regulations, referenced in the Dickey-Wicker Amendment, which govern research involving human subjects.

constitute a declaration of the statute's "plain language." The court opined that if Congress had meant to enact the distinctions reflected in NIH interpretations, "Congress could have written the statute that way." Add. 12. It is sufficient, however, that the legislative language is fully consistent with the longstanding NIH interpretation cited by Congress in reenacting the Dickey-Wicker Amendment. Indeed, if Congress had meant to ban all federal funding for "research involving human embryonic stem cells," as the district court held, it could certainly "have written the statute that way" when it first enacted the Amendment or on later occasions, rather than use the markedly different language "research in which a human embryo or embryos are destroyed." Thus, the district court's conclusion that a stay pending appeal "would flout the will of Congress," Add. 20 (Sept. 7 Stay Order), is not well founded.

II. The Balance Of Harms And The Public Interest Strongly Favor A Stay.

Even if the government's case on the merits were far less compelling, the balance of harms would warrant issuance of a stay.

The district court's assessment of the injuries resulting from its order is altogether asymmetric. On the one hand, the court accepted uncritically plaintiffs' assertion "'that obtaining NIH funding is necessary for their continued research.'" Add. 14 (citing plaintiffs' opposition at 44.). To demonstrate irreparable harm, the

court found it sufficient that the plaintiffs might suffer some competitive injury if research funds were awarded to other scientists whose research involves embryonic stem cell lines. It was irrelevant to the court's analysis that Dr. Deisher has never applied for research funding from NIH and states only that she is "in the process of applying" for funding. Add. 56, ¶ 24; 59, ¶ 4. Dr. Sherley's declaration states only that he has in the past received NIH grants and now has two grants pending. Add. 72-73 (Decl. of Dr. Sherley). It fails to note that he has received $425,500 in NIH grant funds *since* implementation of the current Guidelines. Add. 55-56, ¶ 23. Indeed, NIH funding for adult and induced pluripotent stem cell research far exceeds funding for embryonic stem cell research. For FY 2010, NIH has provided approximately $380 million in funding to non-embryonic stem cell research and $131 million in funding human embryonic stem cell research. The $380 million provided during FY 2010 is also far greater than the $297 million for non-embryonic stem cell research provided in 2008. Add. 135-36, ¶ 18 (Decl. of Sarah Jean Rockey); Add. 55, ¶ 22. There is, moreover, no reason to conclude that an immediate halt of funding of embryonic stem cell research would result in a reallocation of funds in a way that would have any short-term impact whatsoever on Dr. Sherley's pending applications.

The harm to the current, ongoing NIH funded research using embryonic stem cellls, on the other hand, is direct and immediate, and potentially blocks lifesaving medical advances. Under the injunction, NIH is barred outright from funding such

research. The district court nevertheless declared that its injunction "would not seriously harm [embryonic stem cell] researchers" because it "would not interfere with their ability to obtain private funding for their research." Add. 15. But it is unclear why the federal funding that the court deemed *"necessary* for [plaintiffs'] continuing research," Add. 14 (quoting plaintiffs' opposition at 44), is not similarly necessary to the research of those scientists who are now cut off altogether. *See also* Add. 59, ¶ 4 (Decl. of Dr. Deisher) (stressing that "private funding is scarce").

The declaration of the Director of NIH, Dr. Collins, explains that the injunction bars funding for an additional 20 human embryonic stem cell research projects, which have successfully completed NIH's rigorous peer review process. Add. 53, ¶ 15. NIH planned to award $24 million in funding to these projects by September 30. *Ibid;* Add. 49-50, ¶ 9. The injunction also halts NIH consideration of all pending applications for projects using embryonic stem cells. NIH has ceased peer review activities of all human embryonic stem cell research applications and estimates that if the injunction is not stayed pending appeal, it will take as long as 6 to 8 months for the process to begin again. Add. 54, ¶ 18. As a result of the injunction, NIH has also ceased reviewing stem cell lines to determine whether they are eligible for placement on the NIH Human Embryonic Stem Cell Registry and has put on hold work on a revision of the NIH guidelines that has been under development for over 7 months. Add. 54, ¶¶ 19, 20.

In denying the government's motion for a stay, the district court stated that plaintiffs, in their opposition to the government's district court stay motion, "question whether this Court's order prevents NIH from doing peer review of applications." Add. 20. The injunction enjoins NIH "from *implementing, applying, or taking any action whatsoever* pursuant to the" challenged Guidelines "or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." Add. 1 (emphasis added). The court did not explain how its order could be construed to continue the application review process. Indeed, plaintiffs did *not* question whether the injunction applies to the peer review process, arguing instead that "the processing of additional Registry and grant applications contributes directly to the competitive injuries to Plaintiffs (and other scientists) that the preliminary injunction was designed to prevent, and was properly enjoined." Add. 28. The district court disregarded that argument, however, and instead stated that "one would have expected these issues to have been briefed and decided with the preliminary injunction motion." Add. 20. As noted, the Court issued its injunction without any supplemental briefing to address developments that had taken place over the course of the intervening 10 months during which there had been no stay in place.

