ORAL ARGUMENT SCHEDULED FOR APRIL 23, 2012

No. 11-5241

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

JAMES L. SHERLEY, *et al.*,

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia

District Court No. 1:09-cv-01575-RCL

BRIEF OF THE COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH AND THE GENETICS POLICY INSTITUTE, INC., AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties and Amici

All parties, intervenors and amici appearing before the District Court and in this Court are listed in the Brief for Appellants filed on January 12, 2012.

Disclosure statements for proposed amici Coalition for the Advancement of Medical Research (CAMR) and the Genetics Policy Institute are provided immediately following this Certificate and incorporated herein.

B. Rulings Under Review

The rulings under review are the July 27, 2011 Order and Memorandum Opinion of the District Court granting summary judgment. *Sherley v. Sebelius*, Civ. No. 1:09-cv-1575 (Chief Judge Royce C. Lamberth). The opinion is available at 776 F. Supp. 2d 1, and the order and opinion appear at page 655 of the Joint Appendix.

C. Related Cases

This matter has previously come before this Court in *Sherley v. Sebelius*, No. 10-5287 (April 29, 2011). The opinion is available at F.3d and at page 508 of the Joint Appendix. This matter also came before this Court in *Sherley v. Sebelius*,

No. 09-5374 (June 25, 2010). The opinion is available at 610 F.3d 69 and at page 216 of the Joint Appendix. Counsel is not aware of any other related cases within the meaning of D.C. Circuit rule 28(a)(1)(c).

DISCLOSURE STATEMENT OF COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH

Pursuant to Circuit Rule 26.1, proposed amicus curiae Coalition for the Advancement of Medical Research ("CAMR") hereby provides this Disclosure Statement.

CAMR, a not-for-profit organization under section 501(c)(4) of the Internal Revenue Code, 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. CAMR's members are listed below.

CAMR's members do not have any ownership interests in the non-profit organization, which is in the nature of a trade association or professional association. CAMR's members are not for profit organizations and are not publicly held companies that issue shares or debt securities to the public.

LIST OF CAMR MEMBERS

Albert Einstein College of Medicine of Yeshiva University
Alliance for Aging Research
Alpha-1 Foundation
ALS Association
ALS Association, NY Chapter
American Academy of Neurology
American Academy of Pediatrics
American Association for Cancer Research
American Association for Dental Research
American Association of Neurological Surgeons/Congress of Neurological Surgeons
American Autoimmune Related Diseases Association
American Diabetes Association
American Society for Microbiology
American Society for Neural Therapy and Repair
American Society for Reproductive Medicine
American Society of Hematology
Association of American Medical Colleges
Association of American Universities
Association of Independent Research Institutes
Association of Public and Land-Grant Universities
Axion Research Foundation
Biophysical Society
Biotechnology Industry Organization
Brown University
Fight Colorectal Cancer
California Institute for Regenerative Medicine
California Institute of Technology
Californians for Cures
Cedars-Sinai Medical Center
Cerebral Palsy International Research Foundation
Children's Hospital Boston
Christopher and Dana Reeve Foundation
City of Hope
Coalition for Life Sciences

Columbia University Medical Center
Cornell University
Duke University Medical Center
Emory University
Familial Dysautonomia Hope Foundation (FD Hope)
FasterCures
Federation of American Societies for Experimental Biology
Foundation Fighting Blindness
Friends of Cancer Research
Genetics Policy Institute
Hadassah
Harvard University
Hereditary Disease Foundation
International Cancer Advocacy Network (ICAN)
International Society for Stem Cell Research
Johns Hopkins Institutions
Juvenile Diabetes Research Foundation International
Leukemia & Lymphoma Society
LIVESTRONG
Missouri Coalition for Life Saving Cures
Mount Sinai School of Medicine
National Alliance for Eye and Vision Research
National Coalition for Cancer Research
National Health Council
National Multiple Sclerosis Society
National Parkinson Foundation
Nebraska Coalition for Life Saving Cures
New York Stem Cell Foundation, Inc.
Northwestern University
NYU Langone Medical Center
Packard Center for ALS Research
Parkinson's Action Network
Parkinson’s Disease Foundation
Penn State University College of Medicine
Prevent Cancer Foundation
Rensselaer Polytechnic Institute
Research!America

Resolve: The National Infertility Association
Rutgers University
Sarcoma Foundation of America
Society for Women's Health Research
Stanford University
Stony Brook University
Student Society for Stem Cell Research
Texans for the Advancement of Medical Research
The American Society for Cell Biology
The Association for Research in Vision and Ophthamology
The Michael J. Fox Foundation for Parkinson's Research
The Ohio State University Comprehensive Cancer and Medical Center
The Parkinson Alliance
The Travis Roy Foundation
Tourette Syndrome Association, Inc.
Unite 2 Fight Paralysis
United Spinal Association
University of California System
University of Massachusetts Medical School
University of Michigan
University of Minnesota
University of Pittsburgh
University of Rochester Medical Center
University of Southern California
University of Vermont College of Medicine
University of Wisconsin-Madison
Vanderbilt University and Medical Center
Washington University in St. Louis
Wayne State University School of Medicine
WiCell Research Institute, Inc./Wisconsin Alumni Research Foundation
Yale University

DISCLOSURE STATEMENT OF
THE GENETICS POLICY INSTITUTE, INC.

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1, amicus curiae Genetics Policy Institute states that it has no parent corporation and that no publicly owned corporation owns 10% or more of its stock.

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GLOSSARY

ASC	Adult stem cell
CAMR	The Coalition for the Advancement of Medical Research
Guidelines	National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009)
hESC	Human embryonic stem cell
iPSC	Induced pluripotent stem cell
IVF	In vitro fertilization
JA	Joint Appendix
NIH	The National Institutes of Health

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief for Appellants.

