UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

BRIEF AMICUS CURIAE OF COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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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] Its members include, among many others, the American Diabetes Association, the Familial Dysautonia Hope Foundation, the Juvenile Diabetes Research Foundation International, the Leukemia and Lymphoma Society, the Parkinson's Action Network, Harvard University, Johns Hopkins University, the University of Michigan, Stanford University, the American Academy of Neurology, and the American Society for Cell Biology. CAMR respectfully submits this brief as amicus curiae in further support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment (Dkt. 57) and in further support of Defendants' Motion For Summary Judgment (Dkt. 58).

INTRODUCTION

For nearly a decade, the National Institutes of Health (NIH) has funded, with Congressional approval, research using human embryonic stem cells (hESCs), as well as research involving other types of human stem cells. Congressional authorization for federal funding of NIH for each year has included the Dickey-Wicker amendment, which provides in relevant part that federal funds may not be used for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death * * * ." Consolidated Appropriation Act of 2010, Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81. From 2001-2009, NIH spent, with Congressional approval pursuant to appropriations

[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 A-1. (All exhibits referred to herein as A-__ are exhibits to the Declaration of Elizabeth Leise attached hereto as Exhibit A.) Detailed information about CAMR is located on its website: http://www.camradvocacy.org (last visited Sept. 27, 2010).

bills that included the Dickey Wicker Amendment, half a billion dollars on research using hESCs.[2] (In contrast, during that same period NIH spent more than $1.8 billion (approximately $203 million *annually*) on non-embryonic stem cell research – or nearly *four times* the amount spent on research involving hESCs.)[3] Pursuant to policies adopted by the Bush Administration, federally funded research using hESCs was limited to research using hESC lines that were derived prior to August 9, 2001.[4]

On March 9, 2009, President Obama issued Executive Order 13,505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. In that Order, he stated that he would "expand NIH support for the exploration of human stem cell research" and thereby "enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind."[5] To that end, he directed NIH to "review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order."[6] Thereafter, pursuant to notice-and-comment rulemaking, in July 2009 NIH adopted new Guidelines governing federal funding for research using hESC lines.[7] Those Guidelines provide that federal funding may be provided to research projects using

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[2] *See* Declaration of Francis S. Collins, M.D., Ph.D. (Aug. 31, 2010) (in support of Defendants' Motion For Stay Of Preliminary Injunction (Dkt. 48-2) ("Collins Decl.") ¶¶ 5, 13 (copy attached for the Court's convenience as Ex. A-2).

[3] *See id.* and Congressional Research Service Report RL3540, Stem Cell Research: Federal Research Funding and Oversight, at 13 (July 10, 2008) ("CRS Report RL3540") (Ex. A-3).

[4] *Id.*

[5] Exec. Order No. 13,505, 74 Fed. Reg. 10,667-68 (March 9, 2009).

[6] *Id.*

[7] National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009) ("Guidelines").

hESCs, but only if the hESCs are from lines that NIH has placed on an NIH Registry after determining that the stringent criteria set forth in the Guidelines have been met.[8] In particular, the Guidelines provide that, to be listed on the NIH Registry, an hESC line must have been derived from an embryo (1) "created using in vitro fertilization [IVF] for reproductive purposes;" (2) determined to be " no longer needed for this purpose;" and (3) "donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes."[9] The Guidelines further require documentation demonstrating satisfaction of these three criteria and additional detailed requirements assuring that the IVF patients' consent to donate the embryo for scientific research was informed, voluntary and not the result of any pressure, coercion, payment or other incentive to donate.[10] The stringency of the Guidelines is reflected in the statistics regarding applications for the NIH Registry: while 75 hESC lines were approved, 48 were rejected – a 39% denial rate.[11]

Congress responded to NIH's adoption of the Guidelines by once again appropriating funds for NIH and once again including the Dickey-Wicker Amendment in the appropriations bill.[12] Far from condemning NIH's conduct, the Senate Committee Report specifically commended NIH for its effort to expand the funding of research using additional hESC lines that satisfied the rigorous new Guidelines. "The Committee is pleased that stem cell research was

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[8] *Id.* at 32,174.

[9] *Id.* at 32,174-75.

[10] *See infra* pp. 15-17 (setting forth relevant text of Guidelines).

[11] *The Promise of Human Embryonic Stem Cell Research: Before the Senate Subcomm. on Labor – HHS – Education*, 111th Cong. (Sept. 16, 2010) (statement of Francis Collins, M.D., Ph.D.) ("Collins 9/16 Hrg. Test.") at 12 (Ex. A-4). *See also* NIH Human Embryonic Stem Cell Registry, *at* http://grants.nih.gov/stem_cells/registry/current.htm and http://grants.nih.gov/stem_cells/registry/not_approved.htm (last visited Sept. 27, 2010).

[12] *See* Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81.

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 with NIH funds * * * ." S. Rep. No. 111-66, at 121 (Aug. 4, 2009). The House Committee further stated that the Dickey-Wicker 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).[13]

This unbroken, nine-year history of appropriations by successive Congresses, during periods of control by Republican and Democratic majorities, refutes Plaintiffs' strained effort to stretch the Dickey-Wicker "research in which" language to bar implementation of the new Guidelines and continued federal funding of hESC research in accordance with those Guidelines. Far from violating the Dickey-Wicker Amendment, the Guidelines represent an effort to implement a policy judgment that has been endorsed – repeatedly and consistently – by both Congress and the Executive Branch. Both these branches of government have recognized that research involving hESCs holds tremendous promise for advancing scientific understanding of human health and developing effective therapies for a host of illnesses for which no effective treatment currently is available. At the same time, both branches have been sensitive to moral issues implicated by research involving hESCs. Thus, while consistently funding hESC research, they have also insisted on the implementation of safeguards to prevent the use of federal funds for either the creation of embryos for research or the derivation of hESCs from embryos. The phrase "research in which a human embryo or embryos are destroyed, discarded,

[13] *See also* 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.").

or knowingly subjected to risk of injury or death" in the Dickey-Wicker Amendment consistently has been construed to prohibit federal funding only for the derivation of hESC lines, and not for research projects that use previously derived hESC lines. The NIH Guidelines are fully consistent with this policy choice and interpretation of the law.

