

[NOT YET SCHEDULED FOR ORAL ARGUMENT]

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

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Case No. 10-5287

DR. JAMES L. SHERLEY, *et al.*,  
Plaintiffs-Appellees,

v.

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

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On Appeal From  
The United States District Court For The District Of Columbia

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**BRIEF OF AMICI CURIAE THE STATE OF WISCONSIN,  
COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH,  
AND THE GENETICS POLICY INSTITUTE, INC.  
SUPPORTING REVERSAL OF THE PRELIMINARY INJUNCTION**

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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 October 14, 2010.

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 August 23, 2010, Order and Memorandum Opinion of the District Court issuing a preliminary injunction. *Sherley v. Sebelius*, 704 F. Supp. 2d 63 (D.D.C. 2010) (Chief Judge Royce C. Lamberth). The order and opinion appear at page 226 of the Joint Appendix.

### **C. Related Cases**

This matter has previously come before this Court in *Sherley v. Sebelius*, No. 09-5374 (June 25, 2010). The opinion is available at 610 F.3d 69 and at page 214 of the Joint Appendix. Counsel is not aware of any other related cases within the



UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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DR. JAMES L. SHERLEY, *et al.*, )  
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 v. )  
 )  
 KATHLEEN SEBELIUS, *et al.*, )  
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 Appellants. )  
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**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 in Exhibit A hereto.

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.

Respectfully submitted,

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Dated: October 18, 2010

## **EXHIBIT A**

Albert Einstein College of Medicine of Yeshiva University

Alliance for Aging Research

Alpha-1 Foundation

ALS Association

American Academy of Neurology

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 Gastroenterological Association

American Parkinson Disease Association: Arizona Chapter

American Society for Cell Biology

American Society for Microbiology

American Society for Neural Therapy and Repair

American Society for Reproductive Medicine

American Society of Hematology

Association of Public and Land-Grant Universities

Association of American Medical Colleges

Association of American Universities

Association of Independent Research Institutes

Axion Research Foundation

Biophysical Society

Biotechnology Industry Organization

B'nai B'rith International

Brown University

California Institute for Regenerative Medicine

California Institute of Technology

Californians for Cures

Cedars-Sinai Health System

Cerebral Palsy International Research Foundation

Children's Hospital Boston

Children's Neurobiological Solutions

Christopher and Dana Reeve Foundation

City of Hope

Coalition for Life Sciences

Columbia University Medical Center

Cornell University

C3: Colorectal Cancer Coalition

Davis Phinney Foundation

Duke University School of Medicine

Emory University

Familial Dysautonomia Hope Foundation (FD Hope)

FasterCures

Federation of American Societies for Experimental Biology (FASEB)

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

The Leukemia & Lymphoma Society

LiveStrong

The Methuselah Foundation

The Michael J. Fox Foundation for Parkinson's Research

Michigan Citizens for Stem Cell Research and Cures

Missouri Coalition for Lifesaving Cures

Mount Sinai School of Medicine

National Alliance for Eye and Vision Research

National Association for Biomedical Research

National Coalition for Cancer Research

National Health Council

National Multiple Sclerosis Society

National Parkinson Foundation

Nebraska Coalition for Lifesaving Cures

New York Stem Cell Foundation

New York University Langone Medical Center

Northwestern University

Packard Center for ALS Research at Johns Hopkins

Parkinson's Action Network

The Parkinson Alliance

Parkinson's Disease Foundation

Penn State College of Medicine

Prevent Cancer Foundation

Rensselaer Polytechnic Institute

Research!America

Resolve: The National Infertility Association

Rutgers, The State University of New Jersey

Sarcoma Foundation of America

Society for Women's Health Research

Stanford University

Stony Brook University

Student Society for Stem Cell Research

Texans for Advancement of Medical Research

Tourette Syndrome Association, Inc.

Travis Roy Foundation

Unite 2 Fight Paralysis

United Spinal Association

University of California System

University of Michigan

University of Minnesota

University of Pittsburgh School of Medicine

University of Rochester Medical Center

University of Southern California

University of Wisconsin-Madison

Vanderbilt University and Medical Center

Washington University in St. Louis

Wayne State University School of Medicine and Physician Group

Wisconsin Alumni Research Foundation

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No. 10-5287

**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.

Respectfully submitted,

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\*Authorities chiefly relied on are designated by asterisks.