INTERESTS OF AMICI CURIAE[1]

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. A list of CAMR's members is provided in the Certificate contained in the front of this brief.

The Genetics Policy Institute, Inc. is a not-for-profit corporation devoted to promoting and defending stem-cell research (including hESC research) and other cutting-edge medical research.

Amici support continued federal funding of stem cell research, including human embryonic stem cell research, to advance medical and scientific knowledge and to facilitate the development of therapies to treat a wide variety of diseases.

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[1] No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and no person (other than amici's counsel) contributed money that was intended to fund preparing or submitting this brief.

STATEMENT OF FACTS

The record in the District Court established beyond dispute that the federal government has funded research using hESCs for well over a decade.[2] The NIH Guidelines challenged by Appellants did not alter this longstanding policy choice by the elected branches of the government. Rather, the Guidelines expanded the number of previously derived hESC lines that could be used in federally funded research by establishing new criteria governing what hESCs could be used in a federally funded research project.

A. The Unique Characteristics of Human Embryonic Stem Cells

hESCs are derived from blastocysts, which develop five days after fertilization of an egg by a sperm.[3] A blastocyst is smaller than the period at the end of this sentence.[4] Although hESCs are derived from blastocysts, hESCs are not embryos.

Most hESCs are derived from "excess" blastocysts produced in the process of in-vitro fertilization (IVF). IVF clinics typically fertilize all of a woman's

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[2] *See* Br. of Appellants (App. Br.) at 4.

[3] Nat'l Acads., *Understanding Stem Cells: An Overview of the Science and Issues from the National Academies* 4 (2009), *available at* http://dels.nas.edu/resources/static-assets/materials-based-on-reports/booklets/Understanding_Stem_Cells.pdf (cited in JA 231). This Court may take judicial notice of documents maintained by government agencies on their website. *See* Fed. R. Evid. 201; *Nebraska v. EPA*, 331 F.3d 995, 998 n.3 (D.C. Cir. 2003); *see also Coleman v. Dretke*, 409 F.3d 665, 667 (5th Cir. 2005).

[4] *Id.* at 4.

retrieved eggs to maximize the chance of successful implantation.[5] This process often results in blastocysts that are not implanted and that are typically are destroyed or frozen indefinitely if they are not used to derive hESCs.[6]

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 can differentiate into any of the approximately 200 different types of cells in the human body.[7] In contrast, ASCs can be differentiated into some, but not all, different cell types.[8] iPSCs—which were developed in 2007 as a direct result of hESC research[9]—are "adult cells that have been genetically

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[5] Nat'l Acads., *supra* note 3, at 5-6.

[6] *Id*. at 5-6, 19; *see also* NIH, *Regenerative Medicine* 3 (2006), *available at* http://stemcells.nih.gov/info/staticresources/info/scireport/PDFs/Regenerative_Medicine_2006.htm (last visited Feb. 24, 2012).

[7] *See* JA 465 ¶ 17.

[8] *See* NIH, *Stem Cell Basics* 3, at 12-13, *available at* http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf ("Stem Cell Basics") (last visited Feb. 15, 2012); NIH, *supra* note 3 at 4-5; The President's Council on Bioethics, *Monitoring Stem Cell Research* 126 (Jan. 2004), *available at* http://bioethics.georgetown.edu/pcbe/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf ("*Monitoring Stem Cell Research*").

[9] JA 249 ¶ 7; *see also The Promise of Human Embryonic Stem Cell Research: Hearing Before the Subcomm. on Labor, Health and Human Servs., Educ, and Related Agencies of the S. Comm. on Appropriations*, 111th Cong. (Sept. 16, 2010) (statement of George Q. Daley, M.D., Ph.D.) ("Daley 9/16/10 Testimony"), *available at* http://appropriations.senate.gov/ht-labor.cfm?method=hearings.view&id=0bea2354-dc3d-4623-9905-6dbff89581ac. Statements made before congressional

reprogrammed to an embryonic stem cell-like state."[10] While iPSCs offer promising opportunities for research in some areas, they are not a substitute for hESCs.[11] Even Appellants do not deny that iPSCs are not identical to hESCs.[12]

The scientific value of research using hESCs is widely recognized.[13] hESCs were first derived in 1998, only fourteen years ago, whereas ASCs have been used in research for more than fifty years.[14] Yet, despite this short history, researchers

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committees are appropriate for judicial notice. *See Adarand Constructors, Inc. v. Slater*, 228 F.3d 1147, 1168 n.12 (10th Cir. 2000).

[10] NIH, *supra* note 8, at 13.

[11] JA 249 ¶ 7; *see* Melissa K. Carpenter, et al., *Developing Safe Therapies from Human Pluripotent Stem Cells*, 27 Nature Biotech. 606, 612 (July 2009); Judith A. Johnson & Erin Williams, Cong. Research Serv. RL3540, Stem Cell Research: Federal Research Funding and Oversight 7 (July 10, 2008); *see also* K. Kim et al., *Epigenetic Memory in Induced Pluripotent Stem Cells*, 467 Nature 285 (July 2010).

[12] *See* App. Br. at 9 ("[iPSCs] are *virtually* indistinguishable from [hESCs]") (emphasis added).

[13] *See infra* p. 30; *see also* Remarks of President Barack Obama—As Prepared for Delivery, Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (March 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/.

