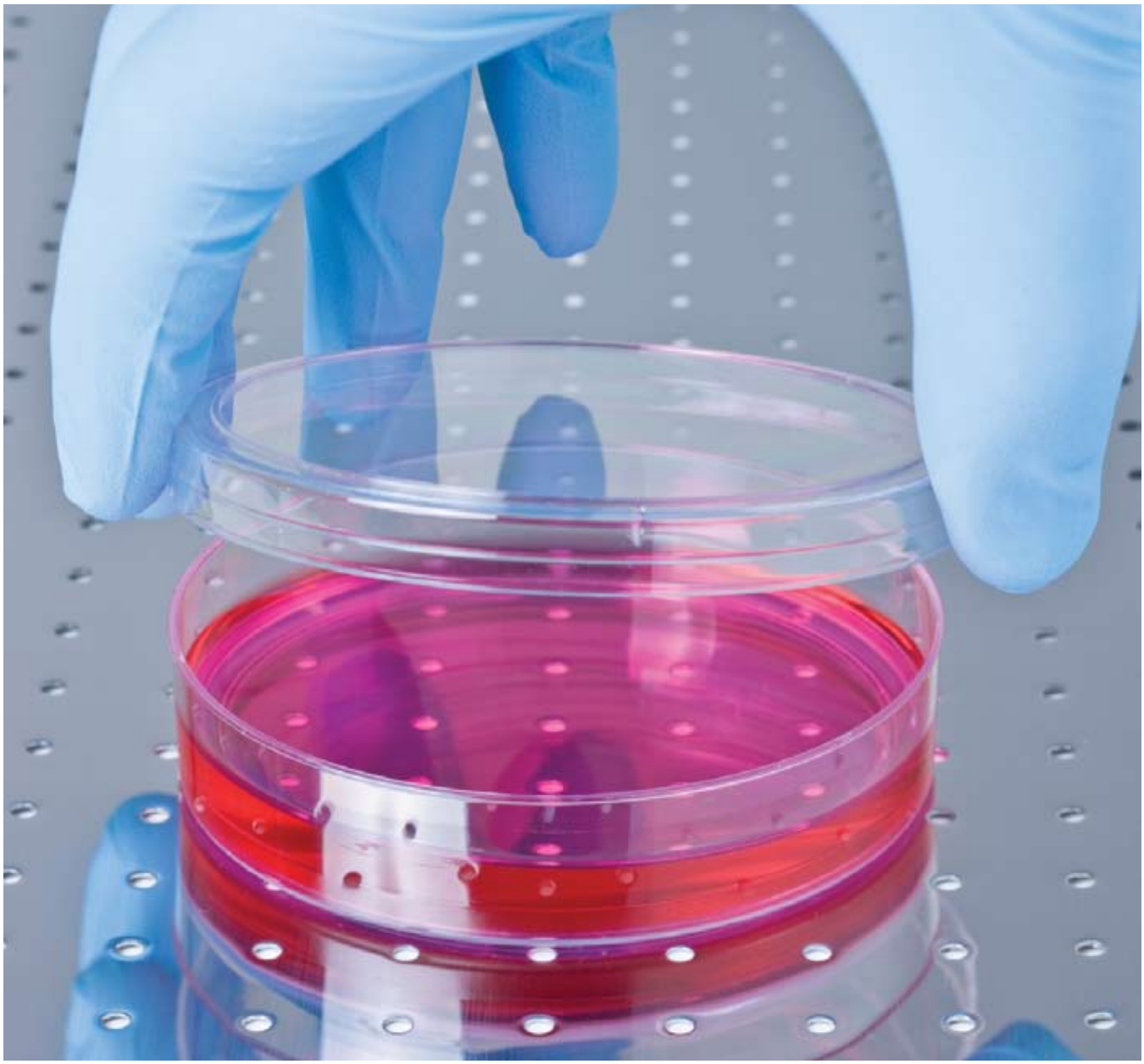
Stem Cell Funding Controversy Creates Uncertainty for Ongoing and Future Research[1]

By Antoinette F. Konski and George C. Best, Foley & Lardner LLP, Palo Alto, CA

On March 9, 2009, President Barack Obama signed an Executive Order that overturned the previous administration's policy banning the use of federal funds for research using embryonic stem cells created after August 9, 2001.[2] Pursuant to the 2009 Executive Order, the National Institutes of Health (NIH) issued new Guidelines for Human Stem Cell Research[3] (2009 NIH Guidelines) setting forth the requirements for research to be eligible for federal funding. In addition to funding new research activities using embryonic stem cells, the 2009 Executive Order and NIH Guidelines also provided scientists whose research was supported by federal funds with access to a greater number of embryonic stem cells such as those created after August 9, 2001.