## **GLOSSARY**

<b>ASC</b>	adult stem cell
<b>CAMR</b>	The Coalition for the Advancement of Medical Research
<b>Guidelines</b>	National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009)
<b>hESC</b>	human embryonic stem cell
<b>iPSC</b>	induced pluripotent stem cell
<b>IVF</b>	in vitro fertilization
<b>JA</b>	Joint Appendix
<b>NIH</b>	The National Institutes of Health

## STATUTES AND REGULATIONS

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

## INTERESTS OF AMICI CURIAE

This brief is submitted on behalf of the following amici curiae:<sup>1</sup>

**The State of Wisconsin** has an interest in the outcome of these proceedings in light of the significant impact on ongoing and future human embryonic stem cell (hESC) research in Wisconsin if the preliminary injunction is upheld.

A large number of medical researchers and scientists are engaged in hESC research in public research universities and institutions in Wisconsin. Embryonic stem cell research originated at the University of Wisconsin-Madison when Dr. Jamie Thomson was the first to isolate embryonic stem cell lines in 1998. Today, a large number of medical researchers and scientists conduct hESC research in public and non-profit research institutions in Wisconsin, including the University of Wisconsin-Madison, the Medical College of Wisconsin, the Blood Center of Wisconsin, and the WiCell Research Institute. This research not only adds to the body of scientific knowledge, but also enables the state's public universities and

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<sup>1</sup> Amicus the State of Wisconsin is filing this brief pursuant to Fed. R. App. P. 29(a), which grants the State an unconditional right to file an amicus brief in this Court. Amici Coalition for the Advancement of Medical Research and The Genetics Policy Institute, Inc. seek leave to join in the brief pursuant to Circuit Rule 29(b), (d) and have filed motions for leave to do so.

institutions to attract and retain high-quality graduate and medical students, researchers, and faculty, advancing their higher education missions. The majority of hESC research in Wisconsin is federally funded through the National Institutes of Health. In addition, the state has invested in public infrastructure, programs, and resources to attract, develop, and retain researchers engaged in this leading-edge and globally competitive field of biomedical research. As discussed in the brief, the abrupt loss of federal funding to support hESC research, even temporarily, jeopardizes these state investments and research programs.

Wisconsin also has significant economic interests at stake in this case. The state seeks to protect its biotechnology sector devoted to developing therapeutic applications of hESC research. Wisconsin is engaged in a global competition to attract and foster this rapidly expanding biotechnology industry sector.

Biotechnology companies contribute billions of dollars and thousands of jobs to the state's economy. Biotechnology focused on hESCs is recognized as a potent area for innovation and growth. The biotechnology industry is tied to basic research findings emerging from the state's academic institutions. The interruption of federal funding for hESC scientific research undermines the opportunities for collaboration and growth in the state's biotechnology industry. Wisconsin has a significant economic interest in the continuation and expansion of this research and economic activity.

Finally, the State of Wisconsin has a strong interest in protecting the interests of its citizens in the development of medical treatments using hESC research. As discussed in the brief, hESC research holds great promise for alleviating human suffering and pain caused by debilitating and frequently-occurring medical conditions and diseases, such as cancer, stroke, heart attack, diabetes, Parkinson's Disease, spinal cord injury, and Alzheimer's Disease. Translating basic research into therapeutic treatments is a lengthy process. Each day that hESC research is halted or delayed by an injunction frustrates the interests of citizens in obtaining timely treatments or cures for currently untreatable diseases. The state recognizes an interest on behalf of its citizens in the development of successful hESC therapies.

**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. CAMR is a not-for-profit organization under section 501(c)(4) of the Internal Revenue Code. Its members include, among many others, the American Diabetes Association, the Familial Dysautonomia 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, the American Society for Cell Biology, and BIO, the Biotechnology Industry Organization.<sup>2</sup> CAMR and its members support continued federal funding of stem cell research, including human embryonic stem cell research, to advance medical and scientific knowledge generally and to facilitate the development of therapies that may benefit current and future patients suffering from a wide variety of diseases.

**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. The Institute's activities include co-sponsoring the World Stem Cell Summit, an annual conference that brings together researchers, industry leaders, policymakers, advocates, patients, and others; publishing the World Stem Cell Report, an annual collection of articles dealing with a wide range of issues relating to stem-cell research; promoting education about stem-cell research; and engaging in other public-outreach activities.

