ORAL ARGUMENT SCHEDULED FOR APRIL 23, 2012

No. 11-5241

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

DR. JAMES L. SHERLEY, et al.,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, et al.,

Defendants-Appellees.

On Appeal From
The United States District Court for the District of Columbia

---

BRIEF FOR *AMICI CURIAE* ROBERT GEORGE, DONALD LANDRY, MICHAEL BIRRER, ERIC COHEN, FARR CURLIN, AUSTIN HUGHES, WILLIAM HURLBUT, PETER LAWLER, YUVAL LEVIN, PAUL MCHUGH, GILBERT MEILAENDER, CHARLES RUBIN, DIANA SCHAUB, O. CARTER SNEAD, MEIR SOLOVEICHIK, AND CHRISTOPHER TOLLEFSEN, IN SUPPORT OF PLAINTIFFS-APPELLANTS

Adam J. White
BOYDEN GRAY & ASSOCIATES
1627 I St. N.W., Suite 950
Washington, D.C. 20006
(703) 371-4743
adam@boydengrayassociates.com

January 27, 2012

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*

Plaintiffs in the district court, and Appellants in this appeal, are Dr. James L. Sherley and Dr. Theresa Deisher. Nightlight Christian Adoptions, Shayne Nelson, Tina Nelson, William Flynn, Patricia Flynn, Christian Medical Association, and Embryos were Plaintiffs in the district court, but have been dismissed for lack of standing.

Defendants in the district court, and Appellees in this appeal, are Kathleen Sebelius, in her official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. Department of Health and Human Services; Francis S. Collins, in his official capacity as Director of the National Institutes of Health; and the National Institutes of Health.

An *ad hoc* coalition of bioethics scholars, comprising Robert P. George, Donald W. Landry, Michael J. Birrer, Eric Cohen, Farr A. Curlin, Austin L. Hughes, William B. Hurlbut, Peter Augustine Lawler, Yuval Levin, Paul R. McHugh, Gilbert C. Meilaender, Charles T. Rubin, Diana J. Schaub, O. Carter Snead, Meir Y. Soloveichik, and Christopher O. Tollefsen, are *amici curiae* supporting Plaintiffs-Appellants in this appeal. The Coalition for the

Advancement of Medical Research, the Genetics Policy Institute, Inc., and the State of Wisconsin were *amici* in the district court.

There are no intervenors.

B. Rulings Under Review

This appeal is from the final Order and Judgment and Memorandum Opinion of the United States District Court for the District of Columbia, entered on July 27, 2011, which entered judgment for Defendants, granted Defendants' Motion for Summary Judgment, denied Plaintiffs' Motion for Summary Judgment, and dismissed all claims, JA 655-93; and all other orders and rulings adverse to Plaintiffs in *Sherley v. Sebelius*, No. 09-cv-01575 (D.D.C.) (Lamberth, J.). The Memorandum Opinion is published at 776 F. Supp. 2d 1 (D.D.C. 2011). JA 655-92.

C. Related Cases

The present case was previously before this Court in *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010) (Case No. 09-5374) (JA 216-27), and *Sherley v. Sebelius*, 644 F.3d 388 (D.C. Cir. 2011) (Case No. 10-5287) (JA 508-28). Counsel is not aware of any related case that is currently pending in this Court or any other court.

/s/ Adam J. White
Adam J. White
BOYDEN GRAY & ASSOCIATES
1627 I St. N.W., Suite 950
Washington, D.C. 20006
(703) 371-4743
adam@boydengrayassociates.com

Counsel for Amici Curiae

January 27, 2012

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

PUBLIC LAWS AND U.S. CODE

* ***Starred entries are authorities on which this brief principally relies.***

PUBLIC LAWS AND U.S. CODE (CONT'D)

LEGISLATIVE HISTORY

REGULATORY MATERIALS

* ***Starred entries are authorities on which this brief principally relies.***

MISCELLANEOUS

GLOSSARY

NIH ..... National Institutes of Health

STATUTES AND REGULATIONS

All applicable statutes, etc., are contained in the Brief for Plaintiffs-Appellants.

STATEMENT OF IDENTITY, INTEREST IN CASE, AND SOURCE OF AUTHORITY TO FILE

Amici Bioethics Scholars are:

Robert P. George, J.D., D.Phil., is McCormick Professor of Jurisprudence and Director of the James Madison Program in American Ideals and Institutions, Princeton University; a former member of the President's Council on Bioethics; and Co-Chairman of the Witherspoon Council on Ethics and the Integrity of Science ("Witherspoon Council");

Donald W. Landry, M.D., Ph.D., is Samuel Bard Professor and Chair of the Department of Medicine, and Director of the Division of Experimental Therapeutics at Columbia University's College of Physicians and Surgeons; Director of the Medical Service at New York-Presbyterian Hospital/Columbia University Medical Center; a former member of the President's Council on Bioethics; and Co-Chairman of the Witherspoon Council;