Plaintiffs are, therefore, wrong to assert that the "research in which" prohibition of Dickey-Wicker unambiguously extends beyond the scope of the specifically funded research project to encompass the prior derivation of an hESC line by different people at a different time and place.[14] Plaintiffs' theory that an NIH *regulation* that supposedly construes the word "research" broadly and necessarily defines the word in the *statute* is unpersuasive. At best, Plaintiffs' strained construction is a potential definition; however, in light of the lengthy history of government funding of research using hESCs, it is surely not the only possible one, nor even the most plausible one. To find the statute unambiguous, the Court would have to conclude that Congress repeatedly contradicted itself by consistently acquiescing in – and, indeed, expressly endorsing – federal funding of research involving hESCs, while at the same time expressly prohibiting that research via the Dickey-Wicker amendment. The law rejects such a presumption of Congressional irrationality. *Hecht v. Pro-Football, Inc.*, 444 F.2d 931 (D.C. Cir. 1971).

[14] *See* Mem. of Law in Supp. of Pls.' Mot. for Summ. J. at 13-19 (Dkt. 55) ("Pl. Mem.").

RELEVANT FACTUAL BACKGROUND

Plaintiffs' Statement of Material Facts relies heavily on a submission opposing the Guidelines that Plaintiffs and organizations that categorically oppose hESC research submitted during the rulemaking process.[15] In relying on that submission, Plaintiffs have, regrettably, provided an incomplete and distorted picture of the relevant scientific facts concerning stem cell research.

The scientific merit of research involving hESC lines is, of course, not an appropriate matter for judicial determination. Whether such research has sufficient scientific merit to warrant federal funding is, ultimately, a policy judgment to be made by Congress, using its constitutional spending power, and, to the extent authorized by federal law, the Executive Branch, including NIH officials with the relevant scientific expertise. *See Lincoln v. Vigil*, 508 U.S. 182, 193 (1993). As Plaintiffs do not and cannot dispute, for nearly a decade the judgment of these two branches has been that research involving hESC lines is worthy of federal support.

We address below the relevant facts concerning research involving hESCs, and other stem cell research, for two reasons. First, they make clear the context in which Congress and the Executive Branch have acted and within which the Dickey-Wicker language has been and must be construed. Second, they are relevant to assessing the impact of the injunctive relief sought by Plaintiffs, which would devastate ongoing research programs involving hESCs and deprive innumerable patients with a wide variety of diseases of the benefits of that ongoing, cutting-edge research.

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[15] *See generally* Ex. D to Pls.' Mot. for Summ. J. at 1-2 and App. A (Dkt. 55-7). *See also* Plaintiffs' Statement of Material Facts (Pl. Mat. Facts) ¶¶ 28-34; Pl. Mem. at 5-7. *Cf.* Defs.' Response to Pl. Mat. Facts (Dkt. 59).

A. The Unique Characteristics Of Embryonic Stem Cells

hESCs are derived from blastocysts, which are pre-implantation embryos that develop within five days after fertilization of an egg by a sperm.[16] A blastocyst is smaller than the period at the end of this sentence.[17] Although derived from blastocysts, hESCs are not embryos.

The most common source of blastocysts used for hESC line derivation is in-vitro fertilization (IVF) clinics, which typically fertilize all of a woman's retrieved eggs to maximize the chance of successful implantation.[18] Because not all fertilized eggs are implanted, the IVF process often produces "excess" blastocysts. These blastocysts would not be viable unless they were implanted and must be stored in a freezer to be preserved. Typically, if not used for IVF, the blastocysts would be destroyed or frozen indefinitely.[19] In order for an embryo to be donated for scientific research purposes, the patients must first have determined that they no longer need the embryo for family building purposes and consent to the donation of the blastocyst. *See supra* pp. 2-3 (quoting Guidelines).

hESCs have unique characteristics that distinguish them from both adult stem cells (ASCs) and induced pluripotent stem cells (iPSCs). hESCs are "pluripotent" – that is, they have

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[16] 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. 27, 2010) ("*Understanding Stem Cells*") (cited in *Sherley v. Sebelius*, No. 1:09-cv-01575-RCL, Mem. Op. at 3(D.D.C. Aug. 23, 2010) (Dkt. 44) ("PI Mem. Op.")).

[17] *Id.*

[18] *Id.* at 5-6.

[19] *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. 27, 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. *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).

the capability to differentiate into any of the approximately 200 different types of cells in the human body.[20] hESCs' pluripotency has led to research into and development of directed differentiation, which allows scientists to achieve differentiation of hESCs into specific types of human cells. hESCs have been differentiated in vitro into neural, cardiac, endothelial (vascular), hematopoietic (blood), pancreatic, hepatic (liver), bone, and trophoplast cells.[21] 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 basic mechanics of human disease, and the development of new tools for drug testing and development. *See infra* pp. 10-12.

In contrast, ASCs are multipotent – capable of differentiation into some, but not all, different cell types – but not fully pluripotent, like hESCs.[22] Even researchers working primarily with ASCs recognize the benefit of using hESCs in their research. For example, most of Dr. Sean Morrison's research involves ASCs, but he routinely uses hESC lines in his laboratory as part of his work.[23]

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[20] PI Mem. Op. at 3.

[21] *Regenerative Medicine*, *supra* n.10, at 8 and Table 1; *see also* Declaration of Derek J. Hei ("Hei Decl.") ¶ 6 (Ex. B).

[22] *Id.* at 3; *see also* Nat'l Insts. of Health, *Stem Cell Basics*, at 12-13, *at* http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.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. 27, 2010) ("*Monitoring Stem Cell Research*"); *see also* Declaration of Sean J. Morrison ("Morrison Decl.") ¶ 4 (Ex. C).