Amici jointly submit this brief amicus curiae to provide relevant scientific background that the Court may find useful and to address the third and fourth

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<sup>2</sup> A list of CAMR's members is provided in the Certificate contained in the front of this brief.

factors relevant to preliminary injunction analysis – that is, the impact on third parties and the public interest.

## STATEMENT

### **A. Human Embryonic Stem Cells Are Derived From Embryos Donated By IVF Patients Who No Longer Need Them.**

Human 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.<sup>3</sup> A blastocyst is smaller than the period at the end of this sentence.<sup>4</sup> Although hESCs are derived from blastocysts, hESCs are not embryos.

The most common source of blastocysts used for hESC line derivation is patients at in-vitro fertilization (IVF) clinics, which typically fertilize all of a woman's retrieved eggs to maximize the chance of successful implantation.<sup>5</sup> 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

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<sup>3</sup> Nat'l Acad. of Scis., *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](http://dels.nas.edu/resources/static-assets/materials-based-on-reports/booklets/Understanding_Stem_Cells.pdf) ("*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.")). (JA 229).

<sup>4</sup> *Understanding Stem Cells*, at 4.

<sup>5</sup> *Id.* at 5-6.

for IVF, the blastocysts would be destroyed or frozen indefinitely.<sup>6</sup> 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* JA 42 (Nat'l Insts. of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009) (“Guidelines”)).

**B. Federal Funds Have Never Been Used For hESC Derivation.**

Federal funds are not used for the process by which an hESC line is derived from a blastocyst. Rather, that process is undertaken separately, with non-federal funds.<sup>7</sup> The NIH Guidelines challenged in this case maintain this longstanding restriction and expressly “prohibit[ ]” “NIH funding of the derivation of stem cells from human embryos.” JA 47 (74 Fed. Reg. 32,175).

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

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<sup>6</sup> *Id.*; *see also* Dep't of Health and Human Servs., *Regenerative Medicine* 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, that are not subject to reasonable dispute and capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. *See* Fed. R. Evid. 201; *Power, Inc. v. NLRB*, 40 F.3d 409, 426 n.11 (D.C. Cir. 1994); *Hamilton v. Paulson*, 542 F. Supp. 2d 37, 52 n.15 (D.D.C. 2008); *see also* *Coleman v. Dretke*, 409 F.3d 665, 667 (5th Cir. 2005) (“fail[ing] to see any merit to an objection” to appellate court taking judicial notice of the contents of a state agency’s website).

<sup>7</sup> *See, e.g.*, Nat'l Insts. of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000).

derived previously, generally by different scientists in different institutions. Those lines may have been derived years before their use in hESC research and, once derived, are an ongoing source of cells that may be used in many subsequent research projects.

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 intending to use hESCs in research for which federal funding is sought to identify the previously derived, pre-existing approved hESC line on the NIH's Registry.<sup>8</sup> The new NIH Guidelines maintain this separation and continue to reflect the longstanding policy against federal funding of derivation of hESCs from a blastocyst. *See* JA 47 (74 Fed. Reg. 32,175). NIH's funding notices direct applicants seeking federal funding for research using hESCs to review the NIH

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<sup>8</sup> Dep't of Health & Human Servs. Grant Application, at 4 (Rev. 11/2007), available at <http://www.yale.edu/grants/forms/pdf/398yale-11-07.pdf> (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.

Embryonic Stem Cell Registry to identify the approved, previously derived hESC line they intend to use in the research project for which federal funding is sought.<sup>9</sup>

**C. Research Using Previously-Derived hESCs  
Has Been Federally Funded Since 2001  
With Congressional Knowledge And Approval.**

For nearly a decade, NIH has funded, with Congressional approval, research using 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 bills that included the Dickey Wicker Amendment, half a billion dollars on research using hESCs.<sup>10</sup> Pursuant to policies adopted by the Bush

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<sup>9</sup> 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 Servs. Public Health Service Grant Application (PHS 398) at 32 (Rev. 06/2009).