Michael J. Birrer, M.D., Ph.D., is Professor, Department of Medicine, Harvard Medical School; Director, Gynecologic Medical Oncology,

Massachusetts General Hospital Cancer Center; Co-Chair, Gynecologic Cancer Steering Committee, National Cancer Institute; and a member of the Witherspoon Council;

Eric Cohen is Executive Director of the Tikvah Fund; Editor-at-Large, *The New Atlantis*; and a member of the Witherspoon Council;

Farr A. Curlin, M.D., is Associate Professor of Medicine and Co-Director of the Program on Medicine and Religion, University of Chicago; and a member of the Witherspoon Council;

Austin L. Hughes, Ph.D., is Carolina Distinguished Professor of Biological Sciences, University of South Carolina; and a member of the Witherspoon Council;

William B. Hurlbut, M.D., is Consulting Professor, Department of Neurology and Neurological Sciences, Stanford Medical Center; a former member of the President's Council on Bioethics; and a member of the Witherspoon Council;

Peter Augustine Lawler, Ph.D., is Dana Professor of Government, Berry College; and a former member of the President's Council on Bioethics;

Yuval Levin, Ph.D., is Editor of *National Affairs*; Hertog Fellow, Ethics and Public Policy Center; and a member of the Witherspoon Council;

Paul R. McHugh, M.D., is University Distinguished Service Professor of Psychiatry, Johns Hopkins University School of Medicine; and a former member of the President's Council on Bioethics;

Gilbert C. Meilaender, Ph.D., is Richard and Phyllis Duesenberg Professor of Christian Ethics, Valparaiso University; a former member of the President's Council on Bioethics; and a member of the Witherspoon Council;

Charles T. Rubin, Ph.D., is Associate Professor of Political Science, Duquesne University; and a member of the Witherspoon Council;

Diana J. Schaub, Ph.D., is Professor of Political Science, Loyola University Maryland; a former member of the President's Council on Bioethics; and a member of the Witherspoon Council;

O. Carter Snead, J.D., is Professor of Law, University of Notre Dame; and a member of the Witherspoon Council;

Rabbi Meir Y. Soloveichik, Ph.D., is Director of the Zahava and Moshael Straus Center for Torah and Western Thought at Yeshiva University; Associate Rabbi, Congregation Kehilath Jeshurun, Manhattan; and a member of the Witherspoon Council; and

Christopher O. Tollefsen, Ph.D., is Professor of Philosophy, University of South Carolina; Senior Fellow, Witherspoon Institute; and a member of the Witherspoon Council.

Amici are scholars with expertise regarding embryonic stem cell research and related subjects, including law, ethics, medicine, biology, and political science. As noted above, they include members of the President's Council on Bioethics, a presidential advisory body created in 2001. *See* Exec. Order No. 13,237 (Nov. 28, 2001), *reprinted in* 66 Fed. Reg. 59,851 (Nov. 30, 2001). They also include members of the Witherspoon Council on Ethics and the Integrity of Science, a project of the Witherspoon Institute, a research and educational organization based in Princeton, New Jersey; in that capacity, those *amici* wrote and signed the Witherspoon Council's recent report, *The Stem Cell Debates: Lessons for Science and Politics*, 34 The New Atlantis 1 (2012).[1]

Pursuant to Rule 29(a) of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 29(b), all parties have consented to the filing of this brief.

STATEMENT OF AUTHORSHIP AND FINANCIAL CONTRIBUTION

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 preparing or submitting this brief; and no person (other than *amici*'s counsel) contributed money that was intended to fund preparing or submitting this brief.

[1] http://www.thenewatlantis.com/witherspoonreport

INTRODUCTION

In 2009, the National Institutes of Health ("NIH") promulgated rules allowing the expenditure of federal funds on research activities involving stem cells derived from embryos. *National Institutes of Health Guidelines For Human Stem Cell Research*, 74 Fed. Reg. 32,170 (July 7, 2009) ("NIH Guidelines"). NIH's rules violate the letter and spirit of the "Dickey-Wicker Amendment," a longstanding, perennial appropriations restriction that prohibits the expenditure of federal funds on "research in which" a human embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death." *See* Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, div. F, § 508, 125 Stat. 786, 1112 (2011).

Defendants argue that the NIH Guidelines are not unlawful, and that the Dickey-Wicker Amendment prohibits *only* the use of federal funds for the specific act of destroying an embryo. Federal funds may still flow, they argue, to subsequent research activities conducted on the materials obtained by—and only by—destroying embryos.