[23] Morrison Decl. ¶ 5 (Ex. C).

hESCs also must be distinguished from iPSCs. iPSCs – which were developed in 2007 as a direct result of hESC research[24] – 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."[25] As the Court has recognized, research involving iPSCs is at an early stage.[26] Its potential is not yet known, and iPSCs are not yet well understood.[27] Recent studies indicate that iPSCs may retain characteristics of the adult tissue they once were, which would render them less truly pluripotent than hESCs.[28] While iPSCs offer promising opportunities for research in some relevant areas, they are not a substitute for hESCs, and hESC research is necessary as controls to validate the development and progression of iPSC research.[29] Even Plaintiffs do not deny that iPSCs are not identical to hESCs.[30]

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[24] Collins Decl. ¶ 7 (Ex. A-2); *See also The Promise of Human Embryonic Stem Cell Research: Before the Senate Subcomm. on Labor – HHS – Education*, 111th Cong. (Sept. 16, 2010) (statement of George Q. Daley, MD, PhD) ("Daley 9/16 Hrg. Test.") at 4 (Ex. A-5).

[25] *Stem Cell Basics*, at 13.

[26] PI Mem. Op. at 4.

[27] Collins Decl. ¶ 7 (Ex. A-2); Kouichi Hasegawa, et al., Current Technology for the Derivation of Pluripotent Stem Cell Lines from Human Embryos, 6 Cell Stem Cell 521 (June 2010) (Ex. A-6).

[28] 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) (Ex. A-7); Daley 9/16 Hrg. Test. at 4 (Ex. A-5).

[29] Melissa K. Carpenter, et al., Developing safe therapies from human pluripotent stem cells, 27 *Nature* 606, 612 (July 2009) ("The knowledge base that is currently being generated with hESCs will undoubtedly accelerate the development of iPSC-derived therapies.") (Ex. A-8); CRS Report RL3540 at 3 and n.12 (Ex. A-3); *see also* Daley 9/16 Hrg. Test. at 4-5 (Ex. A-5).

[30] *See* Pl. Mem. at 28 (iPSCs "*essentially* indistinguishable" from hESCs) (emphasis added); Pl. Mat. Facts ¶ 12 (ASCs are substitutes in some uses). Moreover, Plaintiffs' dismissal of the value of hESC research relies on an article that was not peer-reviewed or written by an expert in the field. *See id.* ¶ 54 (citing Ex. G, Bernadine Healy, M.D., Why Embryonic Stem Cells Are Obsolete, U.S. News & World Report, Mar. 4, 2009).

B. The Scientific Value Of hESC Research

hESC research has a much shorter history than ASC research. hESCs were first derived in 1998, only 12 years ago, whereas ASCs have been used in research for more than fifty years.[31] Notably, the Nobel Prize awarded for research involving ASCs in 1990 came after more than 30 years of research using them.[32] As this history reflects, scientific research is a lengthy, complicated process. It is, therefore, not surprising that the much newer field of research using hESCs has not yet produced fully approved medical therapies. Moreover, such research undoubtedly has been slowed by prior policy restricting federal funding to research projects using hESC lines derived prior to August 2001.

Yet, despite its shorter history, research using hESCs has produced substantial benefits to medical science. 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.[33] The first clinical trials using hESCs for spinal cord injuries have been approved by the Food and Drug Administration and began last week.[34] hESCs are being used as tools for accelerated, efficient screening of potential drug candidates for effectiveness and toxicity, reducing the time for such testing by months or years.[35]

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[31] *Stem Cell Basics*, at 8. *See also* Collins 9/16/10 Hrg. Test. at 3 (Ex. A-2); *The Promise of Human Embryonic Stem Cell Research: Before the Senate Subcomm. on Labor – HHS – Education*, 111th Cong. (Sept. 16, 2010) (statement of Sean J. Morrison, PhD) ("Morrison 9/16 Hrg. Test.") at 5-6 (attached to Morrison Decl., Ex.C).

[32] *See* Collins 9/16/10 Hrg. Test. at 3 (Ex.A-4); Morrison 9/16 Hrg. Test. at 6 (Ex. C).

[33] *Understanding Stem Cells*, at 16-17.

[34] *See* Collins Decl. ¶ 6 (Ex. A-2); Northwestern First Site Open for Spinal Cord Stem Cell Trial, Press Release, http://www.feinberg.northwestern.edu/news/2010D-September/Spinal_Cord_Stem_Cell_Trial.html.

[35] Collins 9/16/10 Hrg. Test. at 9 (Ex. A-4).

More fundamentally, hESCs are being used in research into basic questions of human development and the causes of medical conditions that occur because of abnormal cell division and differentiation.[36] Moreover, hESCs play a valuable role in research using other types of stem cells, including both ASCs and iPSCs, because they serve as critical "controls" used for comparison.[37]

Thus, although approved hESC therapies do not yet exist, research using hESCs is contributing daily to the development of new therapies. The range of potentially groundbreaking and life-saving research involving hESCs is reflected in the many peer-reviewed articles published since 2002 that address such research projects.[38]

The scientific value of research using hESCs also is reflected in the resources that the scientific community has devoted to such research. Major research institutions and universities, including the University of Texas Medical School at Houston and Harvard University, have established hESC research programs.[39] Since 2002, NIH, the primary federal agency for conducting and supporting medical research, has invested more than half a billion dollars in

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[36] *Stem Cell Basics*, at 14. *See also* Collins 9/16/10 Hrg. Test. at 5 (Ex. A-4); Hei Decl. ¶¶ 3, 5-6 (Ex B).