<sup>10</sup> See JA 244 (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); Statement of Francis S. Collins, M.D., Ph.D., Director, NIH, Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services, Education, and Related Agencies (Sept. 16, 2010) (“Collins

Administration, federally funded research using hESCs was limited to research using hESC lines that had been derived prior to August 9, 2001.<sup>11</sup>

Thereafter, Congress passed legislation to expand federal funding of research using hESCs to include hESC lines derived after August 9, 2001. The Stem Cell Research Enhancement Act provided that “[n]otwithstanding any other provision of law (including any regulation or guidance), the Secretary [of Health

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Senate Testimony”) at 1, *available at* <http://appropriations.senate.gov/ht-labor.cfm?method=hearings.view&id=0bea2354-dc3d-4623-9905-6dbff89581ac>; Congressional Research Service, Report RL3540, Stem Cell Research: Federal Research Funding and Oversight, at 13 (July 10, 2008) (“CRS Report RL3540”) (reflecting \$227 million in hESC research expenditures in fiscal years 2004-2009); *see also* H.R. Rep. No. 107-229, at 180 (Oct. 9, 2001) (“The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells and carried out in accordance with policy outlined by the President.”); S. Rep. No. 107-84, at 18 (Oct. 11, 2001); H.R. Rep. No. 110-231 (July 13, 2007); H.R. Rep. No. 108-636 (Sept. 7, 2004); Statement of Elias Zerhouni, Director, NIH, Before the House Comm. on Energy and Commerce, Subcomm. on Health (May 8, 2008), *available at* [http://olpa.od.nih.gov/hearings/110/session2/Testimonies/Elias\\_Zerhouni\\_Stem\\_Cell\\_Science.asp](http://olpa.od.nih.gov/hearings/110/session2/Testimonies/Elias_Zerhouni_Stem_Cell_Science.asp); Statement of Story C. Landis, Director, National Institute of Neurological Disorders and Stroke, NIH, Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services, Education, and Related Agencies (Jan. 19, 2007), *available at* <http://stemcells.nih.gov/StaticResources/policy/Landis2007-01-19.pdf>; Statement of Elias Zerhouni, Director, NIH, Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services, Education, and Related Agencies (May 22, 2003), *available at* <http://olpa.od.nih.gov/hearings/108/session1/testimonies/stemcell.asp>; Statement of Elias Zerhouni, Director, NIH, Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services, Education, and Related Agencies (Sept. 25, 2002), *available at* <http://www.nih.gov/about/director/092502sctestimony.htm>; Statement of Tommy Thompson, Sec’y of Health and Human Servs., Before the Senate Comm. on Health, Education, Labor, and Pensions (Sept. 5, 2001), *available at* <http://www.hhs.gov/news/speech/2001/010905.html>; Message to the House of Representatives (July 19, 2005), *available at* <http://georgewbush-whitehouse.archives.gov/news/releases/2006/07/20060719-5.html>.

<sup>11</sup> CRS Report RL3540 at 12 (citing August 9, 2001, *Remarks by the President on Stem Cell Research*, <http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>); *see also* JA 231 (*Sherley PI Mem. Op.* at 5).

and Human Services] shall conduct and support research that utilizes human embryonic stem cells in accordance with this section (regardless of the date on which the stem cells were derived from a human embryo).”<sup>12</sup> The Act was passed by both houses of Congress, but vetoed by President Bush.<sup>13</sup> The process was repeated in 2007: the legislation was introduced and passed by both houses of Congress, but again vetoed by the President.<sup>14</sup>

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.”<sup>15</sup> To that end, he directed NIH to “review existing NIH guidance and other widely recognized guidelines on human stem cell research, including

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<sup>12</sup> H.R. 810, 109th Cong., 1st Sess. § 2 (2005); S. 471, 109th Cong., 1st Sess. § 2 (2005).

<sup>13</sup> *See* Bill Summary and Status, <http://thomas.loc.gov/cgi-bin/bdquery/z?d109:HR00810:@@R>.

<sup>14</sup> H.R. 3, 110th Cong., 1st Sess. (2007) (passed Jan. 11, 2007); S. 5, 110th Cong., 2d Sess. (2007) (passed April 11, 2007); H. Res. 464, 110th Cong., 1st Sess. (2007) (agreeing to S. 5). *See* Bill Summary & Status, <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:S5:>.