[14] NIH, *supra* note 8, at 2, 8; *see also The Promise of Human Embryonic Stem Cell Research: Hearing Before the Subcomm. on Labor, Health and Human Servs., Educ., and Related Agencies of the S. Comm. on Appropriations*, 111th Cong. (Sept. 16, 2010) (statement of Francis M. Collins, M.D., Ph.D.) ("Collins 9/16/10 Testimony"), *available at* http://appropriations.senate.gov/htlabor.cfm ?method=hearings.view&id=0bea2354-dc3d-4623-9905-6dbff89581ac; *Id.* (statement of Sean J. Morrison, Ph.D.) ("Morrison 9/16/10 Testimony"), *available*

have been able to use hESCs to produce specific types of cells that could be used in the treatment of Parkinson's disease, Type 1 diabetes, spinal cord injury, and macular degeneration.[15] Further, hESCs are being used as tools for accelerated drug screening and for research into basic questions of human development and related medical conditions.[16]

B. The Separate Processes of Deriving hESCs and Later Using Those Cells in Research

Federal funds are not, and never have been, used for the process of deriving hESCs from blastocysts. The NIH Guidelines expressly prohibit "NIH funding of the derivation of stem cells from human embryos."[17]

The separation between the derivation of hESC lines and research that subsequently uses those previously derived lines is reflected in the fact that, of the hESC lines approved by NIH for listing on the Registry as of the close of the

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at http://appropriations.senate.gov/ht-labor.cfm?method=hearings.view&id=0bea2354-dc3d-4623-9905-6dbff89581ac.

[15] *See* Nat'l Acads., *supra* note 3, at 2, 15-17; *see also* JA 248 ¶ 6; Press Release, Northwestern University Feinberg School of Medicine, Northwestern First Site Open for Spinal Cord Stem Cell Trial (Sept. 2010), *available at* http://www.feinberg.northwestern.edu/news/2010/2010D September/Spinal_Cord_Stem_Cell_Trial.html.

[16] *See* NIH, *supra* note 8, at 14; *see also* Collins 9/16/10 Testimony, *supra* note 14, at 5, 9; Daley 9/16/10 Testimony, *supra* note 9, at 4; Nat'l Acads., *supra* note 3, at 18.

[17] JA 49 (NIH Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,175 (July 7, 2009) ("NIH Guidelines")).

record, most were created *before* President Obama issued his Executive Order.[18] Thus, with respect to this vast majority of lines on the Registry, neither the adoption of the Guidelines, nor the subsequent approval of grants for research projects using those pre-existing hESC lines, provided any incentive for derivation.

C. NIH's Decade-Long Funding of Research Using Previously Derived hESCs with Congressional Knowledge and Approval

For nearly a decade NIH has funded research using hESCs with Congressional approval. From 2001-2009 NIH spent, with Congressional approval, half a billion dollars on research using hESCs.[19] In each year, congressional authorization for federal funding of NIH 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 Appropriations Act, 2010, Pub. L. No. 111-117, div. D, § 509(a)(2), 123 Stat. 3034, 3280. Thus,

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[18] *See* JA 464 ¶ 14.

[19] *See, e.g.*, JA 247-48, 253 ¶ 5, 13; Collins 9/16/10 Testimony, *supra* note 14, at 1; Johnson & Williams, *supra* note 11, at 13; *see also* S. Rep. No. 107-84, at 18 (Oct. 11, 2001); H.R. Rep. No. 108-636 (Sept. 7, 2004); H.R. Rep. No. 110-231 (July 13, 2007); *Stem Cell Science: The Foundation of Future Cures: Hearing Before the Subcomm. on Health of the Comm. on Energy and Commerce*, 110th Cong. (May 8, 2008) (Statement of Elias A. Zerhouni, M.D., Director, NIH) ("Zerhouni 5/8 Testimony"), *available at* http://olpa.od.nih.gov/hearings/110/session2/Testimonies/Elias_Zerhouni_Stem_Cell_Science.asp; Testimony Before Subcomm. on Labor, Health and Hum. Servs., Education, and Related Agencies and the Comm. on Health, Educ., Labor, and Pensions (Jan. 19, 2007), *available at* http://stemcells.nih.gov/StaticResources/policy/Landis2007-01-19.pdf.

for nearly a decade while the Dickey-Wicker Amendment was in force, Congress repeatedly authorized NIH funding of research using hESCs.

From 2001 to 2009, the only disagreement between the Executive and Legislative branches was not over whether federal funding of research using hESC was permissible, but over which hESC lines could be used in such research. Under policies adopted by the George W. Bush Administration, federal funding of research projects using hESCs was limited to research using hESC lines that had been derived before August 9, 2001.[20] In 2005 and again in 2007, Congress passed legislation to expand federal funding of research using hESCs to include hESC lines derived after August 9, 2001, but each time President Bush vetoed that legislation.[21]

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[20] Johnson & Williams, *supra* note 11, at 10.

[21] H.R. 810, 109th Cong., § 2 (1st Sess. 2005); S. 471, 109th Cong., 1st Sess. § 2 (2005); *see* Bill Summary and Status, http://thomas.loc.gov/cgibin/bdquery/z?d10 9: HR00810:@@@R; Veto Message from the President (July 19, 2006), *available at* http://thomas.loc.gov/cgi-bin/query/C?r109:./temp/~r109slva2S; *see also* H.R. 3, 110th Cong. (1st Sess. 2007); S. 5, 110th Cong., 2d Sess. (2d. Sess. 2007); H. R. 464, 110th Cong., (1st Sess. 2007) (agreeing to S. 5); *see Bill Summary & Status*, Library of Congress, http://thomas.loc.gov/cgi-bin/bdquery/z?d110:S5 (last visited Feb. 24, 2012).

D. President Obama's Executive Order Directing the Expansion of NIH Funding for Research Using hESC

On March 9, 2009, President Obama issued Executive Order 13,505, in order to "expand NIH support for the exploration of human stem cell research."[22] The order 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."[23]

E. NIH Promulgates The Guidelines

In response to the Executive Order, NIH issued notice in the form of draft guidelines, which "would allow funding for research using human embryonic stem cells" but would not permit "NIH funding of the derivation of stem cells from human embryos." JA 495 (74 Fed. Reg. 18,578, 18,578 (Apr. 23, 2009)). This notice invited comment on how to implement such a rule. In July 2009, NIH adopted the Guidelines governing federal funding for research using hESC lines that are at issue in this case. JA 44.