For the reasons set forth by Plaintiffs-Appellants Dr. Sherley *et al.* (collectively, "Dr. Sherley") in their opening brief, Defendants' position is untenable. The Dickey-Wicker Amendment's terms can only be reasonably interpreted as a prohibition against all research activities predicated directly

upon the destruction of embryos. This substantive prohibition cannot be avoided by nominally distinguishing the discrete act of deriving stem cells from the broader "research" that follows. *See* Dr. Sherley Br. at 13-42.

STATEMENT OF FACTS

The Court previously outlined the basic facts of human embryonic stem cell research in *Sherley v. Sebelius*, 644 F.3d 388, 390 (D.C. Cir. 2011) ("*Sherley II*"), but they bear repeating here with further elaboration.

There are two basic categories of human stem cells: embryonic stem cells and adult stem cells. Embryonic stem cells are generally considered to be "pluripotent"—that is, capable of developing into nearly any of the cell types of a fully mature human being. *See* Witherspoon Council, *The Stem Cell Debates: Lessons for Science and Politics*, 34 The New Atlantis 1, 63-67 (2012).[2] Adult stem cells are typically "multipotent," capable of producing cell types belonging to certain tissues, *see id.* at 62, although this Court previously noted the recent development of "induced pluripotent stem cells," which are adult cells reprogrammed to a stage of development at which they are pluripotent, *Sherley II*, 644 F.3d at 390.

[2] http://www.thenewatlantis.com/witherspoonreport

Adult stem cells can be found in the various tissues and organs of the human body, but embryonic stem cells can be acquired only by using cells extracted from the human embryo. *Id.* Generally, scientists remove the "inner cell mass" from the blastocyst-stage embryo, a procedure that necessarily destroys the embryo. *Id.* Once extracted, the cells of the inner cell mass are then placed in a culture, where they will divide continuously without differentiating, thus forming a "stem cell line" of identical cells. *Id.*

Once a stem cell line has been created, scientists may remove an embryonic stem cell from the line, for use in research experiments. *Id.* "Most stem cell lines are maintained by one or another of several research universities, which make them available for scientific use, usually for a small fee." *Id.*

The embryos used in embryonic stem cell research are created predominantly through in vitro fertilization; the embryos are "left over" in fertility clinics from attempts to aid infertile couples in having children. Embryos are created in a petri dish and allowed to grow for several days before they are either implanted in a woman or frozen and stored. But the clinic typically will produce many more embryos than are used during a course of fertility treatment, and are left over once the treatment has completed; there currently are several hundred thousand "spare" embryos frozen in U.S. in vitro

fertilization clinics. *See* Witherspoon Council, *The Stem Cell Debates: Lessons for Science and Politics*, 34 The New Atlantis at 64-65.

The parents of embryos may choose to allow them to be used in stem cell research, or they may decline to do so, for a variety of reasons: *e.g.*, they may be uncertain as to whether they intend to bear more children. *Id.* at 65. But even when the parents consent to embryos' use in research, the embryos may not ultimately be fit for research purposes, due to degradation experienced in long storage, the hazards of transportation, or other reasons. *Id.*

Embryos that have been donated for research purposes are then made available to research institutions seeking to use them to derive embryonic stem cells. In some cases, clinics will have established relationships with a number of institutions conducting stem cell research, and will allow patients to choose the institution to which their embryos will be donated. *See*, *e.g.*, ReproTech Limited, "Embryo Donation for Research."[3] Once a stem cell line has been established, cells can be removed and shipped to other researchers without disrupting the durability of the line.

[3] http://reprotech.com/about/disposition-options/embryo-donation-for-research.html (last visited Jan. 27, 2012).

ARGUMENT

The NIH Guidelines violate the limits imposed by Congress in the Dickey-Wicker Amendment, which prohibit the expenditure of federal funds on "research in which" a human embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death." *See* Pub. L. No. 112-74, div. F, § 508, 125 Stat. 786, 1112 (2011). Dr. Sherley's opening brief explains this in detail, *see generally* Dr. Sherley Br. at 13-62, but *amici* Bioethics Scholars submit this brief to amplify three points:

First, although a divided panel of this Court gave *Chevron* deference to NIH for purposes of Dr. Sherley's motion for preliminary injunction, that preliminary ruling does not bind this Court (or the district court) at this subsequent summary-judgment stage in the litigation.

Second, this Court should not grant *Chevron* deference to NIH in interpreting the Dickey-Wicker Amendment, because Congress did not delegate to NIH the authority to make binding interpretations of the Dickey-Wicker Amendment. The Dickey-Wicker Amendment does not empower NIH and other agencies; it *disempowers* them.

Third, this *amicus* brief offers a more detailed description of the historical experience undergirding Congress's passage of the Dickey-Wicker Amendment, to facilitate the Court's task of reading the Dickey-Wicker

Amendment "in context," in light of both "the statute's place in the overall statutory scheme" and "the problem Congress sought to solve," *Goldstein v. SEC*, 451 F.3d 873, 878 (D.C. Cir. 2006). In light of this context and purpose, the Dickey-Wicker Amendment's only reasonable interpretation is to prohibit federal funding for the entire process of embryonic stem cell research—both the discrete act of stem cell derivation, which the NIH Guidelines now allow, and the later phases of the research project predicated upon that act.