<sup>15</sup> JA 278 (Exec. Order No. 13,505, 74 Fed. Reg. 10,667-68 (March 9, 2009)).

provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order.”<sup>16</sup>

Thereafter, pursuant to notice-and-comment rulemaking, in July 2009 NIH adopted new Guidelines governing federal funding for research using hESC lines.<sup>17</sup> Those Guidelines provide that federal funding may be provided to research projects using 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.<sup>18</sup> 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.”<sup>19</sup> The Guidelines further require documentation demonstrating satisfaction of these three criteria and additional detailed requirements assuring that the IVF patients’ consent

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<sup>16</sup> *Id.*

<sup>17</sup> Guidelines, JA 42 (74 Fed. Reg. 32,170).

<sup>18</sup> *Id.* at JA 46 (32,174).

<sup>19</sup> *Id.* at JA 46-47 (32,174 to 32,175).

to donate the embryo for scientific research was informed, voluntary, and not the result of any pressure, coercion, payment, or other incentive to donate.<sup>20</sup>

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.<sup>21</sup>

Congress responded to NIH's adoption of the Guidelines in 2009 by once again appropriating funds for NIH and once again including the Dickey-Wicker Amendment in the appropriations bill.<sup>22</sup> 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 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

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<sup>20</sup> See generally *id.*

<sup>21</sup> See NIH Human Embryonic Stem Cell Registry, at [http://grants.nih.gov/stem\\_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm) and [http://grants.nih.gov/stem\\_cells/registry/not\\_approved.htm](http://grants.nih.gov/stem_cells/registry/not_approved.htm); see also Collins Senate Testimony at 12.

<sup>22</sup> See Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81.

President.” H.R. Rep. No. 111-220, at 223 (July 22, 2009).<sup>23</sup> During FY 2010 NIH obligated approximately \$100 million to grants for hESC research.<sup>24</sup>

### **SUMMARY OF ARGUMENT**

The District Court erred in granting the preliminary injunction because, as a matter of law, Plaintiffs-Appellants Sherley and Deisher could not meet their burden of showing a likelihood of success on the merits or irreparable injury. Their claim depends on their assertion that the Dickey-Wicker “research in which” language unambiguously prohibits all federally funded research using previously derived embryonic stem cells. The statutory language, extensive legislative history, Congress’s passage of the Stem Cell Research Enhancement Act, and the consistent funding of research using hESCs for nearly a decade foreclose such an argument.

But even if Plaintiffs could have satisfied the threshold requirement of showing a likelihood of success on the merits, the preliminary injunction still should have been denied. Contrary to the District Court’s conclusion, the preliminary injunction did not preserve the status quo. It overturned it, thereby causing obvious, substantial harm to researchers, institutions, and patients who

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<sup>23</sup> 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.”).

<sup>24</sup> See JA 174 (Rockey Decl. ¶ 18); JA 251-52 (Collins Decl. ¶¶ 13-15); Collins Senate Testimony at 12.

stand to benefit from therapies derived from hESC research. The resulting substantial harm to third parties, and frustration of the public interest in achieving the benefits of stem cell research, tilted the equitable balance heavily against granting the injunction. Granting the injunction was, therefore, an abuse of discretion.

### **ARGUMENT**

As the District Court recognized, a preliminary injunction is “an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing,” establishes (1) that they have a substantial likelihood of success on the merits; (2) that they would suffer irreparable injury absent an injunction; (3) that an injunction would not substantially injure other interested parties; and (4) that an injunction would further the public interest. JA 234 (*Sherley* PI Mem. Op. at 8) (quoting *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004)); *see also* *Munaf v. Green*, 553 U.S. 674, 689-90 (2008). The District Court found that each of these factors in the equitable balance weighed in favor of a preliminary injunction. JA 235-41 (*Sherley* PI Mem. Op. at 9-15).

Amici concur entirely in Appellants’ argument that the District Court erred as a matter of law in its analysis with respect to the first two preliminary injunction factors. *See* Brief for Appellants at 18-20, 21-34. Indeed, amici believe that, in light of Congress’s consistent, nearly decade-long history of knowingly

authorizing funding used for research involving previously-derived hESCs – including after the adoption of the NIH Guidelines, which were praised in the relevant congressional committee reports – Appellees’ core claim that the Dickey-Wicker Amendment “unambiguously prohibits” such research borders on the frivolous. Accordingly, because Appellees Sherley and Deisher could not demonstrate the required “substantial likelihood of success,” their motion for a preliminary injunction should have been denied, and the injunction should be vacated. *See, e.g., Munaf*, 553 U.S. at 690 (“[A] party seeking a preliminary injunction must demonstrate, among other things, ‘a likelihood of success on the merits.’”) (citation omitted); *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1293-95 (D.C. Cir. 2009) (upholding denial of preliminary injunction where plaintiff failed to show substantial likelihood of success or irreparable harm); *id.* at 1296 (Kavanaugh, J., concurring) (“*Munaf* made clear that a likelihood of success is an independent, free-standing requirement for a preliminary injunction.”).