The NIH Guidelines impose stringent requirements for listing on the NIH Registry of approved hESC lines. To be listed, an hESC line must have been derived from an embryo (1) "created using [IVF] for reproductive purposes";

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[22] JA 493 (74 Fed. Reg. 10,667 (March 9, 2009)).

[23] *Id.*

(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."[24] These restrictions ensure that only blastocysts that would otherwise be frozen indefinitely or destroyed may serve as sources of hESC lines.[25] The Guidelines contain additional requirements ensuring that the IVF patients' consent to donate the embryo for research was informed, voluntary, and not the result of any pressure, coercion, payment, or other incentive to donate.[26] These requirements ensure that the possibility of NIH funding of research using hESCs will not create any incentive either to create embryos from which hESCs will be derived to donate embryos created for reproductive treatment.

The stringency of the Guidelines is reflected in the statistics regarding their implementation in screening hESC lines for inclusion on the NIH Registry of hESC that may be used in a federally funded research project. NIH data available prior to the judgment in the district court indicate that, while 75 hESC lines were approved, 48 were rejected—a 39% denial rate.[27]

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[24] JA 44 (74 Fed. Reg. at 32,174).

[25] *See supra* p. 4.

[26] *See* JA 44 (74 Fed. Reg. at 32,174-75).

[27] Collins 9/16/10 Testimony, *supra* note 14, at 12; *compare NIH Human Embryonic Stem Cell Registry, Research Using These Lines is Eligible for NIH*

F. Congress Endorses the NIH Guidelines

Congress responded to NIH's adoption of the Guidelines in 2009 by once again appropriating funds for NIH and again including the Dickey-Wicker Amendment in the appropriations bill.[28] Far from condemning NIH's conduct, the Senate Committee Report commended NIH for its effort to expand the funding of research using additional hESC lines that satisfied the rigorous new Guidelines. "The Committee . . . 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 Report further stated that the Dickey-Wicker Amendment "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).[29] During FY 2010, NIH obligated more than $100 million to grants for hESC research.[30]

Funding, NIH, http://grants.nih.gov/stem_cells/registry/current.htm (last updated July 13, 2011), *with NIH Human Embryonic Stem Cell Registry, Cell Lines Not Approved for NIH Funding Eligibility*, NIH, http://grants.nih.gov/stem_cells/registry/not_approved.htm.

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

[29] *See* H.R. Rep. No. 111-366, at 982 (Dec. 8, 2009).

[30] *See* JA 176 ¶ 18); JA 253-54 ¶¶ 13-15.

SUMMARY OF ARGUMENT

The federal government has funded research using hESC since 2001 through appropriations bills containing the Dickey-Wicker amendment. Appellants assert that for nearly a decade Congress and the Executive Branch have misconstrued the amendment in funding such research. That extraordinary assertion is wrong. The plain language of Dickey-Wicker Amendment is most reasonably read, as it consistently has been, to permit such research. To the extent there is any ambiguity, NIH's longstanding interpretation is entitled to deference.

NIH's implementation of this well-established federal policy Guidelines establishing rigorous criteria for identifying previously derived hESC lines that may be used in federally funded research fully complied with the Administrative Procedure Act. Both the history of congressional funding and President Obama's Executive Order and accompanying statement made clear that the issue of whether research using hESC should continue had been decided. Thus, the issue of the merits of such research was not the subject of the NIH rulemaking and NIH was not required to respond to comments urging an unprecedented ban on federal funding for such research. Yet, NIH nevertheless in fact did address and reject such comments, in reasonable reliance on the abundant scientific literature recognizing the merit of such research.

ARGUMENT

I. The Guidelines Comply with the Dickey-Wicker Amendment.

A. NIH's Interpretation Is the Best Reading of the Statute.

The Dickey-Wicker Amendment does not prohibit federal funding of research using previously derived hESC lines. As the government argues, and as the majority in *Sherley II* held, the word "research" as used in Dickey-Wicker can be understood to refer not only to research in general (a "generic" interpretation) but also to the particular research project for which federal funding is sought (a "nongeneric" interpretation).[31] This is clear from the dictionary definition of "research." For example, one major unabridged dictionary gives the following definition: "a particular instance or piece of research." *Random House Webster's Unabridged Dictionary* 1637 (2d ed. 2001); *see also Webster's Third New International Dictionary, Unabridged* 1930 (1993) (similar definition). NIH's nongeneric reading of the statute's wording—"research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk"—makes particular sense in the context of NIH funding, which is granted only for a specific project that has satisfied a rigorous peer-reviewed grant approval process.[32]

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[31] *See, e.g.*, Gregory Carlson, *Generic Reference*, in 5 Encyclopedia of Language & Linguistics 14 (Keith Brown, ed. 2d ed. 2006).

[32] *See generally* Grant Application Basics, NIH, http://grants.nih.gov/grants/grant_basics.htm (last updated Feb. 6, 2012).

As the *Sherley II* majority noted, "NIH funding decisions are forward-looking, requiring the NIH to determine whether *what is proposed to be funded* meets with its requirements." JA 518 (internal quotation marks omitted) (emphasis added). Thus, interpreting "research" nongenerically in Dickey-Wicker parallels the case-by-case process by which individual funding decisions are made.

This conclusion is not changed by the fact that "research" is defined in 45 C.F.R. § 46.102(d) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." The word "investigation," like "research," can be interpreted nongenerically, and the question of whether an investigation is systematic is independent of whether it encompasses the destruction of embryos. The fact "that a project . . . is 'systematic' does not mean that it includes acts or processes, such as deriving [h]ESCs, that predated the federally funded research." JA 518 n.* (internal quotation marks omitted).