Since 2001, the NIH has invested approximately $3.7 billion on all types of stem cell research.[4] Within this total, the NIH has allocated over $174 million to research studying



human embryonic stem cells; over $1.3 billion to research using human non-embryonic stem cells; over $628 million to research on nonhuman embryonic stem cells; and over $1.5 billion to research involving nonhuman non-embryonic stem cells.[5]

Additionally, in fiscal year 2009, the NIH was projected to spend approximately $41 million on human embryonic stem cell research and about $208 million on human non-embryonic stem cell research, while also investing approximately $105 million on nonhuman non-embryonic stem cell research.[6]

In August 2009, however, Chief Judge Royce C. Lamberth, of the U.S. District Court for the District of Columbia, halted federal funding of human embryonic stem cell research when he granted a preliminary injunction in a lawsuit challenging the NIH Guidelines.[7] The D.C. Circuit subsequently stayed the injunction pending appeal and funding has continued for ongoing projects.[8] Nonetheless, the ultimate fate of human embryonic stem cell research that relies on federal funding is uncertain until final resolution of the underlying legal issues in the courts or in Congress.

The Dickey Amendment

The basis for the lawsuit challenging the NIH Guidelines is a general ban on the federal funding of research involving human embryos imposed by legislation known as the Dickey-Wicker Amendment (Dickey Amendment). Congress originally passed this legislation—named after an appropriation rider attached to the Balanced Budget Downpayment Act[9]—in 1996, and former President Clinton signed it into law. The Dickey Amendment prohibits the Department of Health and Human Services (HHS), which includes the NIH, from funding research where human embryos are destroyed. Congress has included the Dickey Amendment in every subsequent HHS appropriations bill without substantial alteration. In subsequent years, the rider was enacted in Title V (General Provisions) of the Labor, HHS, and Education Appropriations Act.

The Dickey Amendment followed former President Clinton's executive directive that prohibited federal funding for research involving the creation of human embryos for research purposes, which included human cloning, and directed the NIH not to allocate resources for such research.[10]

The language in Division F, Section 509 of the Omnibus Appropriations Act of 2009 (which is substantially identical to the original 1996 bill) states in pertinent part:

> None of the funds made available in this Act may be used for—
>
> (1) the creation of a human embryo or embryos for research purposes; or
>
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
>
> …
>
> (b) For purposes of this section, the term 'human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.[11]

In January 1999, the HHS Office of the General Counsel issued a legal opinion (1999 HHS Legal Opinion) regarding whether and the extent to which federal funding could be used to support research involving human embryonic stem cells (hESCs).[12] This legal opinion was issued in response to a study reporting the isolation of hESCs and the creation of a cell line from human embryos donated for research by persons undergoing in vitro fertility treatments,[13] and a separate study reporting the derivation of hESCs and cell lines from primordial germ cells from non-living fetuses.[14] Private funds wholly supported the underlying research reported in both studies.

The General Counsel determined that the Dickey Amendment prohibits the use of funds appropriated to HHS for human embryo research such as the creation of human embryonic stem cell lines, but the ban would not apply to research utilizing the human embryonic stem cell lines because such cells are not a human embryo within the statutory definition. The General Counsel also concluded that to the extent that hESCs are considered human fetal tissue by law, they are subject to the pre-existing statutory prohibition against the sale of human embryos, the restrictions on fetal tissue transplantation research that is conducted or funded by the HHS, and the federal criminal prohibition on the directed donation of fetal tissue. In addition, research involving hESCs excised from a non-living human fetus must be conducted in accordance with any applicable state or local law. Finally, the General Counsel reiterated that a 1997 presidential directive banning federal funding of human cloning would apply to hESCs[15] only if they were used for that purpose.