Although amici believe the legal flaws in the District Court’s analysis with respect to the first two preliminary injunction factors are dispositive, amici nevertheless respectfully submit this brief to address the remaining third and fourth elements of the equitable balancing test. These factors also clearly weigh heavily against granting the injunction.

**I. THE DISTRICT COURT’S FINDING THAT THE REQUESTED PRELIMINARY INJUNCTION WOULD NOT SIGNIFICANTLY INJURE THIRD PARTIES WAS CLEARLY ERRONEOUS.**

**A. Harm To Researchers And Research Institutions**

The District Court plainly erred in finding that the requested injunction “would not seriously harm [h]ESC researchers because the injunction would simply preserve the *status quo*.” JA 240 (*Sherley* PI Mem. Op. at 14). The record before the District Court clearly showed the contrary. It reflected that the status quo was federal funding of research using hESCs at a level of nearly \$100 million in the current fiscal year. *See supra* p. 12; JA 174 (Rockey Decl. ¶ 18). In addition, the record of congressional appropriations and accompanying legislative history available to the District Court confirmed that government funding of such research, in amounts totaling hundreds of millions of dollars, had been ongoing for nearly a decade. *See supra* pp. 8-9; *see also* JA 231 (*Sherley* PI Mem. Op. at 5) (noting government funding of research using hESCs under President Bush’s policy); JA 174 (Rockey Decl. ¶ 18). The preliminary injunction sought by plaintiffs thus threatened – and, when granted, constituted – a radical departure from the status quo.

The immediate, severe, adverse impact an injunction changing the status quo would have on research using hESCs was obvious. Research is a complex process requiring extensive planning and preparation, trained research scientists and

support staff, and expensive equipment. An injunction halting or disrupting the disbursement of hundreds of millions of dollars in funding for research using hESCs inevitably would affect pending and planned research by eliminating funding for salaries, equipment, and supplies.

Although the District Court speculated that private funding might be obtained to fill the gap, JA 240 (*Sherley* PI Mem. Op. at 14), there was no basis in the record for assuming that adequate private funding would be available at all, let alone on an emergency basis to replace funding lost as a result of an injunction. To the contrary, Plaintiffs' allegations regarding their dependence on federal funds for their own ASC stem cell research undercut that speculative assumption.<sup>25</sup>

Moreover, such an assumption is inconsistent with the typical process through which new therapies are developed and commercialized. Private funding organizations typically will not fund basic medical and biological research.

Instead, such research is conducted with government funding. Only after such research produces discoveries with commercial potential will private funding organizations license that intellectual property to undertake the additional work necessary to develop and test potential therapeutic treatments.

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<sup>25</sup> JA 167 (*Sherley* Decl. ¶ 3); JA 169 (*Deisher* Decl. ¶ 4); *see also* Statement of George Q. Daley, M.D., Ph.D., Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services, Education, and Related Agencies (Sept. 16, 2010) ("Daley Senate Testimony"), *available at* <http://appropriations.senate.gov/ht-labor.cfm?method=hearings.view&id=0bea2354-dc3d-4623-9905-6dbff89581ac>.

In addition to the immediate adverse disruptive impact of an injunction, the unexpected judicial rejection of long-settled understandings regarding the availability of federal funding for research using hESCs also threatened to deter scientists and research institutions from pursuing such research in the future.<sup>26</sup> Thus, the requested injunction threatened both immediate and long-term harm.