There is no merit to Appellants' reliance on the definition quoted above to contend that the act of derivation is part of the "research development" process. App. Br. at 19-20. Appellants' use of that term is not consistent with its accepted meaning. "Research development" refers to activities within a university or other research institution that are undertaken in support of obtaining research funding, and more broadly in support of furthering the institution's research mission. Thus,

the National Association of Research Development Professionals defines "research development" as encompassing "activities designed to facilitate individual faculty members, teams of researchers, and central research administrations in attracting extramural research funding, creating relationships, and developing and implementing strategies that increase institutional competitiveness."[33]

Only where such "research development" activities are supported by federal funds are they subject to Dickey-Wicker. This interpretation fits neatly with the regulations' purpose of regulating the conduct of entities that subsequently receive support in the form of research funding from the federal government. *See* 45 C.F.R. § 46.101. Appellants' argument thus ignores the real meaning of "research development."

This conclusion also disposes of Appellants' argument against NIH's present-tense reading of Dickey-Wicker because that argument depends on their mistaken interpretation of "research development." *See* App. Br. at 21; *see also* JA 518. Contrary to the dissent's reading in *Sherley II*, JA 537 (Henderson, J., dissenting), Dickey-Wicker's use of the participial verb form "destroyed" does not indicate that the statue refers to "past or completed action or time." When a

[33]*What Is Research Development?*, Nat'l Org. of Research Dev. Professionals, http://www.nordp.org/index.php?option=com_content&view=article&id=29&Itemid=118 (last visited Jan. 28, 2012); *see* Jacob Levin, *The Emergence of the Research Development Professional*, Chron. of Higher Educ. (March 27, 2011), http://chronicle.com/article/The-Emergence-of-the/126906/.

participial verb form is used for that purpose, it is preceded by a form of the verb "have," not a form of the verb "be."[34] This can be shown by example (the asterisks indicate that the example is ungrammatical or has an unintended meaning):

I *have* visited Paris several times.
*I *am* visited Paris several times.
It *has* rained for the past three days.
*It *is* rained for the past three days.
By the time they arrived, we *had* already eaten.
*By the time they arrived, we *were* already eaten.

Thus, Dickey-Wicker uses the phrase "are destroyed" not as an indication of "past or completed action or time" but as part of a present-tense use of the passive voice.[35] Accordingly, Dickey-Wicker's use of the participial form "destroyed" is entirely consistent with NIH's present-tense reading of the statute.[36]

A close look at the text of Dickey-Wicker also reveals the flaws in Appellants' "subjected to risk" argument. In addition to prohibiting federal funds for research in which human embryos "are destroyed," Dickey-Wicker prohibits the use of such funds for research in which human embryos "are knowingly

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[34] *See, e.g.*, Rodney Huddleston & Geoffrey K. Pullum, *The Cambridge Grammar of the English Language* 77 (2002).

[35] *See id.* at 1427-30.

[36] Appellants argue that if NIH can fund research on hESCs derived before the period of funding, "NIH could retroactively fund the already-completed act of destroying embryos." App. Br. 22. Appellants' speculation as to the theoretical possibility of such a situation arising cannot support the argument that the Guidelines are invalid on their face. *See Reno v. Flores*, 507 U.S. 292, 301 (1993); *Sherley II*, 644 F.3d at 397.

subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 C.F.R. § 46.204(b) and [42 U.S.C. § 289g(b)]." Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, div. D, § 509(a)(2), 123 Stat. 3034, 3280. Appellants contend that this provision bars funding of hESC research because (a) research using hESC may create a demand for additional stem cells, which (b) may create an incentive to derive more lines of stem cells, (c) thereby putting additional embryos at risk. *See* App. Br. at 25-29.

According to Appellants, the risk to embryos from this attenuated, speculative chain of causation is greater than would be allowed for research on fetuses in utero under 45 C.F.R. § 46.204(b). That regulation, however, deals with the risks to a fetus arising when that fetus is involved in research *as a research subject—i.e.*, when experiments are performed on the fetus. Section 46.204(b) refers to the risk "to *the* fetus," meaning the fetus that is undergoing the experimentals. It does not refer generally to risks "to *fetuses*," as would have been appropriate if Congress had intended to prevent the sort of speculative risk-through-future-incentivization that Appellants hypothesize.

Because the risks are so different in *kind*, they cannot be compared against one another in terms of *degree*. The logical conclusion is that the kind of risk Dickey-Wicker refers to is the same kind that § 46.204(b) addresses: the risk to an

embryo from having an experiment performed on the embryo. It is undisputed that the Guidelines create no such risk.

NIH's interpretation of the statutory text is, therefore, the best available reading of that language. Moreover, for nine years NIH, with the full knowledge, consent and endorsement of Congress, consistently construed Dickey-Wicker to permit federal funding of research using previously derived hESCs. Thus, at the very least, the phrase "research in which" reasonably can be construed differently than Appellants use it. Certainly, it cannot fairly be characterized as unambiguously prohibiting federal funding of research using hESC.

B. NIH's Interpretation is Supported by the Relevant Legislative History.

The relevant legislative history confirms the reasonableness of NIH's interpretation. What is referred to as "the Dickey-Wicker Amendment" is, of course, a series of separate appropriations riders, each of which applied, by its own terms, only to the appropriations bill to which it was appended. Each time another iteration is enacted, the relevant legislative intent is that of the enacting Congress, and although the language stays the same, the same is not necessarily true of that Congress's intent. Rather, the intent of each enacting Congress must be determined on the basis of the facts in existence existed at the time of enactment, because those facts provided the context in which Congress acted.