I. *Sherley II*'s Preliminary Conclusions Do Not Bind The Court At This Later Stage In The Case

When this Court reviewed the district court's preliminary injunction order and analyzed the parties' "likelihood of success on the merits," it gave "*Chevron* deference" to NIH's interpretation of the Dickey-Wicker Amendment. *Sherley II*, 644 F.3d at 393-97 (citing *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984)). On remand, however, the district court held that *Sherley II* bound it to give *Chevron* deference to NIH not just at the preliminary-injunction stage, but *also* at the subsequent summary-judgment stage. *Sherley v. Sebelius*, 776 F. Supp. 2d 1, 13-21 (D.D.C. 2011).

By treating *Sherley II*'s preliminary analysis as final and irrevocable, the district court erred. "The decision of a trial or appellate court whether to grant or deny a preliminary injunction does not constitute the law

of the case for the purposes of further proceedings and does not limit or preclude the parties from litigating the merits . . . ." *Berrigan v. Sigler*, 499 F.2d 514, 518 (D.C. Cir. 1974); *see also Belbacha v. Bush*, 520 F.3d 452, 458 (D.C. Cir. 2008) (quoting *Berrigan*). Even though the Court ruled in Defendants' favor for purposes of the preliminary injunction motion, both the district court and this Court must take a "fresh look" at the issues; its previous preliminary analysis is "not controlling" authority. *Berrigan*, 499 F.2d at 518.

II. NIH Is Not Entitled To *Chevron* Deference In Interpreting The Dickey-Wicker Amendment

Dr. Sherley already has identified numerous reasons why this Court should not defer to NIH in interpreting the Dickey-Wicker Amendment. *See* Sherley Br. at 38-42. *Amici* add one more: *Chevron* deference is inappropriate because Congress did not delegate to NIH the authority to interpret any ambiguous terms contained within the Dickey-Wicker Amendment. Quite the contrary: the Dickey-Wicker Amendment was enacted to *restrain* Defendants, not empower them.

Chevron deference "comes into play, of course, only as a consequence of statutory ambiguity, and then *only* if the reviewing court finds an implicit delegation of authority to the agency." *Am. Bar Ass'n v. FTC*, 430 F.3d 457, 469 (D.C. Cir. 2005) (emphasis in original). Even if a statute's terms are ambiguous, "[m]ere ambiguity" is not itself "evidence of congressional

delegation of authority" under *Chevron*. *Id.* Instead, to determine whether an agency is entitled to *Chevron* deference, the Court must ascertain whether Congress intended to delegate interpretive authority to an agency—an inquiry that "must be guided to a degree" by "common sense." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

In this case, that "common sense" inquiry must begin and end with the basic nature and purpose of the Dickey-Wicker Amendment: it is an appropriations rider passed not to empower NIH, the Department of Health and Human Services, and the Department of Labor, but to *constrain* them. Because "the question at issue here is the degree to which [an agency's] discretion has been *circumscribed* by Congress . . . 'it seems highly unlikely that a responsible Congress would implicitly delegate to an agency the power to define the scope of its own power.'" *Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 199 (2d Cir. 2004) (quoting *ACLU v. FCC*, 823 F.2d 1554, 1567 n.32 (D.C. Cir. 1987)) (emphasis added).

Accordingly, in cases such as the present one, where the statute at issue was "enacted specifically to prohibit agency action," the Court "ought to be especially careful not to allow" the agency to "thwart congressional intent expressed with reasonable clarity, under the guise of deferring to agency expertise on matters of minimal ambiguity." *Indep. Ins. Agents of Am., Inc. v. Bd.*

of Governors of the Fed. Reserve Sys., 838 F.2d 627, 632 (2d Cir. 1988). In this case, Defendants identify no grounds to rebut these presumptions against *Chevron* deference; accordingly, the Court should interpret the Dickey-Wicker Amendment's terms without deferring to NIH or any other agency.

One final note on *Chevron* deference: As Dr. Sherley's opening brief explained, one of the reasons the Court should not give *Chevron* deference to NIH is that the Dickey-Wicker Amendment was not committed to NIH's exclusive jurisdiction; it is an appropriations rider that applies to multiple agencies. *See* Dr. Sherley Br. at 42. As it happens, this Court reiterated that principle in a case decided the day after Dr. Sherley's brief was filed, holding that an agency "receives *no deference* . . . when it has endeavored to reconcile its organic statute with another statute—such as *a federal appropriations statute*—not within its area of expertise." *U.S. Dep't of the Navy v. FLRA*, No. 10-1304, slip op. at 14-15, 2012 WL 104384 at *7 (D.C. Cir. Jan. 13, 2012) (emphasis added; quotation marks omitted).