**B. Harm To Individuals Who Stand To Benefit From Medical Treatment Developed Through Research Using hESCs**

The District Court similarly was wrong to dismiss as “speculative” the harm to individuals who suffer from currently untreatable diseases for which research using hESCs may yield effective therapies. JA 240 (*Sherley* PI Mem. Op. at 14). Both the record before the District Court and information available to it reflect that ongoing research using hESCs promises the development of scientific knowledge that will translate into therapies that could benefit millions of patients.<sup>27</sup> See JA

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<sup>26</sup> The tremendous disruption to hESC research that in fact was caused by the preliminary injunction is described in detail in several documents of which the Court may take judicial notice. These include declarations that were submitted by defendants-appellees in support of their motion for emergency stay, which are court records, as well as testimony before a subcommittee of the Senate Committee on Appropriations. See Declarations of Francis S. Collins, M.D., Ph.D. [Dkt. 48-2] and Story Landis, Ph.D. [Dkt. 58-1]; Collins Senate Testimony, *supra* n. 10; Daley Senate Testimony, *supra* n. 25; Statement of Sean J. Morrison, Ph.D., Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services, Education, and Related Agencies (Sept. 16, 2010) (“Morrison Senate Testimony”), available at <http://appropriations.senate.gov/ht-labor.cfm?method=hearings.view&id=0bea2354-dc3d-4623-9905-6dbff89581ac>.

<sup>27</sup> 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. See, e.g., CAMR website, [http://www.camradvocacy.org/about\\_us.cfm](http://www.camradvocacy.org/about_us.cfm).

229 (*Sherley* PI Mem. Op. at 3) (recognizing likelihood that “[h]ESCs will contribute to the development of medical knowledge in the future”).

As the District Court recognized, hESCs have unique properties among naturally occurring human stem cells in that they are pluripotent, *i.e.*, they have the capability to give rise to any of the approximately 200 types of cells in the human body. JA 229 (*Sherley* PI Mem. Op. at 3). 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.<sup>28</sup>

Although research using hESCs has not yet resulted in fully approved medical therapies, such research 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.<sup>29</sup> The first clinical trials using hESCs for spinal cord injuries were approved by the Food and Drug Administration prior to the District Court’s issuance of the preliminary injunction and commenced last week.<sup>30</sup> hESCs

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<sup>28</sup> *Regenerative Medicine*, at 8 and Table 1.

<sup>29</sup> *Understanding Stem Cells*, at 16-17.

<sup>30</sup> See Northwestern First Site Open for Spinal Cord Stem Cell Trial, Press Release, [http://www.feinberg.northwestern.edu/news/2010D-September/Spinal\\_Cord\\_](http://www.feinberg.northwestern.edu/news/2010D-September/Spinal_Cord_)

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.<sup>31</sup>

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.<sup>32</sup> hESCs also play a critical role in research using other types of stem cells, including both adult stem cells (ASCs) and genetically reprogrammed cells called induced pluripotent stem cells (iPSCs), because they serve as critical “controls” used for comparison.<sup>33</sup> For this reason,

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Stem\_Cell\_Trial.html; Rob Stein, *First Patient Gets Embryonic Cells*, Wash. Post, Oct. 12, 2010, at A2.

<sup>31</sup> Collins Senate Testimony at 9.

<sup>32</sup> *Stem Cell Basics*, at 14; see also Collins Senate Testimony at 5.

<sup>33</sup> See, e.g., Daley Senate Testimony at 4 (“Today, human ES cells remain the gold standard against which our cultures of human iPS cells are compared.”); Morrison Senate Testimony at 4 (“I want to emphasize this point – we wish to use tissue-specific stem cells (often described as ‘adult’ stem cells in the newspaper) for the therapy, but we will obtain them from embryonic stem cells. This illustrates why it is scientifically meaningless to frame this debate as a choice between adult and embryonic stem cells. We sometimes need embryonic stem cells to generate adult cell types for therapy.”); see also Luigi Warren, et al., *Highly Efficient Reprogramming to Pluripotency and Directed Differentiation of Human Cells with Synthetic Modified mRNA*, *Cell Stem Cell* 7, 1-13, at 4-7 (Nov. 5, 2010), available at <http://download.cell.com/cell-stem-cell/pdf/PIIS1934590910004340.pdf?intermediate=true>; Bao-Yang Hu, et al., *Neural differentiation of human induced pluripotent stem cells follows developmental principles but with variable potency*, 107 *Proceedings of the National Academy of Sciences* 4335 (March 2, 2010).

the consensus among scientists working in the field is that research should be done regarding all forms of stem cells, including hESCs.<sup>34</sup>

In particular, as the District Court recognized, research involving the recently discovered iPSCs is at an early stage, and they are not well understood. JA 230 (*Sherley* PI Mem. Op. at 4). However, research to date indicates that iPSCs appear to differ in certain respects from hESCs, which scientists must use as controls to evaluate iPSCs.<sup>35</sup> The promise of iPSCs therefore does not negate the scientific need for hESC research; to the contrary, it underscores the importance of hESCs in stem cell research.