While it may be true that in the late 1990s there were statements in the legislative history hostile to research using hESCs, as Appellants and their amici contend,[37] the relevant factual context and legal landscape was dramatically changed in August 2001 when President Bush decided to that the federal government to fund hESC research using stem-cell lines that were already in existence.

From that point forward, NIH funded research using hESCs in accordance with the President's directive, and Congress passed each iteration of the Dickey-Wicker Amendment—without changing its language—knowing that research using hESCs would be funded. Moreover, beginning in 2001, the enactment of iterations of the Dickey-Wicker Amendment has repeatedly been accompanied by committee reports saying that Dickey-Wicker 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."[38] And that practice continued after President Obama eliminated the Bush-era limits on federal funding or

[37] App. Br. at 35-36; George Br. at 14-27.

[38] *E.g.*, H.R. Rep. No. 110-231 (July 13, 2007); H.R. Rep. No. 108-636 (Sept. 7, 2004); H.R. Rep. No. 108-188 (July 8, 2003); H.R. Rep. No. 107-229 at 180 (Oct. 9, 2001). *See also*, *e.g.*, S. Rep. No. 107-84, at 18 (Oct. 11, 2001).

research using hESCs and NIH issued the Guidelines that are now at issue.[39] Neither Appellants nor their amici have cited anything to the contrary in the legislative history after the Bush policy was adopted.[40]

Under these circumstances, Congress's repeated enactment of the Dickey-Wicker Amendment without changing its language amounts to ratification of NIH's construction. *See, e.g.*, *Barnhart v. Walton*, 535 U.S. 212, 220 (2002); *Doris Day Animal League v. Veneman*, 315 F.3d 297, 300 (D.C. Cir. 2003). Indeed, this is not merely a case in which "Congress revisits a statute" with knowledge of how an agency has interpreted it and then fails to amend the statute

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[39] *E.g.*, H.R. Rep. No. 111-220, at 273 (July 22, 2009). *See also, e.g.*, H.R. Conf. Rep. No. 111-366, at 982 (Dec. 8, 2009); S. Rep. No. 111-66, at 121 (Aug. 4, 2009).

[40] With one exception, the legislative history and administrative interpretations on which Appellants and their amici rely predate the Bush Administration policy. App. Br. at 35-36; George Br. at 14-27. The exception relates to Congress's failure in 2001 to enact a revised version of Dickey-Wicker that would have expressly allowed funding of research using hESC. App. Br. at 38, According to Appellants, the fact that the bill was introduced means that "[e]ven the members of Congress who support human embryonic stem-cell research have recognized that federal funding thereof does not comport with Dickey-Wicker[.]" *Id.* But that argument is mistaken because it ignores the context in which the bill was introduced. The proposed revision of Dickey-Wicker was introduced in October 2001—two months after the Bush Administration had announced its policy severely limiting the number of hESC lines that could be used in federally funded research. *See* Library of Congress, *Bill Summary & Status, 107th Congress (2001 -2002), S.1536*, , http://thomas.loc.gov/cgi-bin/bdquery/z?d107:s.01536: (last visited Feb. 23, 2012). The proposed revision thus represented an attempt to override the restrictions in the Bush Administration policy, not an implicit statement about the scope of Dickey-Wicker.

to overturn that interpretation. *Doris Day Animal League*, 315 F.3d at 300. Rather, this is a case in which Congress has, with that knowledge, enacted the same language in a new appropriations rider for a decade. That is strong evidence that Congress approved of NIH's interpretation and *a fortiori* that the agency's interpretation was a reasonable one.

Moreover, Appellants and their amici ignore the fact that after the Bush policy was adopted, Congress twice passed legislation to overturn that policy and permit funding of research using hESCs, only to have the legislation vetoed each time.[41] There can be no clearer or more authoritative statement of Congressional intent than the passage of a bill by both houses of Congress, and during the period 2005–2007, Congress unmistakably expressed its support for funding research using hESCs. So even if one accepts the argument that the early iterations of Dickey-Wicker reflected opposition to funding research using hESCs, by the period 2005–2007 the tide had turned and opposition had turned into support. In light of that history, there can be no doubt that by 2005–2007 Congress did not intend, in annually adopting the Dickey-Wicker amendment, to prohibit federal funding of research using hESCs.

Appellants' "incentivization" argument based on the "subjected to risk" clause is similarly unavailing. The promulgation of the current NIH Guidelines in

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[41] *See supra* p. 7.

2009, which eliminated the Bush policy's limitation, again changed the factual context in which Congress acted. With knowledge of that changed context, Congress enacted additional iterations of Dickey-Wicker without any change, thus indicating ratification of that change. *See Doris Day Animal League*, 315 F.3d at 300. Pertinent committee reports state that Dickey-Wicker 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."[42] This legislative history, combined with the fact that so many of the relevant hESC lines were derived long before the issuance of the NIH Guidelines,[43] seriously undermines Appellants' argument regarding incentivization.

Viewed in light of the statutory language and appropriate context, NIH's interpretation of "research" should be upheld as entirely permissible.

C. NIH's Interpretation Is Entitled to Deference.

Where a statute is ambiguous, the court must decide 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

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[42] *E.g.*, H.R. Rep. No. 111-220, at 273 (July 22, 2009).

[43] *See supra* p. 7.

interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Appellants do not dispute that NIH has authority to make rules governing grants of federal funding for medical 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. at 32,173.[44] Appellants attempt to dismiss this consistent construction of the Dickey-Wicker Amendment on the grounds that NIH did not engage in an express linguistic exegesis of the phrase "research in which." However, all that is required is that "the agency's path may reasonably be

[44] Appellants are wrong to attack NIH's interpretation of the statute as nothing more than a *post hoc* rationalization by counsel. *See* App. Br. at 41. NIH's consistent articulation of this policy over the last ten years is clear. *See* NIH Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000); *see also* Memorandum from Alex M. Azar II, General Counsel, NIH, to Dr. Ruth Kirchstein, Acting Director, NIH, Compliance of the President's Embryonic Stem Cell Decision with the Dickey Amendment for Fiscal Year 2002 (Jan. 11, 2002).

discerned." *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1810 (2009); *see 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 easily satisfies that standard.