III. The Dickey-Wicker Amendment Was Enacted To Prevent Federal Agencies From Funding The Entire Process Of Embryonic Research—Not Merely To Deny Federal Funds To The Discrete Act Of Deriving Stem Cells From Embryos

Congress did not create the Dickey-Wicker Amendment in a vacuum. It was enacted in response to a specific event: namely, NIH's and the Department of Health and Human Services' efforts to end a *de facto* twenty-

year moratorium on embryonic research and begin to federally fund such research despite the harm to or destruction of embryos that necessarily would ensue. That was "the problem Congress sought to solve." *Goldstein*, 451 F.3d at 878. But the new NIH Guidelines' nominal distinction between the specific act of embryo destruction and the rest of the "research" process nullifies that solution, and renders moot the entire debate surrounding the Dickey-Wicker Amendment's original enactment.

A. The Dickey-Wicker Amendment Was Preceded By A Twenty-Year *De Facto* Moratorium On Fetal And Embryonic Research

Decades before the Dickey-Wicker Amendment was enacted in 1995, Congress began to debate the propriety of federally funded embryonic research in Senate hearings convened by Senators Walter Mondale and Edward Kennedy. Senator Mondale was particularly "attuned to developing issues in the biomedical sciences," due to his "close ties to the University of Minnesota where pioneering work, particularly in organ transplantation, was being done," and over the course of several years he convened hearings and sponsored resolutions calling for the creation of a presidential commission on health, science, and society. Albert R. Jonsen, *The Birth of Bioethics* 90 (1998); *see generally id.* at 90-94.

The issue took on much greater urgency in 1973, when NIH's Human Embryology and Development Study Section recommended "the use

of newly delivered live fetuses for medical research before they died." *Id.* at 94. In front-page news coverage, one scientist applauded NIH's recommendation, arguing that it "is not possible to make this fetus into a child, therefore we can consider it as nothing more than a piece of tissue. It is the same principle as taking a beating heart from someone and making use of it in another person." Victor Cohn, *Live-Fetus Research Debated*, Wash. Post (Apr. 10, 1973), at A1, A9; *see also* Jonsen, *The Birth of Bioethics* at 94.

This news, and the further news coverage that ensued, spurred Congress to intervene. Senator Kennedy and others convened hearings on the subject of the ethical implications of scientific experiments, and legislative debate ensued regarding fetal research and other ethical issues, giving rise to legislative proposals to create various commissions for setting ethical standards for experimentation. *Id.* at 97-98. Debate on those issues culminated in 1974 with the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, to study "the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such purposes." *See id.* at 98-99; Pub. L. No. 93-348, § 202(b), 88 Stat. 350 (1974).

That Commission, in turn, interpreted its statutory mandate broadly, issuing a report that covered not just the ethical implications of the

specific act of conducting experiments on post-abortion fetuses, but also the ethical principles that should guide researchers' obtainment of fetuses with the informed consent of donor mothers. *See* Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research on the Fetus* 74 (1975).[4]

Also pursuant to a Commission recommendation, the Department of Health, Education, and Welfare—*i.e.*, the Department of Health and Human Services' predecessor—chartered an Ethics Advisory Board to review all in vitro fertilization research proposals before funding could be approved. *See* Jonsen, *The Birth of Bioethics* at 106. The Board published a general report on the issue of in vitro fertilization research but did not reach a conclusion on whether any human in vitro fertilization experiments should be funded. *See* Ethics Advisory Board, *HEW Support of Research Involving Human* In Vitro *Fertilization and Embryo Transfer* (1979).[5]

In 1980, after the Ethics Advisory Board issued its report, the Department dissolved the Board altogether, having approved no federal

---

[4] http://bioethics.georgetown.edu/pcbe/reports/past_commissions/research_fetus.pdf

[5] http://bioethics.georgetown.edu/pcbe/reports/past_commissions/HEW_IVF_report.pdf

funding for human embryo research. *See* Nat'l Bioethics Advisory Comm'n, 1 *Ethical Issues in Human Stem Cell Research* 34-35 (1999).[6] The Board's dissolution, in turn, created a *de facto* moratorium on federal funding for "experimentation involving human embryos," because federal regulations prohibited federal funding for those activities absent Board approval. *Id.*; *see also Doe v. Shalala*, 862 F. Supp. 1421, 1424 (D. Md. 1994) ("federal regulations governing research on human embryos . . . required such research to be reviewed by an EAB before such research might proceed"). The *de facto* moratorium continued through the Reagan and Bush Administrations, which declined to appoint Ethics Advisory Board members to review applications for federal funding. *See Doe*, 862 F. Supp. at 1424 ("Because prior presidential administrations apparently chose not to appoint an EAB, no funding for such research had in fact been approved.").

