

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JAMES L. SHERLEY, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Case Number 1:09-cv-01575-RCL
)	
KATHLEEN SEBELIUS, <i>et al.</i> ,)	
)	
Defendants.)	

**BRIEF AMICUS CURIAE OF
COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH
IN SUPPORT OF DEFENDANTS' EMERGENCY MOTION
TO STAY PRELIMINARY INJUNCTION PENDING APPEAL**

The Coalition for the Advancement of Medical Research (“CAMR”) is a coalition of nearly 100 nationally recognized patient organizations, universities, scientific societies, and foundations that engages in advocacy and education regarding breakthrough research and technologies in the field of medical and health research, including stem cell research.¹ CAMR respectfully submits this brief as amicus curiae in further support of Defendants’ Emergency Motion To Stay Preliminary Injunction Pending Appeal (Dkt. 48). This brief seeks to assist the Court in addressing two of the four factors relevant to evaluating Defendants’ emergency stay motion: the public interest and the likelihood of harm to other parties.²

¹ CAMR is a not-for-profit organization under section 501(c)(4) of the Internal Revenue Code. A list of CAMR’s members is attached hereto as Exhibit 1. Detailed information about CAMR is located on its website: <http://www.camradvocacy.org> (last visited Sept. 3, 2010).

² See *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987) (factors include (1) the movant’s likelihood of prevailing on the merits of the appeal, (2) whether the movant will suffer irreparable harm absent a stay, (3) the harm to third parties if a stay is granted, and (4) the public interest.) Defendants address all four factors in their motion and supporting memorandum. See generally Mot. And Mem. In Supp. Of Defendants’ Emergency Mot. To Stay Preliminary Injunction

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As demonstrated by Defendants, and further explained herein, a stay of the preliminary injunction will serve the public interest and avoid substantial – indeed, irreparable – harm to other parties, including CAMR’s member organizations and their constituents, who include scientists conducting cutting-edge human embryonic stem cell (“hESC”) research and millions of patients who stand to benefit from such research.³ Absent a stay, the preliminary injunction will halt – and in some cases, permanently impair – research projects that have been in progress for years, wasting millions of dollars invested in such research.⁴ It will preclude the funding and initiation of some 20 new research projects that have passed the rigorous, competitive peer review process operated by the National Institutes of Health (“NIH”).⁵ It will cause serious economic harm to research institutions and the researchers who have committed their professional careers to hESC research.⁶ And, most critically, the resulting delay and disruption will inevitably mean that potential beneficiaries of hESC research risk losing the benefit of therapeutic treatments that would have been developed and deployed but for the injunction. These potential beneficiaries include a vast range of current or future patients, many of whom are afflicted with diseases or conditions that currently have no effective treatment options.

Thus, the preliminary injunction, if not stayed, will not maintain the status quo, but will instead effectuate a dramatic change and irreparably damage one of NIH’s most important

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Pending Appeal And For Expedited Briefing And Consideration (Dkt. 48 and 48-1) (“Def. Stay Mem.”).

³ See Def. Stay Mem. at 2-4, 18-20 & Declaration of Dr. Francis Collins (Dkt. 48-2) (“Collins Decl.”) ¶¶ 5, 8, 10-17.

⁴ Collins Decl. ¶¶ 10-12.

⁵ *Id.* ¶¶ 5, 15.

⁶ *Id.* ¶¶ 8, 14.

research programs.⁷ It will radically disrupt research planned and implemented by researchers and through institutions that reasonably understood that their federal funding, to which successive Congresses repeatedly have acquiesced, was fully legal. Keeping the preliminary injunction in place pending an appeal would, in effect, function as a decision on the merits and frustrate effective appellate review.

ARGUMENT

I. THE PUBLIC INTEREST IN ONGOING HESC RESEARCH IS CLEAR.

A. hESCs Possess Unique Attributes That Offer Great Therapeutic Promise.

hESCs are derived from blastocysts, which are pre-implantation embryos that develop within five days after the fertilization of an egg by a sperm and are smaller than the period at the end of this sentence.⁸ The most common source of these blastocysts is in-vitro fertilization (“IVF”) clinics, which typically fertilize all of a woman’s retrieved eggs to maximize the chance of successful implantation.⁹ Because not all fertilized eggs are implanted, the IVF process most often produces “excess” blastocysts that are stored in freezers and typically would otherwise be destroyed.¹⁰ In order for an embryo to be donated for scientific research, the patients must first

⁷ Indeed, even Plaintiffs and their counsel have reportedly conceded that they were surprised by the scope of the injunction halting previously-commenced research, which granted relief they did not seek. *See Stem Cell Plaintiffs Cite Ethical Motivation*, Wall St. J., at A-4 (Sept. 2, 2010).