The General Counsel reasoned that the statute defines an embryo as an "organism" that when implanted into the uterus is capable of becoming a human being. Because hESCs cannot develop into an organism as defined by the statute, research on embryonic stem cells was not considered to be within the scope of the statute. A short time later, then HHS Secretary Donna Shalala stated in a letter that the funding ban applied only to research in which human embryos are discarded or destroyed but not to research preceding or following such projects.[16]

The statutory phrase "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death" was not specifically addressed in the General Counsel's letter.

Why Embryonic Stem Cells?

Human stem cells can develop into some or all of the large number of specialized cells found in the human body. For that reason, stem cells are thought to have great potential for the development of new treatments for a wide range of diseases and conditions, including spinal cord injury, joint injury, multiple sclerosis, Parkinson's disease, Alzheimer's disease, and diabetes.

Typically, the term "stem cell" is used to refer to a stem cell line, which is a group of identical cells that are grown and multiplied in a lab dish. Stem cells generally are categorized into two types: adult or somatic and embryonic or pluripotent, based on the tissue they originally came from and their regeneration potential.

"Adult" stem cells (ASCs) can be isolated from any organ from a fetus through an adult. They also may be called tissue or somatic stem cells. Research on some adult stem cells began almost 50 years ago. In the 1950s, researchers discovered that bone marrow contains at least two types of stem cells.[17] These stem cells have been used in bone marrow transplants for 40 years. More recently, ASCs have been isolated from almost all other types of tissue, including nervous tissue, cardiac tissue, skeletal tissue, muscle tissue, adipose or fat tissue, and brain tissue. ASCs are thought to only differentiate themselves into a limited number of cell types, usually related to the type of tissue from which they are isolated. They also are present in very small numbers and, once isolated, have a limited capacity to divide. Obtaining large quantities of adult stem cells therefore is difficult.

Unlike ASCs, pluripotent stem cells (PSCs) can be induced to differentiate into a wide range of cell types from a variety of tissues and can be maintained in cell culture. Because PSCs are believed to have the potential to differentiate into almost all tissue types, they might be used to supplement or replace almost all cell types and tissues. This property not only distinguishes them from adult stem cells, it also generates great promise that they can be used to treat many degenerative and genetic disorders.

Until recently, the only sources of PSCs were embryonic stem cells (ESCs). ESCs are derived from human embryos. Most commonly, the embryos are created by in vitro fertilization and then donated for research purposes with the informed consent of the donors. They are not derived from fertilized eggs in a woman's body.[18] Recently, however, scientists have created induced pluripotent stem cells (iPSCs) by reprogramming adult cells to an embryonic-like state. Initially, the cells were made by inserting genes into the cells to reprogram them. More recently, researchers have been working to replace the genes with other factors because one of the initial genes used for reprogramming and vectors to introduce the genes into the cells sometimes cause cancer. Although initial studies with iPSC are very promising, much work is still needed to fully characterize and understand how similar to embryonic stem cells the iPSCs are and whether they have the same clinical potential as ESCs.

Executive Orders, Congress, and the NIH

Soon after the General Counsel's 1999 legal opinion, which approved funding for research using hESCs in limited circumstances, the NIH issued guidelines that separated research using hESCs into stages and set forth procedures that would fund research using hESCs, but would not fund creation of additional hESC cell lines (2000 NIH Guidelines).[19] To ensure that an "after creation" researcher was not implicitly involved with the destruction of the embryo that provided the cells for the later-funded research, the 2000 NIH Guidelines only permitted funding of hESC lines: (a) created from donated frozen embryos in excess of that needed for reproductive purposes; (b) with informed consent from the donors; and (c) without financial inducement to the donors. Also, the researcher or investigator deriving and/or proposing to use the hESCs could not be the same as the attending physician responsible for the donor's fertility treatment.