B. NIH Ended The Moratorium By Proposing To Fund Embryonic Research, And The Ethics Advisory Board Recommended Funding Embryonic Stem Cell Research

President Clinton inaugurated a regulatory environment much more favorable to embryonic research. On his second day in office, the president ended an executive branch moratorium on federal funding for fetal

[6] http://bioethics.georgetown.edu/nbac/stemcell.pdf.

tissue transplantation research. Nat'l Bioethics Advisory Comm'n, 1 *Ethical Issues in Human Stem Cell Research* at 31. And just two months later, the president signed into law the National Institutes of Health Revitalization Act of 1993, which ended the *de facto* moratorium on fetal research by eliminating the prior requirement that an Ethics Advisory Board approve embryonic research in advance, and authorized federal funding for research on transplantation of fetal tissue, subject to ethical limits. Pub. L. No. 103-43 § 111, 107 Stat. 130 (1993), *codified at* 42 U.S.C. § 289g-1(c)(4); *see also Doe*, 862 F. Supp. at 1424-25 (describing the 1993 Act).

The Revitalization Act had other effects more directly related to this case. "With the passage of the Revitalization Act" of 1993, NIH "received a number of applications seeking financial support of research involving human embryos." *Id.* at 1425.

In response, the Secretary of Health and Human Services and the Director of NIH created the Human Embryo Research Panel, an *ad hoc* committee assembled "to consider various areas of research involving the ex utero human embryo and provide advice as to those areas it views to be acceptable for Federal funding, areas that warrant additional review, and areas that are unacceptable for Federal support." 59 Fed. Reg. 28,874, 28,875 (June 3, 1994).

When the panel provided its advice a short time later, its report recommended federal funding for research using "embryos donated by couples in [in vitro fertilization] programs," in certain circumstances. *See* NIH, 1 *Report of the Human Embryo Research Panel* xiii-xiv (1994).[7] The Panel report's analysis prefigured the NIH Guidelines at issue in this case, in multiple ways.

The Panel specifically endorsed "[r]esearch involving the development of embryonic stem cells, but only with embryos resulting from [in vitro fertilization] for infertility treatment or clinical research that have been donated with the consent of the progenitors." *Id.* at xvii. Indeed, embryonic stem cell research was discussed repeatedly in the Panel's report. *See*, *e.g.*, *id.* at 2 (noting the "research area" of "development of pluripotent embryonic stem cell lines"); *id.* at 27 (on the possibility of creating a "bank" of embryonic stem cells). And evidencing a broad conception of embryonic stem cell "research," the report concluded that "[r]esearch with donated embryos resulting from [in vitro fertilization] treatment or clinical research may be conducted to develop cell lines through the isolation and culture of pluripotential stem cells from the blastocyst"—*i.e.*, from the early-stage embryo. *Id.* at 50

---

[7] http://bioethics.georgetown.edu/pcbe/reports/past_commissions/human_embryo_vol_1.pdf

The Panel focused first on "spare embryos" left over from in vitro fertilization treatments, *see id.* at xiii, attempting to remove "the profit motive" from the process of securing embryos for research, *id.* at 55. But then it went still further, endorsing federal funding for projects in which embryos were created specifically for the sake of research itself, in order to, *e.g.*, test "the efficacy of new contraceptives," or when otherwise "necessary for the validity of a study that is potentially of outstanding scientific and therapeutic value." *Id.* at 44-45.

The Panel's controversial recommendations sparked a substantial public backlash. *See* O. Carter Snead, *Science, Public Bioethics, and the Problem of Integration*, 43 U.C. Davis L. Rev. 1529, 1546 & n.72 (2010). In implementing his Administration's policy on embryo research, President Clinton pared back the Panel's most controversial recommendation, declaring instead that federal funds would be spent only on research using preexisting human embryos, and not on the creation of embryos specifically for research. *See* Stmt. on Federal Funding of Research on Human Embryos (Dec. 2, 1994), *reprinted in* 2 *Pub. Papers of the Presidents of the United States: William J. Clinton* 2142 (1994). And in turn, NIH Director Varmus determined that NIH could fund research activities using "surplus" embryos. *See* Nat'l Bioethics Advisory Comm'n, 1 *Ethical Issues*

in Human Stem Cell Research 34-35 (1999) (recounting Director Varmus's actions).[8]

C. Congress Passed The Dickey-Wicker Amendment To Prevent The NIH From Funding Research Requiring The Destruction Of Embryos

The Panel's report, and the president's and NIH Director's further actions sparked a sharply negative reaction in Congress, leading directly to Congress's passage of the Dickey-Wicker Amendment. *See Sherley II*, 644 F.3d at 400 (Henderson, J., dissenting). The breadth of the Dickey-Wicker Amendment prohibitions was evident on the face of the Amendment itself, which incorporates by reference preexisting regulatory language. The term at the center of this case—"research"—appears not just in the prohibition against "research in which a human embryo or embryos are destroyed," but also in the Dickey-Wicker Amendment's reference to "research on fetuses in utero under 45 C.F.R. § 46.204(b) . . . ." Pub. L. No. 112-74, div. F, § 508, 125 Stat. 786, 1112 (2011).