Thus, although approved hESC therapies do not yet exist, research using hESCs is contributing daily to the development of new knowledge that can be used to develop new therapies. The range of potentially groundbreaking and life-saving

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<sup>34</sup> International Society for Stem Cell Research, Endorse the Open Letter: Support all Forms of Stem Cell Research, <http://www.isscr.org/ScienceStatementEndorsers.cfm> (last accessed October 15, 2010). The text of the statement ("*ISSCR Statement*") is available at <http://www.isscr.org/documents/ScienceStatementSept162008.pdf>.

<sup>35</sup> See Kouichi Hasegawa, et al., *Current Technology for the Derivation of Pluripotent Stem Cell Lines from Human Embryos*, 6 *Cell Stem Cell* 521 (June 2010); 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>); see also Daley Senate Testimony at 4; Majlinda Lako et al., *Induced Pluripotent Stem Cells: It Looks Simple but Can Look Deceive?*, 28 *Stem Cells* 845 (2010); William E. Lowry & William L. Quan, *Roadblocks en route to the clinical application of induced pluripotent stem cells*, *Journal of Cell Science* 123, 643-651, at 644 (2010).

research involving hESCs is reflected in the many peer-reviewed articles published since 2002 that address such research projects.<sup>36</sup>

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.<sup>37</sup> In addition, private companies are participating in efforts to develop and obtain regulatory approval for therapies based on hESC research.

The harm to individuals from a preliminary injunction halting federal funding of research using hESCs could not, therefore, reasonably be dismissed as “speculative.” This ignores the fundamental nature of medical and scientific research and the relationship between such research and the development of effective therapies.

The basic research needed to develop varied 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

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<sup>36</sup> Lists of the hESC research papers highlighted on the NIH’s website were provided to the District Court on the motion for stay as Exhibits 2A and 2B to the Declaration of Kevin Wilson (Wilson Decl.) [Dkt 52-3]. 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/>.

<sup>37</sup> See, e.g., Nat’l Insts. of Health, *Research Programs at Universities and Institutions*, <http://stemcells.nih.gov/research/educResearch.asp>.

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.<sup>38</sup>

Far from rendering injury “speculative,” the lengthy process of translating research into therapeutic treatments means that any injunction hindering or delaying such research inevitably must work a significant hardship on current patients suffering from currently untreatable diseases. For at least some of these individuals, the delay literally may mean the difference between life or death. For others, the delay will mean a delay in effective treatment and an improved quality of life. In the context of medical research, that delay is a real and serious injury.

## **II. THE PUBLIC INTEREST FAVORED DENIAL OF THE INJUNCTION.**

The District Court properly recognized that it is in the public interest for courts to carry out the will of Congress. JA 240-41 (*Sherley* PI Mem. Op. at 14-15). Congress’s will is reflected in its continuous history during the past nine years, under both Republican and Democratic majorities, of providing NIH with a total of nearly half a billion dollars of funding to be used for research using previously-derived hESCs. *See supra* p. 8 & n. 10. This reflects a policy judgment, endorsed by both the Legislative and Executive branches of government, that research using hESCs holds tremendous promise for advancing

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<sup>38</sup> *Understanding Stem Cells*, at 15.

scientific understanding of human health and developing effective therapies for a host of illnesses for which no effective treatment currently is available and is in the public interest.

In light of this history, an injunction precluding implementation of the NIH Guidelines and continued funding of research using hESCs plainly was contrary to the public interest. Thus, this element of the equitable balance, like the other elements, weighed heavily against issuance of a preliminary injunction.

### **CONCLUSION**

The District Court's Order granting the preliminary injunction should be vacated.

Respectfully submitted,

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/s/

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October 18, 2010

## 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 5,837 words, as counted by Microsoft Office Word 2007(2).

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## CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2010, I filed and served the foregoing Brief of Amici Curiae The State of Wisconsin, the Coalition for the Advancement of Medical Research, and Genetics Policy Institute with the Clerk of the Court by causing a copy to be electronically filed via the appellate CM/ECF system. I also hereby certify that I hand delivered 8 copies.

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