Before the NIH disbursed any funds, however, the Bush administration first suspended and then revoked the 2000 NIH Guidelines. On August 21, 2001, former President Bush announced that the funding of embryonic stem cells research would be limited to "existing stem cell lines where the life and death decision had already been made."[20] The eligibility criteria noted in the 2000 NIH Guidelines remained, but federal funds could not be used on research involving any human embryonic stem cell lines created after August 9, 2001, even those created with private money. President Bush also directed the NIH to evaluate all existing human embryonic stem cell lines and create a registry of cell lines that satisfied the administration criteria. The NIH originally identified 78 human embryonic stem cell lines as eligible for use in federally funded research (termed the Presidential Embryonic Stem Cell Lines) under the August 2001 Bush administration policy. Many of these cell lines, however, were either unavailable or unsuitable for research. As of early 2007, the registry listed a total of 21 stem cell lines available from seven sources.[21]

Many in the scientific and research community believe that the 21 Presi-

dential Embryonic Stem Cell Lines are insufficient to support clinical research. Some of these stem cell lines contain genetic anomalies that make them a poor choice for most research. Others have been contaminated with viral or animal components from the culturing conditions. The original lines also were isolated from a non-diverse patient population which means that discoveries based on the use of these cell lines may only apply to that population and cause a more severe immune reaction if transplanted into genetically diverse people as a cell-based therapy. More recently, investigators have learned that five of the lines were created without proper consent from in vitro fertilization donors.[22]

In 2004, over 200 members of the U.S. House of Representatives responded to concerns over access to viable human embryonic stem cell lines by sending a letter to then-President Bush asking the administration to revise its restrictive stem cell policy and allow use of the excess embryos created during the treatment of infertile couples for hESC research.[23] At White House direction, NIH Director Elias A. Zerhouni responded to the House lawmakers by restating the Bush administration position against using federal funds in research involving the destruction of human embryos.[24] In the same year, a group of 58 Senators also urged President Bush to adopt a less restrictive policy. The Senators argued that lack of federal funding was causing "leadership in this area of research [to shift] . . . to other countries such as the United Kingdom, Singapore, South Korea and Australia."[25]

Congressional interest in loosening restrictions on the use of federal funds to support hESC research continued for the rest of the Bush administration. Congress ultimately passed several bills, which President Bush vetoed.[26]

2009 NIH Guidelines

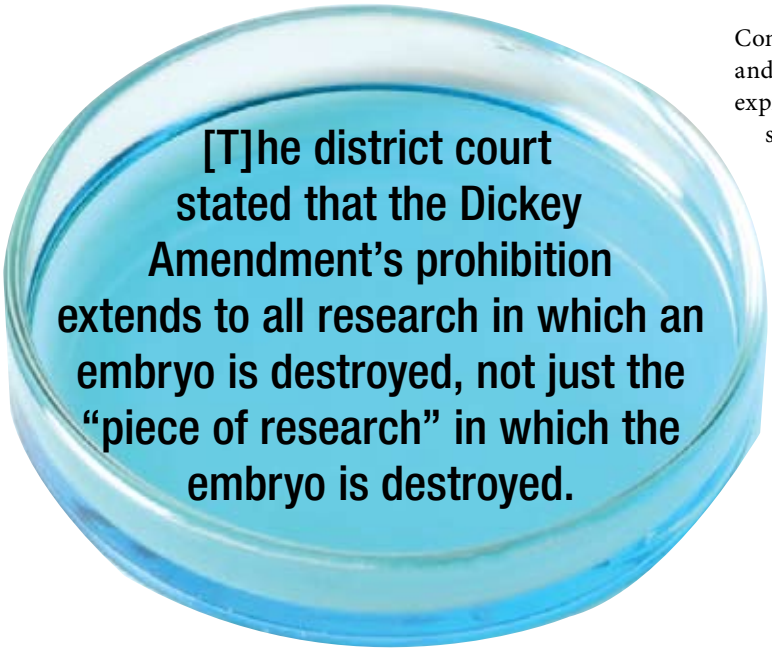
Early in his administration, President Obama issued an Executive Order overturning the prior administration's policy restricting public funding of research using embryonic stem cells and cell lines.[27] On July 6, 2009, the NIH issued new guidelines for human stem cell research as required by the Executive Order. To help ensure funding of the greatest number of derived hESCs and cell lines, the 2009 NIH Guidelines were divided into several sections that apply specifically to embryos donated in the United States and foreign countries, both before and on or after the July 7, 2009 effective date.

