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' REPLY TO PLAINTIFFS' OPPOSITION TO EMERGENCY MOTION TO STAY PRELIMINARY INJUNCTION PENDING APPEAL AND REQUEST FOR IMMEDIATE ADMINISTRATIVE STAY

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INTRODUCTION AND SUMMARY

Plaintiffs urge in this Court that the Dickey-Wicker amendment, first enacted in 1996, has for 14 years precluded any and all federal funding of scientific research using embryonic stem cell lines. As plaintiffs do not dispute, the National Institutes of Health ("NIH") has funded research using embryonic stem cells since 2002, and has not interpreted the Amendment to bar such grants. Add. 47 (Decl. ¶ 5). Fully aware of NIH practice, Congress has used the same language in reenacting the funding limitation, and has repeatedly made clear that NIH's practice is consistent with the statute. Indeed, the relevant Committee Report for the 2010 appropriations bill, 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).

The district court held, however, that the amendment's language has posed an absolute and unambiguous bar to all federal funding of research using embryonic stem cells. In this view, the executive branch has for years contravened the law, and Congress, unaccountably, has approvingly reenacted the same statutory language.

The bar posited by plaintiffs and the district court has never existed. Instead, the amendment prohibits NIH from funding "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." As NIH explained in issuing the current guidelines, the amendment prohibits funding "of the

derivation of stem cells from human embryos," Add. 94, and, as NIH explained ten years ago, and reiterated in 2009, 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," Add. 96; *see also* Add. 92.

Plaintiffs insist that this consistent interpretation reflects a "warped reading of the term 'research,'" Opp. 6, which should be understood to mean a "systematic investigation," Opp. 5 (quoting 45 C.F.R. § 46.102(d)). Referring to scientific research projects as "systematic investigations" adds nothing to plaintiffs' argument and does not expand research funded by NIH to include antecedent acts that were not funded by NIH.

Plaintiffs do not take serious issue with the impact of the preliminary injunction on NIH in the absence of a stay. As plaintiffs do not dispute, the order precludes NIH from acting on embryonic stem cell grant applications that have already been fully reviewed, bars NIH from considering dozens of other applications in various stages of the review process, halts the agency's own intramural research, and threatens extramural research projects that depend for their continued existence on the provision of NIH funds on a yearly basis. Disruption of ongoing research will result in irreparable setbacks and, in many cases, may destroy a project altogether. In contrast, the two plaintiff scientists identify no imminent irreparable injury.

DISCUSSION

A. 1. Plaintiffs argue in this Court that Congress has, since 1996, barred all NIH funding of research using embryonic stem cells. Plaintiffs do not dispute that NIH has never interpreted the Dickey-Wicker amendment to create such a bar. They also do not dispute that Congress has repeatedly reenacted the same language with full knowledge of the way in which the restriction was being implemented.

The executive branch and Congress have not, as plaintiffs suggest, consistently failed to recognize the "unambiguous" meaning of the amendment. The provision precludes funding for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." As NIH explained in the 2000 guidelines, embryonic stem cells are not embryos. When NIH funds embryonic stem cell research, it is not funding research in which "embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." *See* Add. 92. If Congress had meant to ban all federal funding for all research involving human embryonic stem cells, as plaintiffs urge, it could have said so in any of the reenactments of the amendment.

Plaintiffs reformulate the statute to "plainly prohibit[] funding for any 'research' that entails, as one part of an overall 'systematic investigation,' the discarding or destruction of an embryo." Opp. 6. The critical term in this reformulation is not, as plaintiffs suggest, "systematic investigation." To say that research is "systematic" does not mean that it includes actions that occurred prior to the beginning of the "systematic

investigation" funded by NIH. The critical term introduced in plaintiffs' reformulation is "entails," which, as used by plaintiffs, extends the statute to cover acts antecedent to the research being funded. The statute itself, however, refers to the funding of "research *in which*" a human embryo is destroyed, discarded or endangered. When NIH funds "research" it is funding a discrete project, which does not include all the independent actions that predate the project. Plaintiffs cannot convert the text of the amendment into an unambiguous ban on funding for research using embryonic stem cells.[1]

2. Plaintiffs make no attempt to reconcile their interpretation of the statute with Congress's repeated reenactment of the Dickey-Wicker amendment with full knowledge that it was not being interpreted in the manner proposed by plaintiffs. Nor can plaintiffs properly discount as "snippets" of legislative history, Opp. 8, the committee reports endorsing the executive branch's interpretation of the statutory language. *See, e.g.,* 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 * * * welcomes the recent release of guidelines for the use of human embryonic stem cells [hESC] with NIH funds * * * ."); Gov't Stay Motion 10-11.