And 45 C.F.R. § 46.204(b), in turn, defines "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

---

[8] http://bioethics.georgetown.edu/nbac/stemcell.pdf.

45 C.F.R. § 46.102(d). In short, that is the appropriate definition of "research," reaching not just "testing" and "evaluation" of stem cells but also their "development." *See* Dr. Sherley Br. at 19-20.

The Dickey-Wicker Amendment's broad conception of "research" was recognized by the bill's proponents and critics alike, who disagreed over the merits of the prohibition but were unanimous in characterizing its prohibition in categorical terms: the Amendment "prohibit[s] human embryo research," 141 Cong. Rec. at H8203 (Rep. Pelosi); it "bans Federal funds from being used for embryo research," *id.* at E1644 (Rep. Furse); it "stops medical experimentation on human embryos outside the womb," *id.* at H8236 (Rep. DeLay); it "bans human embryo research by NIH," *id.* at H8315 (Rep. Porter); it is "a total prohibition of Federal funding for human embryo research," 142 Cong. Rec. at S433 (Sen. Boxer); and so on. And in the House Committee Report, the Dickey-Wicker Amendment's critics argued that this "ban on all federal funding" would move all embryonic research into private laboratories. H.R. Rep. No. 104-209, at 385 (1995).

In sum, the Dickey-Wicker Amendment was well understood at the time of its original enactment as a categorical prohibition against federal funding for research activities that either destroyed embryos or used materials derived by destroying embryos.

D. Shortly After The Dickey-Wicker Amendment's Enactment, The Same Congress—And NIH—Reiterated The Amendment's Broad Reach

Less than one year after the Dickey-Wicker Amendment was signed into law, Congress returned to the subject yet again, with the Amendment's critics in the House proposing to delete its prohibition on research in which embryos are destroyed or harmed. *See* 142 Cong. Rec. H7339-H7344 (July 11, 1996). Their proposal ultimately failed to secure House approval, *id.* at H7364, but their arguments confirmed once again the original understanding that the Dickey-Wicker Amendment prohibited all embryonic research.

Rep. Lowey, the new legislation's sponsor, referred to the Dickey-Wicker Amendment as "the ban on early-stage embryo research[.]" *Id.* at H7339. Rep. Fazio argued that the Amendment "will bar the Federal Government from pursuing life saving research." *Id.* at H7342. Rep. Waxman described the Amendment's prohibitions as "the bans on this research that could lead to lifesaving results." *Id.* at H7340. And Rep. Porter, in a comment directly relevant to the case at hand, stressed that the Dickey-Wicker Amendment would prevent "breakthroughs in the use of embryonic stem cells[.]" *Id.* at H7340.

In sum, the critics of the Dickey-Wicker Amendment—in the Congress that originally created and twice approved it—interpreted the Amendment's prohibition as categorically precluding federal funding for research involving or predicated upon the destruction of embryos; none evidenced any notion that the Amendment's prohibition could be avoided by simply redefining the "research" at issue as commencing after the embryos themselves were harmed or destroyed. Rep. Porter's statement, in particular, clearly evidenced an understanding that the Dickey-Wicker Amendment prevented the development of embryonic stem cell lines for subsequent experimentation. *See id.* at H7340.

In October 1996, shortly after the Dickey-Wicker Amendment was enacted for the second time, NIH personnel acknowledged that the Amendment's prohibitions were broad enough to prevent the expenditure of federal funds on experiments conducted not just on embryos *per se*, but also on material derived from embryos. As NIH's Deputy Scientific Director explained to a federally funded researcher at the Georgetown Medical Center, "you may not engage in embryo related research with funds, equipment or other support from [NIH's National Center for Human Genome Research]. This includes preimplantation genetics involving molecular or cytogenetic analysis from DNA *derived from a human embryo* . . . ." JA 507 (emphasis added).

Indeed, as the National Bioethics Advisory Commission later recounted (and as Dr. Sherley notes in his brief (at 35-36 & n.6)), NIH went so far as to *fire* a researcher "for using NIH laboratory equipment to analyze DNA that was extracted from human embryos for the purpose of detecting genetic defects. NIH took the position that the ban prohibited federal support for" research using "DNA derived from a human embryo." Nat'l Bioethics Advisory Comm'n, 2 *Ethical Issues in Human Stem Cell Research* at p. D-8 (2000).[9] NIH fired the researcher even though the researcher had not "extracted the DNA from the embryos himself." *Id.* As the NIH Director later recounted in his memoir, the researcher undertook this "illegal research" even after having "been told directly, by me and by others, that such work could not be done on the NIH campus or with federal funds . . . . Needless to say, this was a mess[.]" Harold Varmus, *The Art and Politics of Science* 178-79 (2009).