[37] *See, e.g.*, Declaration of David Michael Gamm ("Gamm Decl.") ¶ 3 ("Ongoing efforts to compare and contrast the properties of iPS cells and ES cells are essential to optimize the utility of the former.") (Ex. D); Daley 9/16/10 Hrg. Test. at 4 ("Today, human ES cells remain the gold standard against which our cultures of human iPS cells are compared.") (Ex. A-5); Morrison Decl. ¶ 6 ("Much remains to be learned regarding the biology of stem cells and it is not yet clear which stem cells will lead to scientific breakthroughs or new therapies. For this reason, it will be critical to continue studying all types of stem cells.") (Ex. C).

[38] Lists of the hESC research papers highlighted on the NIH's website are provided for the Court's convenience as Exhibits A and B to the Declaration of Kevin Wilson (Wilson Decl.) (Ex. E). 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/.

[39] *See, e.g.*, Nat'l Insts. of Health, *Research Programs at Universities and Institutions*, http://stemcells.nih.gov/research/educResearch.asp (last visited Sept. 27, 2010).

research using hESCs, including $131 million for fiscal year 2010.[40] The Food and Drug Administration has approved for clinical trial hESC-derived therapy for spinal cord injury patients, and the first clinical trial site opened last week.[41] The International Society for Stem Cell Research, an independent, nonprofit professional society comprised of more than 3000 stem cell scientists from all over the world (including plaintiff Dr. Sherley), issued a release in March 2009 stating: "The ISSCR believes that research using all types of stem cells should be selected for funding based on scientific merit and conducted under transparent ethical oversight."[42]

C. The Separate Processes Of Derivation Of hESC Lines And Later Research Using Cells From Those Previously Derived Cell Lines

Federal funds are not, and never have been, used for the process by which a human embryonic stem cell line is derived from a blastocyst. Rather, that process is undertaken separately, with non-federal funds.[43] The NIH Guidelines maintain this restriction and expressly "prohibit[ ]" "NIH funding of the derivation of stem cells from human embryos."[44]

Scientists who conduct federally funded research using hESCs do not derive those cells from embryos as part of their hESC research. Rather, they use cells that were derived

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[40] Collins Decl. ¶¶ 5, 13 (Ex. A-2). 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 hESCs – nearly triple the amount planned for research using in 2010. *Id.* ¶ 22. This is an *increase* from spending on non-hESC research in prior years. *See supra* p. 2. These facts refute any assertion that funding of research using hESCs has in any way reduced or restricted the funds available for adult stem cell research and threatened any harm to plaintiffs.

[41] *See supra* p. 10 & n.34.

[42] *See* Morrison Decl. ¶ 6 (Ex. C) & Ex. 3 thereto. ISSCR recently reiterated this position, noting that ESC research "provides critical insight into human development and disease that is needed to advance our understanding and treatment of a wide range of diseases and conditions." *Id.*

[43] *See, e.g.*, *See* Nat'l Insts. of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000).

[44] 74 Fed. Reg. 32,175.

previously, generally by different scientists in different institutions.[45] Those lines may have been derived years before their use in hESC research and, once derived, are a source of cells that may be used in many subsequent research projects. Indeed, under the Bush Administration policy, only hESC lines derived before August 2001 could be used.

The separateness of the derivation process and research using hESCs is reflected in the grant requests themselves. For example, NIH's operative grant application in place before the Guidelines were adopted required a scientist using hESCs in her proposed research to identify the hESC line that would be used from among those registered with NIH.[46] The declarations of Drs. Morrison, Hei, and Zhang show that scientists conducting research using hESCs identify

[45] *See* Morrison Decl. ¶ 7 ("Like the vast majority of stem cell scientists, my laboratory does not derive human ESCs from embryos. Rather, we use existing human ESC lines that were derived previously - often years ago - by other scientists in labs at other institutions. . . . The derivation of embryos is a process that is entirely separate from the research conducted in my laboratory and in which I do not participate in any way.") (Ex. C); Hei Decl. ¶ 12 ("[M]y work and that of my laboratory does not include the derivation of embryonic stem cell lines. Our proposals and our work taking research forward to clinical trials use existing stem cell lines derived elsewhere and at earlier times. Thus, while we rely on the existence of the lines, we do not derive them as a part of our research.") (Ex. B); Declaration of Su-Chen Zhang ("Zhang Decl.") ¶ 8 ("My work and that of my laboratory does not include the derivation of embryonic stem cell lines. Our proposals and our work taking research forward to clinical trials use existing stem cell lines derived elsewhere and at earlier times.") (Ex. F); Declaration of Anita Bhattacharyya ("Bhattachryya Decl.") ¶ 3 ("Although I rely on a supply of hESC lines for my research, my lab does not work with embryos themselves or derive hESCs from embryos.") (Ex. G); *see also* Def. Mot for Summ. J. n.12 [Dkt. 58].

[46] Dep't of Health & Human Services Grant Application, at 4 (Rev. 11/2007), *available at* http://www.yale.edu/grants/forms/pdf/398yale-11-07.pdf (Ex. A-9) (including a check box for hESCs used or not used in the proposed project and stating: "If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. Use continuation pages as needed. If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used."). The section is separate from the research plan submitted as part of the grant application. *See id.* at 5.

existing stem cell lines that will be used in their research and do not derive these lines in their research.[47]

The new NIH Guidelines maintain this separation, both on their face and in their application as relevant to this case. As noted, they continue to reflect the policy against federal funding of derivation of hESCs from a blastocyst.[48] NIH's funding notices direct applicants seeking federal funding for hESC research to review the NIH Embryonic Stem Cell Registry to identify the hESC lines that they intend to use as one of those which NIH previously has approved for use in federally-funded research, and the application contains the same direction to identify from the Registry any hESC line to be used in the proposed research.[49]

The separation between the derivation of hESC lines and research that may subsequently use those previously derived lines is reflected in the fact that of the 75 hESC lines approved by NIH for listing on the Registry, the vast majority – at least 62 lines, were created *before* President Obama issued his Executive Order and *before* NIH issued the Notice of Proposed Rulemaking in April 2009. Indeed, almost half of those 62 lines were in fact derived in 2004 or earlier.[50]

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[47] Morrison Application for Federal Assistance at 19 (Ex. 1 to Morrison Decl.); Hei Technical Proposal (Ex. to Hei Decl.); Zhang Excerpt from Grant Proposal (Ex. to Zhang Decl.).