Plaintiffs likewise err in asserting that no weight should be given to the agency's interpretation of the statute because "[t]o receive deference, an agency must in fact

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[1]Plaintiffs urge that discarding an embryo is not a discrete research project, and incorrectly reason that it must therefore form part of the of the subsequent stem cell research. *See* Opp. 5-6. That a prior act is not part of the research project does not require that the prior act *itself* have been a research project.

interpret the statutory provision in question[.]" Opp. 6. As plaintiffs recognize, NIH's 2000 guidelines explained 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." Add. 92. They insist, however, that "this assertion is entirely beside the point, because it does not interpret the critical term 'research.'" Opp. 6.

This argument does not withstand scrutiny. The 2000 guidelines concluded that research using embryonic stem cells obtained from a stem cell line is not research involving the destruction of an embryo because stem cells are not embryos. NIH distinguished between embryos and stem cells precisely because the amendment precluded funding for destruction of embryos, but did not preclude funding for research involving stem cells obtained from a stem cell line. The agency was not, as plaintiffs suggest, required to explicitly articulate the meaning of "research" reflected in its analysis. *See Nat'l R.R. Passenger Corp.* v. *Boston & Me. Corp.*, 503 U.S. 407, 420 (1992) (that agency "did not in so many words articulate its interpretation" did not preclude deference).

Seeking to discover an inconsistency in the agency's interpretation of the amendment, plaintiffs cite a 1996 letter from NIH stating that federal dollars should not be used to conduct genetic tests on DNA isolated from embryos. *See* Opp. 8 (citing Supp. Add. 120). The project in question did not involve stem cells obtained from a stem

cell line,[2] but rather involved preimplantation genetic diagnosis, which is research done directly on human embryos to detect genetic abnormalities. The research discussed in the 1996 letter would thus not be eligible for funding under the 2009 NIH guidelines.[3]

3. Plaintiffs, on the other hand, mistakenly attribute significance to language that Congress considered but did not include in the Dickey-Wicker amendment in 2001, which would have allowed funding of "all 'stem cell research.'" Opp. 9. As the Supreme Court has repeatedly cautioned, "Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.* 511 U.S. 164, 187 (1994) (citation omitted).

Although plaintiffs do not here expressly contend that the policy issued under President Bush would be consistent with their reading of the statute,[4] the district court, in denying a stay, stated that the Bush guidelines "allowed research only on existing stem

[2]Indeed, human embryonic stem cells were not isolated until 1998. Add. 47.

[3]Contrary to plaintiffs' implicit suggestion, the government has never maintained that the Dickey-Wicker amendment prohibits only funding for the creation of stem cell lines. For example, a research project designed to improve in vitro fertilization techniques through experimenting on an embryo and subjecting that embryo to risk of harm or destruction would be ineligible for federal funding.

[4]In their opposition to the government's motion for stay in the district court, plaintiffs suggested that the stem cell lines approved for use by President Bush did not come within the district court's injunction. *See* Add. 19, 27.

cell lines, foreclosing additional destruction of embryos." Add. 19. Plaintiff's "plain language" argument does not permit such distinctions and neither does the district court's decision, which held that embryonic stem cell research is "research in which an embryo is destroyed." Add. 13. Moreover, whether current funding guidelines will cause "additional destruction of embryos" is speculative. Most of the stem cell lines approved under the guidelines were derived from embryos donated prior to the issuance of the guidelines in 2009. And the guidelines require that stem cell lines used in federally funded research be derived from embryos that were created for reproductive purposes, but are no longer necessary for those purposes or were unsuitable because of abnormalities. Whether more embryos will be destroyed in the future as a result of the guidelines depends on whether an embryo used in research would not otherwise have been discarded due to the decision of the third-party donor.