⁸ National Academy of Sciences, *Understanding Stem Cells: An Overview of the Science and Issues from the National Academies*, at 4 (2009), available at http://dels.nas.edu/resources/static-assets/materials-based-on-reports/booklets/Understanding_Stem_Cells.pdf (last visited Sept. 3, 2010) (“*Understanding Stem Cells*”) (cited in *Sherley v. Sebelius*, No. 1:09-cv-01575-RCL, Mem. Op. at 3(D.D.C. August 23, 2010) (Dkt. 44) (“PI Mem. Op.”)).

⁹ *Id.* at 5-6.

¹⁰ *Id.*; see also Department of Health and Human Services, *Regenerative Medicine*, at 3 (2006), available at <http://stemcells.nih.gov/info/scireport/2006report.htm> (last visited Sept. 3, 2010). This Court may take judicial notice of documents maintained by government agencies on their website, such as this report and the majority of the other materials cited herein, because they are “capable of accurate and ready determination by resort to sources whose accuracy cannot

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have determined that the embryo is no longer needed for family building purposes. After that determination, they then may choose to consent to the use of such an embryo for scientific research. After donation, hESCs are then derived from the donated embryo.¹¹ This process is always funded privately and results in an hESC line that has great therapeutic and research promise. It is the federally-funded research using such hESC lines that is the subject of this lawsuit.

As the Court recognized, hESCs are “pluripotent” – that is, they have the capability to differentiate into any of the approximately 200 different types of cells in the human body.¹² This capability distinguishes them from adult stem cells (“ASC”), which are multipotent – capable of differentiation into some different cell types – but not fully pluripotent, like hESCs.¹³ The pluripotency of hESCs has led to research into and development of directed differentiation, which allows scientists to achieve differentiation of hESCs into specific types of human cells. These differentiated cells are used for research intended to lead to the development of cures and therapeutic treatments for a variety of diseases, the improvement of our understanding of the

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reasonably be questioned,’ and therefore subject to judicial notice by the Court.” *Hamilton v. Paulson*, 542 F. Supp. 2d 37, 52 n.15 (D.D.C. 2008) (quoting Fed. R. Evid. 201(b), citing cases, and taking judicial notice).

¹¹ See generally National Institutes of Health Guidelines on Human Stem Cell Research, available at <http://stemcells.nih.gov/policy/2009guidelines.htm>.

¹² PI Mem. Op. at 3.

¹³ *Id.* at 3; see also Nat’l Insts. Of Health, *Stem Cell Basics*, at 12-13, available at <http://stemcells.nih.gov/staticresources/info/basics/SCPrimer.pdf> (“Stem Cell Basics”); *Understanding Stem Cells*, at 4-5; *Monitoring Stem Cell Research: A Report of the President’s Council on Bioethics*, at 126 (2004), available at http://bioethics.georgetown.edu/pcbe/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf (last visited Sept. 3, 2010) (“*Monitoring Stem Cell Research*”) (hESCs “hold out the promise of being able to be differentiated into a large number of different cell types for possible cell therapies, as contrasted with the more limited number of cell types available by differentiation of specific adult stem cell preparations.”).

basic mechanics of human disease, and the development of new tools for drug testing and development. A wide range of diseases, including Parkinson's and type 1 diabetes, could benefit from one or more of these avenues of research.¹⁴ hESCs have been differentiated in vitro into neural, cardiac, endothelial (vascular), hematopoietic (blood), pancreatic, hepatic (liver), bone, and trophoblast cells. *Regenerative Medicine*, *supra* n. 10, at 8 and Table 1; *see also* Collins Decl. ¶ 5 (describing work of Dr. George Daley and its possible application in treating blood diseases).

hESCs also must be distinguished from induced pluripotent stem cells ("iPSCs"). iPSCs – which were discovered as a direct result of hESC research¹⁵ – are "adult cells that have been genetically reprogrammed to an embryonic stem cell-like state by being forced to express genes and factors important for maintaining the defining properties of embryonic stem cells."¹⁶ As the Court recognized, research involving iPSCs is at an early stage. Its potential is not yet known,¹⁷ and iPSCs are not yet well understood.¹⁸ Recent studies indicate that iPSCs may retain characteristics of the adult tissue they once were, which would render them less truly pluripotent than hESCs.¹⁹ While iPSCs offer promising opportunities for research in some relevant areas, they are not a substitute for hESCs.

¹⁴ *See, e.g., Stem Cell Basics*, at 16-17.

¹⁵ Collins Decl. ¶ 7.

¹⁶ *Stem Cell Basics*, at 13.

¹⁷ PI Mem. Op. at 4.

¹⁸ Collins Decl. ¶ 7.

¹⁹ K. Kim *et al.*, Epigenetic memory in induced pluripotent stem cells, *Nature* (advance online publication, July 19, 2010, *available at* <http://www.nature.com/nature/journal/vnfv/ncurrent/full/nature09342.html>).