II. NIH Complied with the Administrative Procedure Act.

A. NIH Was Not Required to Address the Long-Settled Issue of the Scientific Merit of Research Using hESCs.

Appellants argue at length that the NIH Guidelines must be vacated because NIH failed to respond to public comments addressing the question of whether funding for hESC research should be permitted at all. *See* App. Br. at 42-62. The district court rejected this argument, holding that NIH was not required to consider and respond to comments opposing hESC research entirely because such comments were not relevant to the rulemaking in light of the history of funding of research using hESCs and because the Executive Order required NIH to promulgate a rule permitting such funding. *See* JA 687-92.[45] That decision was correct.

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[45] Appellants' argument relies primarily on various formulations of the proposition that an agency must "respond[] to significant points raised by the public." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977). Every aspect of this argument depends upon the flawed premise that the comments were relevant. Nothing in the law cited by Appellants stands for the proposition that an agency must respond to irrelevant comments. Indeed, in large part, the cases Appellants rely on either are inapposite, *see, e.g.*, *Chamber of Commerce of the United States v. Reich*, 74 F.3d 1322, 1327-28 (D.C. Cir. 1996); *Ass'n of Nat'l Advertisers, Inc.*

Where lawful, NIH must implement executive orders authorizing specific regulatory action. *See Bldg. & Constr. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 33 (D.C. Cir. 2002); *see also Meyer v. Bush*, 981 F.2d 1288, 1303 n.6 (D.C. Cir. 1993). Any resulting regulation must be consistent with the executive order. *See Itek Corp. v. First Nat'l Bank of Boston*, 704 F.2d 1, 7 (1st Cir. 1983). Moreover, an agency's interpretation of a controlling executive order is entitled to deference. *See Udall v. Tallman*, 380 U.S. 1, 16-17 (1965).

As noted, in Executive Order 13,505, President Obama stated that he would "expand NIH support for the exploration of human stem cell research."[46] He expanded on the order's intent in the remarks he delivered when signing it. At the outset, the President said, "we will vigorously support scientists who pursue this research. And we will aim for America to lead the world in the discoveries it one day may yield."[47] He acknowledged that striking the balance between science and morality is "difficult and delicate" but stated that "after much discussion, debate and reflection, the proper course has become clear"[48]:

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v. FTC, 627 F.2d 1151, 1170 (D.C. Cir. 1979), or support NIH's actions, *see*, *e.g.*, *Petrol. Commc'ns, Inc. v. FCC*, 22 F.3d 1164, 1173 (D.C. Cir. 1994); *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984).

[46] Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

[47] Remarks of President Barack Obama, *supra* note 14.

[48] *Id.*

> The majority of Americans . . . have come to a consensus that we should pursue this research. That the potential it offers is great, and with proper guidelines and strict oversight, the perils can be avoided.
>
> That is a conclusion with which I agree. That is why I am signing this Executive Order, and why I hope Congress will act on a bi-partisan basis to provide further support for this research.[49]

It is impossible to read the President's remarks and think that he left it up to NIH to decide whether hESC research should be funded. What comes across loud and clear is that the President supported research using hESCs and wanted funding for it to be expanded. Further confirmation of that intent is provided by a subsequent memorandum to the heads of executive departments and agencies, in which the President described the Executive Order as evidencing his Administration's commitment "to supporting and conducting ethically responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law."[50]

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[49] *Id.*

[50] Memorandum for the Heads of Executive Departments and Agencies (July 30, 2009), *available at* http://www.whitehouse.gov/the_press_office/Memorandum-from-the-President-for-the-Heads-of-Executive-Departments-and-Agencies-Regarding-Guidelines-for-Human-Stem-Cell-Research/. The memorandum "direct[ed] the heads of executive departments and agencies that support and conduct stem cell research to adopt these Guidelines, to the fullest extent practicable in light of legal authorities and obligations." *Id.* Indeed, this memorandum creates a conundrum for the Appellants because, even if they prevail here, other agencies and departments might be bound by the memorandum, a disparity that would make no sense.

Focusing on the Executive Order's statement that NIH should "support and conduct responsible, scientifically worthy" research,[51] Appellants contend that the Executive Order and Draft Guidelines invited comment on the question of whether research using hESC was "responsible" and "scientifically worthy." *See* App. Br. at 45-47. On the contrary, neither contained any indication that a policy prohibiting funding for research using hESC was up for consideration. Following the President's lead, NIH requested comment on *how* best to ensure that "responsible" and "scientifically worthy" research using hESC received funding, not on *whether* any such funding was proper.

Indeed, the question of whether funding for hESC research would be categorically permitted or prohibited had long been laid to rest by the time NIH received the President's directive to adopt a new rule. For nine years, the Executive Branch had endorsed funding for research using hESC,[52] and NIH repeatedly and expressly reported to Congress its funding of research using

[51] JA 493, §§ 2, 3.