The court also stated that "Plaintiffs question whether this Court's order exempts so-called 'intramural' NIH projects—that is, research carried out onsite by NIH researchers." Add. 20. Plaintiffs did not, in fact, question the injunction's

applicability to NIH researchers. Add. 28. The court suggested that additional briefing on plaintiffs' standing to challenge intramural research might be appropriate, Add. 20, but did not narrow the scope of its injunction to make it inapplicable to these activities.

It is extraordinary that the district court would enjoin ongoing federal intramural research without first considering whether plaintiffs have standing to challenge such research. Dr. Collins' declaration explains that the injunction cripples NIH's internal research program. NIH conducts eight intramural human embryonic stem cell research projects staffed by approximately 45 scientists and other personnel, with a combined budget of approximately $9.5 million for 2009. Add. 53-54, ¶ 17. The longer that NIH is prevented from carrying out intramural research, the more likely it is that unique biological materials that have taken years to develop and that require ongoing maintenance and attention will be lost. Add. 52, ¶ 12.

The district court injunction does not apply to funds already received by third parties. *See* Add. 27 (plaintiffs' opposition) (noting that the injunction "on its face * * * applies only to Defendants and their agents, not to third parties" and therefore does not affect funds provided prior to August 23); Add. 19 (citing pl. op. at 5). Dr. Collins explains in his affidavit, however, that 24 multi-year human embryonic stem cell projects were expecting to receive continuation funds on September 30 for their continued existence. Add. 50-51, ¶ 10. It is not clear whether the order applies to

these projects, but if those annual continuation funds are not forthcoming, even during the period of appellate review, many of these research projects will be terminated before the fruits of their research can be realized. *Ibid.* Valuable and unique research resources are likely to be lost, and, with them, the potential for life-saving therapies. Add. 47-52, ¶¶ 6, 12. The premature termination of these 24 federal research projects will also waste much of the approximately $64 million in funds that NIH had already invested in this research. Add. ¶ 10.

The district court dismissed the significance of its ruling to the public interest, stating that "the harm to individuals who suffer from diseases that one day may be treatable as a result of" research using embryonic stem cell lines "is speculative." Add. 15. "It is not certain," the court declared, whether such "research will result in new and successful treatments for diseases such as Alzheimer's and Parkinson's disease." Add. 15. It is quite true that the path to a cure for any disease is fraught with uncertainties. It is quite another thing to describe as "speculative" the importance of one of the most vital areas of research into the origins and treatments of human disease. *See* Add. 46-49, ¶¶ 5-7. The progress made by scientists using human embryonic stem cell lines is real, and is particularly important because embryonic stem cells, unlike adult stem cells, are pluripotent. The district court's discounting of the significance of this research does not reflect the public interest at stake.

CONCLUSION

For the foregoing reasons, the Court should grant a stay pending appeal of the preliminary injunction entered on August 23, 2010, and an immediate administrative stay pending its consideration of this motion.

Respectfully submitted,

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SEPTEMBER 2010

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of September, 2010, I electronically filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system and by hand-delivering four paper copies.

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties And Amici. Plaintiffs in the district court, and appellees in this appeal, are Dr. James L. Sherley, Dr. Theresa Deisher, Nightlight Christian Adoptions, Shayne Nelson, Tina Nelson, William Flynn, Patricia Flynn, Christian Medical Association, and Embryos.

Defendants in the district court, and appellants in this appeal, are Kathleen Sebelius, in her official capacity of Secretary of the Department of Health and Human Services, Department of Health and Human Services, Francis S. Collins, in his official capacity as Director of National Institutes of Health, and National Institutes of Health.

Coalition for the Advancement of Medical Research moved to appear as amicus in the district court, but the district court denied that motion.

B. Rulings Under Review. The rulings under review are the August 23, 2010, order and memorandum opinion of the district court, issuing a preliminary injunction. *Sherley v. Sebelius*, No. 1:09-cv-1575-RCL (D.D.C. Aug. 23, 2010) (Chief Judge Royce C. Lamberth). The order and opinion appear at page 1 of the Addendum. The district court's opinion is also available at 2010 WL 3296974.

Also under review is the district court's September 7 order denying the government's motion for stay. Add. 19.

C. Related Cases. This matter has previously come before this Court in *Sherley v. Sebelius,* No. 09-5374 (June 25, 2010). The opinion is available at 610 F.3d 69 and at page 74 of the Addendum. Counsel is aware of no other related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

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