B. 1. Plaintiffs do not take serious issue with the impact of the injunction on NIH and the federally funded projects discussed in our motion and Dr. Collins' declaration. They declare that "Appellants never briefed the 'peer review' or 'intramural' research issues in opposition to Appellees' motion for a preliminary injunction," Opp. 13, failing to note that the district court issued its preliminary injunction without notice 10 months after dismissing the case, providing no opportunity for NIH to address the current state of research and application review before it filed its stay motion. In opposing the government's motion in district court, plaintiffs declared that "Defendants seek

clarification as to whether this Court's order prevents NIH from doing peer review of applications for human embryonic stem cell research or from maintaining or processing applications for the Human Embryonic Stem Cell Registry," and stated that "[t]he Registry and the peer review processes, of course, are integral parts of the mechanism whereby embryonic stem cell research proposals are submitted and approved for NIH funding in violation of federal law." Add. 28. Plaintiffs further noted that "Defendants argue that this Court's order should exempt so-called 'intramural' NIH projects," declaring that such an exemption would be improper. *Ibid.*

Plaintiffs also note that intramural researchers were instructed to resume work upon issuance of the administrative stay, implying that work could easily be resumed after being halted for an extended period, Opp. 12, a contention without support. Plaintiffs also declare that upon issuance of the administrative stay, NIH allowed embryonic stem cell applications "to leapfrog proposals filed by Appellees or any other NIH grant applicants." Opp. 2. Plaintiffs declare that "there is only one explanation for NIH's actions – an ideological preference for spending as much federal money as practicable on illegal [embryonic stem cell] research." Opp.2

This tendentious assertion implies impropriety where it plainly does not exist. NIH simply resumed the activities that the preliminary injunction had prohibited. *See* Amended Status of Applications and Awards Involving Human Embryonic Stem Cells, and Submissions of Stem Cell Lines for Eligibility Consideration, http://grants.nih.gov/

grants/guide/notice-files/NOT-OD-10-136.html. The preliminary injunction caused the delay of embryonic stem cell research funding that would otherwise have been awarded prior to the end of the fiscal year. NIH directed its institutes and centers to process those funds as necessary to meet the applicable end-of-fiscal-year deadlines. NIH also directed its institutes to commence with the peer review of applications that were *delayed by the preliminary injunction* under the same schedule that was in place prior to the injunction. NIH was restoring the status quo with respect to human embryonic stem cell grants. It in no sense provided those grants with more favorable treatment than other grants.

Plaintiffs also incorrectly imply that money that would have funded human embryonic stem cell research could be redirected to their projects. Opp. 17. As noted in our motion, there is no reason to assume that money that would have supported embryonic stem cell research in FY 2010 could be reallocated for other research in FY 2011; FY 2010 funds must be obligated in 2010. Nor is there any basis for concluding that money allocated for embryonic stem cell research in FY 2011 would be reallocated to adult or induced pluripotent projects. Add. 135, ¶ 16. NIH has consistently funded adult stem cell research at a high level. For FY 2010, NIH has provided approximately $380 million in funding to non-embryonic stem cell research and $131 million to human embryonic stem cell research. Add. 55, ¶ 22. 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.

2. Plaintiffs urge that "[a] stay pending appeal will result only in further injury to Appellees and additional waste of taxpayer dollars being poured into an illegal, unethical, and scientifically speculative enterprise," and assert "the overwhelming scientific and ethical advantages of adult and induced pluripotent stem cell research over hESC research." Opp. 3. They invite this Court to adopt the view of the district court, which 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. No basis exists for setting aside the scientific judgment of NIH and the rigorous peer review process required to grant any application.

CONCLUSION

For the foregoing reasons and the reasons in the government's stay motion, the Court should grant a stay pending appeal of the preliminary injunction.

Respectfully submitted,

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SEPTEMBER 2010

CERTIFICATE OF SERVICE

I hereby certify that on this 20th 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. Service was accomplished on the following by the CM/ECF system:

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