[52] *See, e.g.*, Memorandum from Alex M. Azar II, General Counsel, NIH, to Dr. Ruth Kirchstein, Acting Director, NIH, Compliance of the President's Embryonic Stem Cell Decision with the Dickey Amendment for Fiscal Year 2002 (Jan. 11, 2002).

previously derived hESCs.[53] In each of those years, Congress again authorized funding pursuant to legislation that included the Dickey-Wicker Amendment.[54]

NIH proposed a rule setting standards to ensure that, on a case-by-case basis, responsible, scientifically worthy research projects would receive funding. In considering public comment on this proposal, NIH had no duty to respond to comments addressing the closed, irrelevant question of whether research using hESC should be funded at all. *See Cable & Wireless P.L.C. v. FCC*, 166 F.3d 1224, 1235 (D.C. Cir. 1999) (rejecting argument that agency should have responded to comments because the "notice of proposed rulemaking gives no indication that the agency sought comments on [those] issues"); *see also Public Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993); *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984). Therefore, NIH complied with the Administrative Procedure Act.

B. NIH Appropriately Relied on its Expertise in Concluding that Research Using hESC Has Scientific Merit.

To the extent the scientific merit of research involving hESCs was open for consideration by NIH, the agency reasonably rejected the contention that such research cannot have scientific merit. NIH correctly recognized that this claim had already been rejected by appropriate policymakers and, therefore, crafted

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[53] *See supra* p. 7.

[54] *See id.*

Guidelines that provided a rigorous framework for determining on a case-by-case basis whether a given proposal for research using hESCs had merit, in light of a competitive peer-review process.

The scientific merit of research involving hESC lines is not an appropriate matter for judicial determination. Whether such research has sufficient scientific merit to warrant federal funding is, at the broadest level, a policy judgment to be made by Congress and, to the extent authorized by federal law, the Executive Branch, including NIH officials with relevant scientific expertise. *See Lincoln v. Vigil*, 508 U.S. 182, 193 (1993). Before the issuance of the NIH Guidelines, the executive and legislative branches made a clear policy decision that research using hESC could be scientifically worthy. NIH acted appropriately when it promulgated a rule consistent with these policy judgments, and that decision is entitled to deference. *See Barnett v. Weinberger*, 818 F.2d 953, 963 n.84 (D.C. Cir. 1987); *see also Chevron*, 467 U.S. at 866 ("[F]ederal judges—who have no constituency—have a duty to respect the legitimate policy choices made by those who do.").

The promise of research using hESCs—and the consensus that other forms of stem cells cannot serve as substitutes for hESCs—was well established when the

NIH Guidelines were issued.[55] The range of potentially groundbreaking and life-saving research involving hESCs is reflected in the many relevant peer-reviewed articles published since 2002,[56] as well as in the resources that the scientific community has devoted to such research.[57] The scientific community recognized the unique value of research using hESCs at the time of the NIH rulemaking.[58] Materials demonstrating this are contained in the administrative record, clearly marked as supportive of the NIH Guidelines.[59] Moreover, NIH was permitted "to look outside the record in formulating [the] rule[] and to draw upon its own regulatory experience and expertise." *Action on Smoking & Health v. Civ. Aeronautics Bd.*, 713 F.2d 795, 801 (D.C. Cir. 1983). Promulgated with relevant agency expertise, the NIH Guidelines were consistent with the widely shared views of the scientific community about the value of research using hESCs. Moreover,

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[55] *See* NIH, *supra* note 8, at 12-13 ; *see also* Zerhouni 5/8/10 Testimony, *supra* note 19; Johnson & Williams, *supra* note 11, at 4.

[56] *See* NIH, *Highlights of Stem Cell Research*, *available at* http://stemcells.nih.gov/research/scilit/highlights/ (last visited Feb. 15, 2012).

[57] NIH, *Research Programs at Universities and Institutions*, *available at* http://stemcells.nih.gov/research/educResearch.asp (last visited Feb. 2, 2012); *see also* JA 247-48, 253 ¶¶ 5, 13.

[58] *See supra* pp. 5-6; *see also* Press Release, Int'l Soc'y for Stem Cell Research, ISSCR Scientists Elated for Future of Human Embryonic Stem Cell Research After Obama Lifts Funding Ban (Mar. 9, 2009), *available at* http://www.isscr.org/obama_repeals.html; NIH, *Highlights of Scientific Research: 2008 Articles*, http://stemcells.nih.gov/research/scilit/highlights.htm.

[59] *See, e.g.*, NIH, *supra* note 6; NIH, *supra* note 58.

since the issuance of the Guidelines, support in the scientific community for research using hESCs has increased.[60]

Research using hESCs has the potential to help millions of patients. The relevant scientific community has been convinced of the importance of such research since before the issuance of the NIH Guidelines, and that consensus has only strengthened since that time. Consistent with the policy judgments of the President and Congress, NIH properly relied on its expertise in expanding the funding available for such research.

CONCLUSION

The District Court's order granting summary judgment in favor of Appellees and against Appellants should be affirmed.

[60] *See, e.g.*, Morrison 9/16/10 Testimony, *supra* note14 ("I interact regularly with hundreds of leading stem cell scientists from all over the world and virtually all of them believe that research should continue with all types of stem cells."); K. Hasegawa et al., *Current Technology for the Derivation of Pluripotent Stem Cell Lines from Human Embryos*, Cell Stem Cell: Protocol Review (June 4, 2010).

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CERTIFICATE OF COMPLIANCE

Pursuant to Rules 29(d) and 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I certify that this brief complies with the type-volume limitation in those Rules. The brief is presented in proportionally spaced typeface using Microsoft Office Word 2007(2) in 14-point Times New Roman font. The brief, excluding those portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii), contains 6,791 words, as counted by Microsoft Office Word 2007(2).

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CERTIFICATE OF SERVICE

I hereby certify that on February 27, 2012, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit via the Court's Case Management/Electronic Case Files (CM/ECF) system. Participants in the case who were registered CM/ECF users were served by the CM/ECF system at that time.

Further, I hereby certify that on February 27, 2012, I served nine paper copies on the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit via a third party commercial carrier. I also served two paper copies via U.S. Mail, First-Class postage pre-paid, on the following:

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