Research already has begun to demonstrate the types of treatments that could result from further hESC research. For example, researchers have been able to direct hESC differentiation to produce specific types of cells that could be used in the treatment of Parkinson's disease and Type 1 diabetes.²⁰ The first clinical trials using hESCs for spinal cord injuries and for blindness have been approved by the Food and Drug Administration and are set to begin soon.²¹ Other major, potentially groundbreaking and life-saving research is ongoing, as demonstrated by the many peer-reviewed articles that address hESC research published since 2002.²² The preliminary injunction, which will severely disrupt and, in the case of some ongoing experiments, destroy hESC research will have very real, large, and immediate consequences for both researchers and the millions of patients in urgent need of scientific advances in their medical treatment.

B. The Scientific Community, The Executive Branch, And Congress Have Recognized The Value Of hESC Research For A Decade.

The scientific community has long recognized the tremendous value and potential of hESC research. The NIH's website, which does not list all hESC research, highlights some notable peer-reviewed research papers resulting from hESC research that have been published

²⁰ *Understanding Stem Cells*, at 16-17. See also Juvenile Diabetes Research Foundation, *Embryonic Stem Cells, JDRF Position Paper*: September 2003, at 3 (2003) (describing potential uses of hESC research in treatment of juvenile diabetes), available at http://www.jdrf.org/files/About_JDRF/StemCellPositionPaper092003.pdf (last visited Sept. 3, 2010); *Monitoring Stem Cell Research*, at 129 (describing use of hESC to study the reasons and methods of cell differentiation in vitro, as compared to in vivo where the study is harder to control).

²¹ See Collins Decl. ¶ 6; Rob Stein, *Human tests set for stem cells*, Wash. Post., Aug. 30, 2010, at A1.

²² See *infra* n. 22.

from 2002 to the present.²³ Major research institutions and universities, including the University of Texas Medical School at Houston and Harvard University, have established hESC research programs.²⁴ Since 2002, the NIH, the primary federal agency for conducting and supporting medical research, has invested more than half a billion dollars in hESC research, including \$131 million for fiscal year 2010.²⁵ The Food and Drug Administration has approved hESC-derived therapy for spinal cord injury patients.²⁶

The executive and legislative branches of government also have recognized the value of hESC research. More than nine years ago, President George W. Bush determined that NIH funds could be used for hESC research.²⁷ Thereafter, as noted, NIH funded more than half a billion dollars of such research. Under both Republican and Democratic majorities, the House and Senate Appropriations committees providing oversight over appropriations to NIH have repeatedly endorsed such funding.²⁸ Indeed, in 2010, Congress again passed legislation

²³ Lists of the hESC research papers highlighted on the NIH's website are provided for the Court's convenience as Exhibits 2A and 2B to the Declaration of Kevin Wilson, filed concurrently herewith as Exhibit 2. As set forth in the declaration, the lists were compiled from the publicly available NIH identification and abstracts of the highlights of stem cell research in the scientific literature at <http://stemcells.nih.gov/research/scilit/highlights/>.

²⁴ See, e.g., Nat'l Insts. Of Health, *Research Programs at Universities and Institutions*, <http://stemcells.nih.gov/research/educResearch.asp> (last visited Sept. 3, 2010).

²⁵ Collins Decl. ¶¶ 5, 13. As Dr. Collins' declaration also notes, NIH estimates that in fiscal year 2010 NIH will support \$380 million in human stem cell research other than hESC – nearly triple the amount planned for hESC research in 2010. *Id.* ¶ 22. These facts refute any assertion that ongoing hESC research somehow limits the funds available for adult stem cell research.

²⁶ *Id.* ¶ 6. See also Rob Stein, *Human tests set for stem cells*, Wash. Post., Aug. 30, 2010, at A1.

²⁷ Address to Nation on Stem Cell Research, 37 Weekly Compl. Pres. Doc. 1149 (Aug. 9, 2001); Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007); see also Collins Decl. ¶ 5.

²⁸ See, e.g., H.R. Rep. No. 107-229, at 180 (Oct. 9, 2001) (“The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells and carried out in accordance with policy outlined by the President.”); S. Rep. No. 107-84, at 18 (Oct. 11, 2001); H.R. Rep. No. 110-231 (July 13, 2007); H.R. Rep. No. 108-636 (Sept. 7, 2004).

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providing appropriations to the NIH after its committees again endorsed such funding pursuant to the NIH guidelines challenged in this case.²⁹

II. FAILURE TO STAY THE PRELIMINARY INJUNCTION WILL CAUSE TREMENDOUS, IMMEDIATE, IRREPARABLE HARM TO THE MANY DEDICATED SCIENTISTS WHO CONDUCT HESC RESEARCH AND THE MILLIONS OF POTENTIAL BENEFICIARIES OF SUCH RESEARCH.