Common among the eligibility requirements are that the hESCs and cell lines are derived from human embryos: (1) used with informed consent of the embryo donor, including confirmation that the donation was made without any restriction or direction regarding recipients of medical benefit from the use of the derived hESCs and cell lines; (2) created for reproductive in vitro fertilization (IVF) purposes, and no longer required for that purpose; and (3) for which the donor receives no financial or other benefit from use of the donated material. If the embryo was donated before July 7, 2009 and the applicant cannot comply with all of these requirements, materials establishing informed consent and derivation of the cell line from an embryo from IVF could be submitted to a working group. The working group would review the materials and make a recommendation regarding eligibility to the NIH director, who ultimately decides funding eligibility.

The 2009 NIH Guidelines also mandated the creation of a registry listing hESCs eligible for NIH funding research. When endorsing applications and progress reports submitted to the NIH for projects using hESCs, funding recipients also must provide assurances that the cells are listed on the NIH registry.

The 2009 NIH Guidelines specifically exclude funding research in which hESCs (even if derived from embryos donated in accordance with the Guidelines) or human iPSCs are re-introduced into non-human primate blastocysts, and research involving the breeding of animals where the cells contribute to the germ line. The 2009 NIH Guidelines also note that pursuant to the Dickey Amendment, funds cannot support research involving the derivation of stem cells from human embryos, or support research where the hESCs are derived from other sources such as somatic cell transfer, parthenogenesis, and/or in vitro fertilization embryos created for research purposes.

Consistent with the 2009 NIH Guidelines and in an effort to overturn the Dickey Amendment, Representative Diane DeGette (D-CO) and 137 co-sponsors introduced in March 2010 the Stem Cell Research Advancement Act of 2009, H.R. 4808. The bill seeks to remove limits on federal funding of research that utilized human embryonic stem cells consistent with the 2009 NIH Guidelines. The bill presently is referred to the House Energy and Commerce Committee for further consideration.



The Judicial Challenge

Before Congress could act, the 2009 NIH Guidelines were challenged in court. Several plaintiffs—including Drs. James L. Sherley and Theresa Deisher, Nightlight Christian Adoptions, and the Christian Medical Association—argued that the 2009 NIH Guidelines were contrary to the Dickey Amendment and, therefore, were illegal.

The U.S. District Court for the District of Columbia initially dismissed the entire lawsuit for lack of jurisdiction, holding that none of the plaintiffs had standing to challenge the Guidelines.[28] On appeal, the D.C. Circuit reversed this holding in part and remanded to the district court for resolution on the merits.[29] The appeals court held that Drs. Sherley and Deisher, who perform research using adult stem cells, could challenge the Guidelines because they compete with researchers who use ESCs for a limited pool of federal money supporting stem cell research generally.[30] Because the 2009 NIH Guidelines increased the number of projects competing for these limited funds, they directly harm Drs. Sherley and Deisher.[31]

On remand to the D.C. federal district court, Chief Judge Lamberth determined that the 2009 NIH Guidelines likely violated the Dickey Amendment[32] and granted a preliminary injunction that immediately halted implementation of the guidelines and distribution of funds to researchers.[33]

In the lawsuit, the plaintiffs asserted two independent arguments in challenging the distribution of NIH funds. First, they argued that the 2009 NIH Guidelines violated the plain language of the Dickey Amendment. Second, they contended that in promulgating the 2009 NIH Guidelines, the defendants violated the Administrative Procedure Act (APA).

The defendants countered that the Dickey Amendment is ambiguous because the term "research" is ambiguous, and that as a result, their interpretation of research should be entitled to *Chevron* deference.[34] The district court disagreed and determined that under *Chevron,*[35] the court must first ask whether Congress has "directly spoken to the precise question at issue" and if it has, a court must "give effect to the unambiguously expressed intent of Congress."[36] If, however, the "the statute is silent or ambiguous with respect to the specific issue," then the court defers to the NIH's interpretation provided it is "based on a permissible construction of the statute."[37]

The district court opined that:

> Congress has spoken to the precise question at issue—whether federal funds may be used for research in which an embryo is destroyed. The Dickey-Wicker Amendment provides that *no* federal funds shall be used for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 C.F.R. § 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Pub. L. No. 111-8, § 509(a)(2). Thus, as demonstrated by the plain language of the statute, the unambiguous intent of Congress is to prohibit the expenditure of federal funds on "research in which a human embryo or embryos are destroyed." *Id.* Contrary to defendants' argument, the term "research" as used in the Dickey-Wicker Amendment has only one meaning, *i.e.,* "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d); *see also* Random House Dict. (listing the first definition of research as "diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications, etc."). This is the most common definition of research, and no other definition of research is supported by the language of the statute.[38]

As a result of this interpretation, the district court stated that the Dickey Amendment's prohibition extends to all research in which an embryo is destroyed, not just the "piece of research" in which the embryo is destroyed.