* * *

Of course, NIH eventually departed from the original understanding of the Dickey-Wicker Amendment. In time, the very federal regulators whom the Dickey-Wicker Amendment was enacted to constrain would reinterpret the Amendment, narrowing the concept of "research" to

[9] http://bioethics.georgetown.edu/nbac/stemcell2.pdf

exclude the process of deriving the embryonic stem cells—*i.e.*, the necessary predicate act of harming or destroying an embryo. In so doing, they enlarged their own discretion, allowing NIH to attain the very same purported benefits that the Dickey-Wicker Amendment's original critics declared to be foreclosed by the Amendment. *See* Dr. Sherley Br. at 4-5.[10]

But even in drawing this new distinction between "deriving" stem cells from embryos and "researching" on embryos, the drafters of the current NIH Guidelines, like the drafters of NIH's 2000 guidelines, cannot avoid acknowledging the inherent connection between "derivation" and "research." For while the Guidelines purport to regulate only the subsequent "research," the Guidelines' substance still focuses primarily—indeed, almost *exclusively*—on the act of *deriving* the stem cells from embryos, by requiring that the stem cells be derived only from embryos conceived through in vitro fertilization, and

[10] NIH's initial effort to reinterpret the Amendment, beginning with the 1999 memorandum by Harriet Rabb, General Counsel for the Department of Health and Human Services, was immediately denounced by Rep. Dickey and many other congressmen. In a letter to the Secretary of Health and Human Services, they urged that any "NIH action to initiate funding of such research would violate both the letter and the spirit of" the Dickey-Wicker Amendment. *See* Letter from Rep. Jay Dickey, *et al.* to Donna E. Shalala, Secretary of Health and Human Services, at 1 (Feb. 11, 1999); *see also* Nat'l Bioethics Advisory Comm'n, 2 *Ethical Issues in Human Stem Cell Research* at p. E-43 n.119 (2000) (describing the letter). The letter is available at http://www.witherspooncouncil.org/documents/dickeyletterfeb1999.pdf.

only after satisfying rigorous donor-consent requirements. JA 48-49 (NIH Guidelines); *see also National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*, 65 Fed. Reg. 51,976, 51,979-81 (Aug. 25, 2000) (previous NIH guidelines).

In other words, the regulators acting under the Dickey-Wicker Amendment, like the congressmen who originally supported or opposed the Amendment, continue to treat embryonic stem cell research as a continuous whole, beginning with obtaining stem cells (and thus destroying embryos) and ending with utilizing those stem cells. The NIH Guidelines adopt the derivation-research distinction only in form, not in substance.

And in promoting form over substance, NIH's interpretation of the Dickey-Wicker Amendment necessarily renders Congress's original, substantive debates utterly superfluous. If embryonic stem cell research can be fully funded by the federal government simply by eliminating nominal funding for the brief, discrete act of stem cell derivation, then all of the concerns raised by the Amendment's opponents in Congress were moot. By that interpretation, Congress's repeated, heated debates were "full of sound and fury, Signifying nothing." William Shakespeare, *The Tragedy of Macbeth*, act 5, sc. 5, lines 27-28.

In fact, the Dickey-Wicker Amendment was enormously controversial precisely because it is so prohibitive. It codifies not just Congress's refusal to pay for the discrete act of destroying embryos, but Congress's refusal to devote federal funds to all research that necessarily requires the destruction of human embryos.

CONCLUSION

The NIH Guidelines violate Congress's prohibition, and must accordingly be vacated.

Respectfully submitted,

/s/ Adam J. White
Adam J. White
BOYDEN GRAY & ASSOCIATES
1627 I St. N.W., Suite 950
Washington, D.C. 20006
(703) 371-4743
adam@boydengrayassociates.com

Counsel for Amici Curiae

January 27, 2012

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of FED. R. APP. P. 29(d) because it contains 5,582 words, excluding the parts of the brief exempted by FED. R. APP. P. 32(a)(7)(B)(iii).

This brief complies with typeface requirements of FED. R. APP. P. 32(a)(5) and the type-style requirements of FED. R. APP. P. 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word in Calisto MT 14-point font.

/s/ Adam J. White
January 27, 2012 Adam J. White

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record who have consented to electronic service are being served today with a copy of this document via the Court's CM/ECF. All parties in this case are represented by counsel consenting to electronic service.

/s/ Adam J. White
January 27, 2012 Adam J. White