[48] *See* 74 Fed. Reg. 32,175.

[49] *See* NIH Notice No. NOT-OD-10-020 First Human Embryonic Stem Cells Approved for use under the NIH Guidelines for Human Stem Cell Research (Dec. 2, 2009), *at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-020.html; NIH Notice No. NOT-OD-10-029, Clarification of Terms and Conditions of Awards using Human Embryonic Stem Cells (Dec. 14, 2009), *at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-029.html; U.S. Dep't of Health & Human Services Public Health Service Grant Application (PHS 398) at 32 (Rev. 06/2009) (Exs. A-10-12).

[50] This data was compiled from review of publicly available sources and contact with the researchers who own the hESC lines, and the conclusions reflect the information available to us. *See generally* Declaration of Anthony Mazzaschi and Exhibits thereto (ex. H). Our analysis looks to the derivation date of the hESC line and also identifies hESC lines derived prior to

With respect to this vast majority of lines on the Registry, the effect of the Guidelines is to make possible federal funding of research using existing hESC lines that were derived *before* the Guidelines were proposed (much less adopted) and *before* any research grant application seeking to use hESCs was submitted to (much less approved by) NIH. Put differently, neither the proposal nor adoption of the Guidelines, nor the subsequent approval of NIH grants for research projects using those pre-existing hESC lines, had any impact whatsoever on whether they were derived. That occurred years ago.

D. The Stringent Standards Imposed By The NIH Guidelines

The NIH Guidelines challenged in this case impose stringent substantive and documentation requirements for approval of hESC lines to be placed on the NIH Registry. The Guidelines provide that, to be listed on the NIH Registry, an hESC line must have been derived from an embryo (1) "created using in vitro fertilization [IVF] for reproductive purposes;" (2) determined to be " no longer needed for this purpose;" and (3) "donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes."[51] The Guidelines further require documentation demonstrating satisfaction of these three criteria and additional detailed requirements assuring that the IVF patients' consent to donate the embryo for scientific research was informed,

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President Obama's March 2009 Executive Order. This analysis produces a slightly different number than that in the Declaration of Dr. Story Landis in support of Defendants' motion for summary judgment, which looks at the donation date of the embryo and the July 2009 promulgation date of the Guidelines. *Cf.* Declaration of Story Landis, Ph.D ¶ 14 (Dkt. 58-1). While the two methodologies produce slightly different numbers, they establish the same fundamental point: the vast majority of hESC lines approved pursuant to the NIH Guidelines and listed on the Registry were derived before the Guidelines were adopted.

[51] 74 Fed. Reg. 32,174-75.

voluntary and not the result of any pressure, coercion, payment or other incentive to donate.

Specifically, they provide that documentation and assurance must exist to show that:

> a. All options available in the health care facility where treatment was sought pertaining to the embryos no longer needed for reproductive purposes were explained to the individual(s) who sought reproductive treatment.
>
> b. No payments, cash or in kind, were offered for the donated embryos.
>
> c. Policies and/or procedures were in place at the health care facility where the embryos were donated that neither consenting nor refusing to donate embryos for research would affect the quality of care provided to potential donor(s).
>
> d. There was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes. Specifically:
>
> > i. Decisions related to the creation of human embryos for reproductive purposes should have been made free from the influence of researchers proposing to derive or utilize hESCs in research. The attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize hESCs should not have been the same person unless separation was not practicable.
> >
> > ii. At the time of donation, consent for that donation should have been obtained from the individual(s) who had sought reproductive treatment. That is, even if potential donor(s) had given prior indication of their intent to donate to research any embryos that remained after reproductive treatment, consent for the donation for research purposes should have been given at the time of the donation.
> >
> > iii. Donor(s) should have been informed that they retained the right to withdraw consent for the donation of the embryo until the embryos were actually used to derive embryonic stem cells or until information which could link the identity of the donor(s) with the embryo was no longer retained, if applicable.
>
> e. During the consent process, the donor(s) were informed of the following:

> i. That the embryos would be used to derive hESCs for research;
> ii. What would happen to the embryos in the derivation of hESCs for research;
> iii. That hESCs derived from the embryos might be kept for many years;
> iv. That the donation was made without any restriction or direction regarding the individual(s) who may receive medical benefit from the use of the hESCs, such as who may be the recipients of cell transplants;
> v. That the research was not intended to provide direct medical benefit to the donor(s);
> vi. That the results of research using the hESCs may have commercial potential, and that the donor(s) would not receive financial or any other benefits from any such commercial development;
> vii. Whether information that could identify the donor(s) would be available to researchers.

74 Fed. Reg. 32,174-75. The stringency of the Guidelines is reflected in the statistics regarding applications for the NIH Registry: while 75 hESC lines were approved, 48 were rejected – a 39% denial rate.[52]

ARGUMENT

I. THE NIH GUIDELINES ARE FULLY CONSISTENT WITH THE DICKEY-WICKER AMENDMENT.

Plaintiffs want the Court to ignore NIH's consistent interpretation of the Dickey-Wicker Amendment to permit federal funding of research using previously derived hESCs, NIH's repeated disclosure of that interpretation to Congress, and Congress's consistent acquiescence in – and, indeed, endorsement of – that interpretation. *See supra* pp. 1-5, *infra* pp. 21-22. Plaintiffs assert that the Court must ignore this nine-year history, under Congresses and administrations controlled by both parties, because the phrase "research in which" in the Dickey-Wicker

[52] Collins 9/16 Hrg. Test. at 12 (Ex. A-4). *See also* NIH Human Embryonic Stem Cell Registry, Research Using These Lines is Eligible for NIH Funding, *at* http://grants.nih.gov/stem_cells/registry/current.htm and http://grants.nih.gov/stem_cells/registry/not_approved.htm.