Should the Court decline to stay the preliminary injunction, the result would be an immediate and devastating impact on ongoing research and resulting immediate harm to a vast number of people and institutions, including hESC researchers and the millions of patients who could benefited from treatments developed using hESC research.

The harm to scientists who conduct hESC research, and their sponsoring institutions, is described in Dr. Collins's declaration.³⁰ NIH has had to suspend the issuance of all pending competing and noncompeting continuation hESC awards and the peer review of all pending competing hESC applications and proposals.³¹ This includes, at a minimum, \$54 million in funds to 24 ongoing hESC research projects that otherwise would have received continuation funds by September 30, 2010, all of which use lines that were eligible under the Bush

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The Committees reached such conclusions notwithstanding the inclusion of the Dickey-Wicker amendment in every appropriations bill for Health and Human Services since 1996 without substantive alteration. PI Mem. Op. at 5.

²⁹ See H.R. Rep. No. 111-220 at 272 (July 22, 2009) (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); S. Rep. No. 111-66, at 96 (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..."); Pub. L. No. 111-117, Title V, § 509 (2010).

³⁰ See generally Collins Decl. ¶¶ 8-21.

³¹ Nat'l Insts. Of Health, *Notice No. NOT-OD-10-126, 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-10-126.html> (last visited Sept. 3, 2010).

Administration policy and almost all of which were in place before the Guidelines.³² Collins Decl. ¶ 10. The nature of hESC and other scientific research means that any interruption in funding can have significant impact on the overall research. There are many consequences to delay in this type of research, including the possible loss of biological materials used, laboratory animals, research tools and reagents, and laboratory personnel. Collins Decl. ¶ 12.³³ Indeed, the effect of a preliminary injunction here would not be preservation of the status quo, but the severe disruption and perhaps destruction of this ongoing research.

Under the preliminary injunction, federally funded hESC research would be halted indefinitely, and researchers who have reasonably relied on grant awards for such research will have no way to know when such activities may resume. This uncertainty over whether medical research that, in many cases, has been ongoing for years and has been funded by the executive branch and endorsed by the legislative branch, is devastating to those who have devoted their professional careers to research aimed at developing life-saving treatments for debilitating or fatal diseases.³⁴

hESC research has the potential to help millions of patients suffering from a variety of diseases and conditions. More than 100 million Americans suffer from cancer, Alzheimer's diabetes, Parkinson's, spinal cord injuries, heart disease, ALS and other debilitating diseases and

³² It also affects both grants that have completed peer review and that are currently in the peer review process, which is a total of over 60 grant applications and approximately \$15-20 million in funding. Collins Decl. ¶ 10; *see also* Rob Stein, *All stem cell funding in jeopardy, NIH says*, Wash. Post, Aug. 25, 2010 (quoting NIH Director Collins).

³³ *See also* Lauren Neergaard, *Obama appeals stem cell ruling; some work to stop*, A.P., Aug. 25, 2010 (quoting a medical ethicist at the University of Pennsylvania: "These cells are notoriously finicky and you have to take care of them every day. You can't just lock up a lab and walk away for two weeks and come back and everything's fine.").

³⁴ *Id.* (quoting director of University of Michigan Center for Stem Cell Biology: if it takes "months to settle the legal wrangling, then we will just end our work" with hESCs regarding an intestinal birth defect).

disorders.³⁵ hESC research has the potential to develop treatment for these diseases and injuries, as well as many more, as discussed in Section I.A above. The harm to these patients that will result from the preliminary injunction is substantial and cannot be ignored. Any delay in development has real consequences for these patients and for those who have yet to be diagnosed. This type of research, and translation of research findings into effective therapies, takes years, and even decades.³⁶ Any delay in that process inevitably will harm patients by depriving them of timely access to therapies developed through hESC research.


³⁵ See, e.g., CAMR website, http://www.camradvocacy.org/about_us.cfm (last visited Sept. 3, 2010).

³⁶ *Understanding Stem Cells*, at 15 (“The basic research needed to develop variable therapeutic options is a lengthy process that may extend over many years and decades. Even after science has moved from basic research to developing medical applications, it still takes many years to thoroughly test those applications and demonstrate that they are safe to prescribe for patients. This is true for all medical treatments . . . and is not specific to the living cell therapies made possible by stem cell research.”).

CONCLUSION

Far from preserving the status quo, the preliminary injunction will, if not stayed, radically disrupt, and perhaps permanently cripple, ongoing and planned hESC research that has been funded through successive administrations of both political parties, with the acquiescence and endorsement of Congresses controlled by both political parties, in conformity with Guidelines designed to assure that the research is conducted ethically, in accordance with the highest standards of medical science. On behalf of its members, CAMR respectfully urges that the requested stay pending appeal be granted to avoid such a tragic result.

Respectfully submitted,



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