The district court also dismissed defendants' attempt to separate the derivation of hESCs from research on the hESCs, on the ground that derivation of hESCs from an embryo is an integral step in conducting hESC research.

In granting the preliminary injunction, the district court determined that plaintiffs had demonstrated a strong likelihood of success that the Guidelines violate the Dickey Amendment and therefore did not address whether defendants violated the APA.

The district court also determined that plaintiffs, as researchers using adult stem cells in competition with researchers using hESCs for limited NIH funds, had shown a clear and present need for equitable relief to prevent irreparable harm. The court reasoned that there was no after-the-fact remedy for this injury because the court could not compensate plaintiffs for their lost opportunity to receive funds.[39] Accord-

ingly, plaintiffs would suffer irreparable injury in the absence of the injunction.

The government appealed the preliminary injunction and sought a stay of its enforcement pending resolution of the appeal. The Regents of the University of California sought to intervene in the appeal, arguing that the University was uniquely able to represent the interests of institutions and researchers receiving funding. The D.C. Circuit denied the University's motion to intervene, but granted it permission to file briefs in the case as an amicus curiae.[40]

On September 28, 2010, the D.C. Circuit granted the stay, allowing the Guidelines to be implemented and funds to be distributed to recipients.[41] The court also ordered that briefing in the appeal be completed on an expedited schedule.[42]

The Road Ahead

It is likely that the next significant event in this saga will be the resolution of the government's appeal of the preliminary injunction. Under the current schedule, briefing will be completed by November 4, 2010,[43] and the case has been scheduled for oral arguments on December 6, 2010.[44] It is likely that the panel will issue its opinion in January or February 2011. After the panel issues its decision on the preliminary injunction, there could be further appeal to either or both the full D.C. Circuit and the Supreme Court. Because the district court resolved the issues in this case as a matter of statutory construction, it is possible that the entire case will be resolved on this basis, without remand to the trial court. It is more likely, however, that the matter will be returned to the district court for further development of the record, entry of a final judgment, and another round of appeals.

No matter how the litigation proceeds, it is unlikely that the judicial process will be exhausted in less than a year. It is possible that the process may take several years to play out unless Congress acts in a manner that renders the litigation moot.

Two bills have been introduced in the 111th Congress (2009-2010) seeking to overturn the Dickey Amendment's perceived prohibition on research involving hESCs. As discussed above, prior to the lawsuit challenging the 2009 NIH Guidelines, Representative Diana DeGette (D-CO) and 137 cosponsors introduced the Stem Cell Advancement Act of 2009 (H.R. 4808).[45] This bill and a similar bill (S. 3766) introduced in the Senate on September 13, 2010 by Senator Arlen Specter (D-PA) are both in committee. In light of the recent elections, dispositive action on either bill is unlikely in the short term.

If the plaintiffs are ultimately successful and the Dickey Amendment is not overturned, scientists seeking to conduct research using hESC in the long term in the United States may be limited to grants and loans supported by state initiatives. In 2004, California passed Proposition 71 which created

the California Institute for Regenerative Medicine (CIRM) to distribute bond-funded grants for embryonic and other stem-cell related research over a 10 year period. Connecticut, New Jersey, Maryland, New York, and Ohio have similar funding initiatives.[46] However, the recession and budget cuts may ultimately limit or close down such initiatives. New Jersey awarded $10 million in stem cell research grants in 2007 but announced in July of 2010 that it was closing its science and technology center due to budget cuts.[47]

There is no doubt that Judge Lamberth's injunction has created uncertainty in the field of human embryonic stem cell research. During his September 16, 2010 testimony to the Senate Subcommittee on Labor, HHS, Education, and Related Agencies, NIH Director Francis S. Collins summed up the current state of affairs for ongoing and future research using hESCs:

> [The preliminary injunction] has created uncertainty in the field of human embryonic stem cell research. Many researchers across the country have considered modifying their research plans to turn away from an area of research that, while promising, is now fraught with uncertainty. Some of our nation's best researchers, who have written grant applications proposing innovative new ideas, are now asking, 'Should I even bother to submit my proposal to the NIH?' Likewise, young scientists excited about careers in stem cell research are concerned about going into this field, given the legal uncertainty.[48] C

About the Authors

Antoinette F. Konski (akonski@foley.com) is a partner with Foley & Lardner LLP. She represents life sciences clients, creating and optimizing value in intellectual property portfolios encompassing technologies that include personalized medicine, regenerative and stem cell biology, antibodies, immunology, gene therapy, nanotechnology, diagnostics, small molecules and drug delivery. She represents public and private companies and universities. Ms. Konski was recognized in the *Legal 500 US 2009 Edition* and in the *Legal 500 US: Volume II: Intellectual Property, Media, Technology, and Telecom 2007 Guide* as a top attorney for patent prosecution.

George C. Best (gbest@foley.com) is a partner specializing in IP litigation in Foley & Lardner LLP's Silicon Valley office. Mr. Best received a Ph.D. in Chemistry from Caltech and then attended the University of Chicago Law School. Before joining Foley, he was a clerk for the Hon. Randall R. Rader of the US Court of Appeals for the Federal Circuit.

Endnotes

1 *See* Francis S. Collins, M.D., Ph.D., Director, NIH, *The Promise of Human Embryonic Stem Cell Research*, Testimony Before the Senate Subcommittee on Labor - HHS - Education Appropriations (Sept. 16, 2010), *available at* http://olpa.od.nih.gov/hearings/111/session2/Testimonies/StemCell.pdf.

2 Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 10667 (Mar. 11, 2009).

3 National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170 (July 7, 2009) (hereinafter NIH Guidelines).

4 Elias A. Zerhouni, M.D., Director, NIH, *Stem Cell Science: The Foundation of Future Cures*, Testimony Before the Subcommittee on Health Committee on Energy and Commerce U.S. House of Representatives, *available at* http://olpa.od.nih.gov/hearings/110/session2/Testimonies/Elias_Zerhouni_Stem_Cell_Science.asp.

5 *Id.*

6 *Id.*

7 *Sherley v. Sebelius*, No. 1:09-cv-1585 (Order) (D.D.C. Aug. 23, 2010) *(Sherley IV)*. The preliminary injunction states that: "defendants [the Secretary of Health and Human Services, the Department of Health and Human Services (HHS), the Director of the National Institutes of Health (NIH), and the NIH] and their officers, employees, and agents are enjoined: from implementing, applying, or taking any action whatsoever pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines."

8 *Sherley v. Sebelius*, No. 10-5287 (Order) (D.C. Cir. Sept. 28, 2010) (staying preliminary injunction pending appeal and directing expedited briefing) *(Sherley V)*.