Amendment is unambiguous and can only be read as Plaintiffs read it – to include not only the specific hESC research actually funded by NIH, but also the derivation of the hESCs – even if that was done at a different time, in a different place, by different people, and with no federal funding. Plaintiffs' strained argument is completely unpersuasive.

A. The Dickey-Wicker Amendment Does Not Unambiguously Prohibit Research Using Previously Derived hESC Lines.

The foundation of Plaintiff's argument that "research in which" is unambiguous rests upon two documents. The first is the Human Subjects Protection Regulations, which define "research" as referring to a "systematic investigation." But nothing in this definition suggests that, in the statute, Congress meant to refer to all acts, at other times and by other people, that preceded the actual research project for which federal funding is granted. The second source relied upon by Plaintiffs is informal guidance on an unrelated regulation which includes the words "human" and "research" in some proximity.[53] But the guidance is inapposite because it does not apply to hESC research. No federal funding is provided for derivation of hESC lines, and hESCs are not human subjects.[54] Moreover, Plaintiffs offer no authority supporting the proposition that this informal, nonbinding guidance from NIH in a different context offers a basis for construing a *statute* enacted by Congress.

But even if these were relevant sources for construing the Dickey-Wicker language and could be read to support Plaintiffs' interpretation of "research," that does not establish that the term is unambiguous. To the contrary, there are strong grounds for Defendants' interpretation of the term. As Defendants have demonstrated in their prior filings, "research" commonly is used

[53] Pl. Mem. at 16, citing *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), *at* http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html.

[54] *See* 74 Fed. Reg. 32,173-75.

to refer to specific research projects.[55] Moreover, the context of the word "research" in the statute – "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk" – favors Defendants' interpretation. "In which" suggests something more contained than an entire field of research; it suggests a specific project with definable boundaries. That reading makes particular sense in the context of NIH funding, which is granted only for a specified period for projects with a specific design and objective that have satisfied a rigorous peer-reviewed grant approval process. Similarly, the phrase "are destroyed" suggests that the risk of harm must be contemporaneous with the research being done. As discussed above, since hESC lines are derived separately, prior to research using them, there is no contemporaneous risk of harm from such research.

Finally, the fact that for nine years NIH, with the full knowledge, consent and endorsement of Congress, *see supra* pp. 1-5, *infra* pp. 20-22, consistently construed Dickey-Wicker to permit federal funding of research using previously-derived hESCs suggests – at the very least – that the phrase "research in which" can reasonably be construed differently than Plaintiffs do.[56] It cannot fairly be characterized as "unambiguous."

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[55] *See, e.g.*, Defs.' Mem. in Supp. of Emergency Mot. to Stay at 10-11 (Dkt. 48-1) (quoting, *e.g.*, RANDOM HOUSE DICT. (2009) (defining "research" as "a particular instance or piece of research").

[56] Plaintiffs make a "Catch-22" argument that, because the Guidelines seek to enforce the Dickey-Wicker restrictions and address the moral and legal issues implicated by research using hESCs by imposing stringent substantive and documentation requirements to ensure that only hESC lines derived from embryos created for family planning purposes and donated under circumstances assuring that the donation was voluntary, uncoerced, and not motivated by profit, that means that the Guidelines effectively define "research" as necessarily involving the destruction of embryos. Pl. Mem. at 18. Not so. The Guidelines do not define "research." All they do is establish requirements that previously-derived hESC lines must satisfy in order to be deemed acceptable for use in federally-funded research. The derivation of hESC lines and research using previously derived hESC lines are still two separate activities.

B. NIH's Consistent Interpretation Of The Dickey-Wicker Amendment To Permit Federal Funding Of Research Using hESCs Is Reasonable And Plainly Consistent With The Intent Of Congress.

Where a statute is ambiguous, the court must consider whether the agency has adopted a "permissible construction of the statute." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984). Deference to the agency is appropriate "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Plaintiffs do not dispute that the NIH has authority to make rules governing grants of federal funding for NIH-funded research.

As NIH correctly stated in promulgating the Guidelines,

> Since 1999, the Department of Health and Human Services (HHS) [of which NIH is a constituent part] has consistently interpreted [the Dickey-Wicker Amendment] this provision as not applicable to research using [hESCs], because [hESCs] are not embryos as defined by Section 509. This longstanding interpretation has been left unchanged by Congress, which has annually reenacted the Dickey Amendment with full knowledge that HHS has been funding [hESC] research since 2001. These guidelines therefore recognize the distinction, accepted by Congress, between the derivation of stem cells from an embryo that results in the embryo's destruction, for which Federal funding is prohibited, and research involving [hESCs] that does not involve an embryo nor result in an embryo's destruction, for which Federal funding is permitted.

Guidelines, 74 Fed. Reg. 32,173.[57] Plaintiffs attempt to dismiss this consistent construction of the Dickey-Wicker Amendment on the grounds that NIH did not engage in an express linguistic

[57] Plaintiffs are wrong to attack NIH's interpretation of the statute as nothing more than a *post hoc* rationalization by counsel. NIH's consistent articulation of this policy over the last ten years is clear, including in exhibits attached to Plaintiffs' own summary judgment motion. *See* Nat'l

exegesis of the phrase "research in which." But NIH was not required to do so. All that is required is that "the agency's path may reasonably be discerned." *FCC v. Fox Television Stations, Inc.*, 129 S.Ct. 1800, 1810 (2009). *See also Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 420 (1992). NIH's consistent interpretation of the Dickey-Wicker Amendment, which it repeatedly reported to Congress, easily satisfies that standard.

The relevant legislative history confirms beyond doubt the reasonableness of NIH's consistent interpretation and application of the Dickey-Wicker language and its consistency with Congress's intent. For nine years, NIH repeatedly and expressly reported to Congress its funding of research using previously derived hESCs.[58] In each of those years, Congress again authorized

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Insts. of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000); *see also* Ex. D to Pls. Mot. For Summ. J., App. F at F-6 (Mem. dated Jan. 11, 2002 from Alex M. Azar, NIH General Counsel).

[58] *See, e.g.*, Testimony Before the Subcommittee on Health Committee on Energy and Commerce United States House of Representatives (May 8, 2008) (stating that NIH has funded: more than $174 million in hESC research since 2001) (Ex. A-13); Testimony Before the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, and the Committee on Health, Education, Labor, and Pensions (Jan. 19, 2007) (stating that NIH has funded: more than $130 million in research studying hESCs since 2001) (Ex. A-14); United States Senate Congressional Transcript, Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies Holds Hearing on FY2006 Appropriations, at 27 (April 6, 2005) ("NIH is funding about $30 million worth of human embryonic stem cells…") (Ex. A-15); Statement of Elias Zerhouni, Director, NIH, Before Senate Appropriations Subcommittee on Labor, HHS, and Education (May 22, 2003) (stating that NIH spent approximately $11 million for hESC research in FY 2002) (Ex. A-16); Response to Questions Submitted for the Record, Senate Labor-HHS-Education Appropriations Subcommittee (May 2003) (estimating spending $17.1 million on hESC research in FY 2003) (Ex. A-17); Statement of Elias Zerhouni, Director, NIH, Before Senate Appropriations Subcommittee on Labor, HHS, and Education (Sept. 25, 2002) (similar) (Ex. A-18); Testimony of Tommy Thompson, Sec'y of Health and Human Services, Before Senate Health, Education, Labor, and Pensions Committee (Sept. 5, 2001) (noting that HHS will invest in basic research of hESCs). (Ex. A-19) *See also* Message to the House of Representatives, July 19, 2006 (noting that Bush Administration provided more than $90 million to hESC research) (Ex. A-20); Congressional Research Service, Stem Cell Research, at 8 (Oct. 20, 2004) (listing hESC research funding for FY 2001-2003) (Ex. A-21). For the Court's convenience, these Congressional materials are attached hereto as exhibits to the Leise Declaration.

funding pursuant to appropriations legislation that included the Dickey-Wicker Amendment.[59] And, after NIH adopted the Guidelines, Congress again passed the NIH authorization including the Dickey-Wicker Amendment, and expressly "welcomed the recent release of guidelines for the use of human embryonic stem cells with NIH funds * * * ." S. Rep. No. 111-66, at 121 (Aug. 4, 2009).[60]

Where, as here, Congress repeatedly has acquiesced in – and indeed, has endorsed – an agency's consistent interpretation of statutory language, the courts have recognized that this amounts to legislative ratification of the agency's construction. *See, e.g.*, *Barnhart v. Walton*, 535 U.S. 212, 220 (2002); *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."); *Doris Day Animal League v. Veneman*, 315 F.3d 297, 300 (D.C. Cir. 2003) ("[W]hen Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.'" (quoting *CFTC v. Schor*, 478 U.S. 833, 846 (1986)). The consistent, unbroken history of Congressional assent to NIH's interpretation permits no other conclusion.[61]

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[59] PI Mem. Op. at 4.

[60] *See also supra* p. 4 & n.13.

[61] Plaintiffs seek to minimize the import of the overwhelming legislative history supporting NIH's consistent interpretation by ignoring most of it. The legislative history they cite all predates 2004 and, therefore, ignores the recent congressional endorsement of the Guidelines and reflects statements made in the first few years of hESC research, which only began in 1998. *See* Pl. Mem. at 20-21. Moreover, the law is clear that the committee reports endorsing the NIH approach are entitled to much greater weight than the sponsor statements upon which Plaintiffs rely. *See, e.g.*, *Simpson v. United States*, 435 U.S. 6, 17 (1978), *superseded by statute as stated in* 787 F.2d 71 (2d Cir. 1986), (Rehnquist, J., dissenting) ("The report of a joint conference

Finally, the underlying factual context regarding hESC research shows why the NIH's interpretation is sensible. As discussed above, the derivation of hESC lines and research involving such lines are two separate processes, typically performed by different scientists at different times and places.[62] Even the NIH instructions for grant applications demonstrate that a proposal for research involving hESCs must identify the previously derived hESC lines that the proposed research will use, demonstrating NIH's long-standing interpretation of the term "research in which".[63] In contrast, if the phrase were interpreted as Plaintiffs suggest, the term "research" would mean any step taken by any other person at any other time to use *any* item used in the research project, such as the creation of chemicals, the production of energy, or the manufacturing of materials like beakers or centrifuges. Plaintiffs' unreasonable interpretation must be rejected. Thus, the NIH interpretation is consistent with plain common sense. *See, e.g.*, *Tomasello v. Rubin*, 167 F.3d 612, 618 (D.C. Cir. 1999) (rejecting statutory interpretation that "defies common sense"); *Massachusetts v. U.S. Dep't of Transp.*, 93 F.3d 890, 895 (D.C. Cir. 1996) (same).

II. PLAINTIFFS' ANALYSIS WOULD LEAD TO AN EXTREME, ILLOGICAL RESULT AND DOES NOT SUPPORT THE BROAD INJUNCTIVE RELIEF THEY SEEK.

Wholly apart from its flawed reading of the statute, Plaintiffs' theory in this case suffers from fundamental logical flaws that make clear there is no principled basis for granting the sweeping relief they seek.

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committee of both Houses of Congress, for example, or the report of a Senate or House committee, is accorded a good deal more weight than the remarks even of the sponsor of a particular portion of a bill on the floor of the chamber.") (citing Supreme Court caselaw).

[62] *See* Morrison Decl. ¶ 8 (Ex. C); Hei Decl. ¶ 12 (Ex. B) (quoted at n.45 supra).

[63] *See supra* n.8.