9 Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

10 Congressional Research Services (CRS) Report RS21044, Jon O. Shimabukuro, *Background and Legal Issues Related to Stem Cell Research* (2007), *citing Statement on Federal Funding of Research on Human Embryos*, 30 Weekly Comp. Pres. Doc. 2459 (Dec. 2, 1994).
11 Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803 (2009).
12 Letter from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Director, NIH, Jan. 15, 1999.
13 James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocytes*, 282 Science 1145-1147 (Nov. 1998).
14 Michael J. Shamblott et al. *Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells*, 95 Proc. Nat'l. Acad. Sci. USA 13726 (Nov. 1998).
15 Memorandum from the President of the United States to the Heads of Executive Departments and Agencies (Mar. 4, 1997).
16 *See* CRS Report RS21044, ***supra*** note 10, at CRS-4, *citing* Letter from Secretary Shalala to the Honorable Jay Dickey, Feb. 23, 1999.
17 NIH, *Stem Cell Basics*, *available at* http://stem-cells.nih.gov/info/basics/basics4.asp.
18 *Id.*
19 *Draft National Institute of Health Guidelines for Research Involving Human Pluripotent Stem Cells*, 64 Fed. Reg. 67576 (Dec. 2, 1999), *Guidelines for Research Using Human Pluripotent Stem Cells*, 65 Fed. Reg. 51976 (Aug. 25, 2000), and *Guidelines for Research Using Human Pluripotent Stem Cells; Correction*, 65 Fed. Reg. 69951 (Nov. 21, 2000).
20 CRS Report RL33540, Judith A. Johnson and Erin D. Williams, *Stem Cell Research: Federal Research Funding and Oversight* (2007) *citing* The Aug. 9, 2001, *Remarks by the President on Stem Cell Research, available at* http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html.
21 *Id., citing* the 2007 NIH Human Embryonic Stem Cell Registry.
22 California Institute for Regenerative Medicine, *Why do we need more human embryonic stem cell lines?, available at* www.cirm.ca.gov/?q=StemCellBasics_NewLines.
23 *See* CRS Report RL33540 *supra* note 20, at CRS-18. .
24 *Id.*
25 *Id.* at CRS-19., *citing* Senator Diane Feinstein news release, *available at* http://feinstein.senate.gov/04Releases/r-stemcell-ltr.pdf.
26 *See* CRS Report RL 33554, Erin D. Williams and Judith A. Johnson, *Stem Cell Research: Ethical Issues*, for a review of legislative activity concerning stem cell research.
27 Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 46, 10667 (Mar. 11, 2009).
28 *Sherley v. Sebelius*, 686 F. Supp. 2d 1 (D.D.C. 2009) *(Sherley I)*.
29 *Sherley v. Sibelius*, 610 F.3d 69 (D.C. Cir. 2010) *(Sherley II)*.
30 *Id.* at 75.
31 *Id.*
32 *Sherley v. Sebelius*, 704 F. Supp. 2d 63 (D.D.C. 2010) *(Sherley III)*.
33 *Sherley IV.*
34 *Sherley III*, at 70, *citing Chevron U.S.A., Inc., v. Natural Resources Defense Counsel, Inc.,* 467 U.S. 837, 843 (1984).

35 *Id.*
36 *Id.*
37 *Id.*
38 *Id.*
39 *Id.* at 72, *citing Bracco Diagnostics, Inc. v.Shalala,* 963 F. Supp. 20, 29 (D.D.C. 1997) (quoting *Hoffman-Laroche Inc. v. Califano,* 453 F. Supp. 900, 903 (D.D.C. 1978) (stating that even if an injury is economic in nature, the injury maybe irreparable if "there is 'no adequate compensatory or other corrective relief' that can be provided at a later date").
40 *Sherley v. Sebelius,* No. 10-5287 (Order) (D.C. Cir. Sept. 30, 2010) (denying motion to intervene).
41 *Sherley V.*
42 *Id.*
43 *Sherley v. Sebelius,* No. 10-5287 (D.C. Cir. Sept. 30, 2010) (setting briefing schedule).
44 *The Great Beyond: Court sets date for oral arguments in stem cell appeal*, nature.com, available at http://blogs.nature.com/news/thegreatbeyond/2010/11/court_sets_date_for_important.html.
45 The bill was introduced on March 10, 2010.
46 A summary of state initiatives is *available at* http://stemcells.nih.gov/research/stateResearch.htm.
47 *See* July 16, 2010 press release *New Jersey Commission On Science And Technology Closing Its Doors, available at* www.state.nj.us/scitech/about/news/approved/20100716.html.
48 Statement of Francis S. Collins, M.D., Ph.D., Director, NIH, *The Promise of Human Embryonic Stem Cell Research,* Testimony Before the Senate Subcommittee on Labor – HHS- Education Appropriations, *available at* http://olpa.od.nih.gov/hearings/111/session2/Testimonies/StemCell.pdf.

Thanks go to the leadership of AHLA's Life Sciences Practice Group for sponsoring this feature: **Seth D. Levy,** Davis Wright Tremaine LLP, Los Angeles, CA (Chair); **Jennifer S. Geetter,** McDermott Will & Emery LLP, Washington, DC (Vice Chair - Educational Programs); **Thomas J. Quinlan,** Reed Smith LLP, San Francisco, CA (Vice Chair – Membership); **Jayson S. Slotnik,** Foley Hoag LLP, Washington, DC (Vice Chair – Research & Website); and **Kristian Andrew Werling**, McGuire Woods LLP, Chicago, IL (Vice Chair – Publications).