If Plaintiffs were correct that the "research in which" statutory language precluded funding of research using hESCs, then that necessarily would mean that the NIH's funding of such research for eight years under the prior, Bush Administration, policy also was illegal. Yet Plaintiffs have been coy about whether they challenge continued funding of grants made under that policy.[64] Notably, their predecessor plaintiffs represented by the same counsel and organizations who originally brought suit in this case chose not to challenge that prior policy.[65] Plaintiffs offer no explanation for their inconsistent position. One can only presume it is because they recognize that, in light of the clear, consistent policy choice of Congress and the Executive Branch to fund research using hESCs it would – rightly – be perceived as extreme and unreasonable for Plaintiffs to state plainly that their position requires the elimination of ***all*** funding for ***any*** research involving ***any*** hESCs. But make no mistake: that is the logic of their position.

Plaintiffs cannot evade this conclusion by suggesting that the Bush policy restricting federal funding for research using hESCs only to research using lines created prior to August 2001 was permissible because it allegedly was consistent with the underlying purpose of the Dickey-Wicker provision to eliminate any "inducement" or incentive for the additional destruction of embryos. *See* Pl. Mem. at 19-20. Such an argument effectively introduces a new "no inducement" concept that is nowhere found in the statutory text. It is completely inconsistent with Plaintiffs' argument that "research" unambiguously means the entire field of

[64] Order dated Sept. 7, 2010, at 1 (Dkt. 53).

[65] *See* Docket, *Nightlight Christian Adoptions, et al. v. Thompson, et al.*, No. 1:01-cv-00502-RCL (D.D.C.) (reflecting voluntary dismissal of lawsuit challenging funding of research using hESCs after Bush Administration Executive Order authorizing use only of hESC lines in existence prior to August 2001).

research that uses previously derived hESC lines. Plaintiffs cannot have it both ways. If Plaintiffs' "unambiguous" argument – the linchpin of their claim – is right, then the Bush Administration policy was wrong.

Moreover, acceptance of a "no inducement" interpretation of the Dickey-Wicker amendment would preclude the broad injunction Plaintiffs seek here. As explained above, the vast majority of the hESC lines that have been added to the NIH Registry were derived *before* the Guidelines went into effect in July 2009; many were derived in 2004 or earlier. *See supra* p. 14. Funding research using those pre-existing lines cannot possibly create any "inducement" to destroy an embryo. Thus, analytically, there can be no legal distinction between these lines and the other previously derived hESC lines the use of which was permitted during the Bush Administration on the grounds that they already had been derived and no possible harm to an embryo could result from their use. Acceptance of the validity of the prior policy precludes the conclusion that there is any basis for challenging the implementation of the Guidelines with respect to the vast majority of the hESC lines on the Registry and granting the sweeping injunction sought by Plaintiffs barring use of those long existing cell lines.

III. THE REQUESTED INJUNCTION WILL SEVERELY HARM THE MANY DEDICATED SCIENTISTS WHO CONDUCT hESC RESEARCH AND THE MILLIONS OF POTENTIAL BENEFICIARIES OF SUCH RESEARCH

Plaintiffs' characterization of the balance of hardships and the public interest ignores the harm to scientists conducting research using hESC and to the millions of potential beneficiaries of that research. Plaintiffs focus upon the purported availability of alternatives to using hESCs in research, namely ASC and iPSC, to argue that there is no harm to these third parties. Pl. Mem. at 41. They are wrong. ASC and iPSC research is of undeniable value. But, as shown above,

because of the different characteristics of hESCs, ASCs and iPSCs, research involving the latter types of cells simply cannot substitute for research using hESCs. *See supra* pp. 8-9.

Dr. Collins, in his declaration, provides a comprehensive overview of the harm to scientists and their research, and their sponsoring institutions, that would result from the injunctive relief that Plaintiffs seek.[66] The researchers themselves provide additional specific examples of the harm arising from the requested relief and attest to the fact that significant and immediate consequences would result from an injunction.[67] The nature of research using hESCs and other scientific research means that any interruption in funding can have significant impact on research projects and on the field in general.[68] Moreover, the impact of the injunction would not be limited to research focusing on hESCs, as research involving ASCs and iPSCs that also uses hESCs as controls also would be affected.[69]

Research using hESCs 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 disorders.[70] Research using hESCs has the potential to develop treatments for these diseases and injuries, as well as many more, as discussed at pp. 7-12 above. The harm to these patients that will result from a permanent 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

[66] *See generally* Collins Decl. ¶¶ 8-21 (Ex. A-2).

[67] *See* Morrison Decl. ¶¶ 9-10 (Ex. C); Hei Decl. ¶¶8-10 (Ex. B); Zhang Decl. ¶¶ 5-7 (Ex. F); Gamm Decl. ¶ 7 (Ex. D); Bhattachryya Decl. ¶¶ 4-6 (Ex. G).

[68] *See* Hei Decl. ¶ 8 (Ex. B); *see also* Collins Decl. ¶ 12 (Ex. A-2).

[69] *See, e.g.*, Morrison Decl. ¶ 10 (Ex. C).

[70] *See, e.g.*, CAMR website, http://www.camradvocacy.org/about_us.cfm (last visited Sept. 27, 2010).

diagnosed. This type of research, and translation of research findings into effective therapies, takes years, and even decades.[71] Any delay in that process inevitably will harm patients by depriving them of timely access to therapies developed through research using hESCs.

CONCLUSION

For nearly a decade, Congress has appropriated funds to NIH with the understanding and expectation that NIH would use some of those funds for research projects using human embryonic stem cells. The Guidelines challenged in this case are consistent with the longstanding policy choice by the elected branches of government to fund such research, in order to benefit society by advancing scientific knowledge and facilitating the development of new medical treatments. Plaintiffs are entitled to dissent from that policy choice, and to decline to engage in such research as a matter of their own personal ethical convictions. But they offer no valid legal basis for the Court to invalidate the NIH Guidelines. Plaintiff's motion for summary judgment should be denied and Defendants' motion for summary judgment should be granted.

[71] *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."); Morrison Hrg. Test. at 6 (Ex. C).

Respectfully submitted,

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