IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DR. JAMES THOMSON, DR. ROGER PEDERSEN, DR. JOHN GEARHART, DR. DOUGLAS MELTON, DR. DAN KAUFMAN, DR. ALAN OSBORNE TROUNSON, DR. MARTIN PERA, CHRISTOPHER REEVE, JAMES CORDY, and JAMES TYREE,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 01-CV-0973 (RCL)
TOMMY G. THOMPSON, DEPARTMENT OF HEALTH AND HUMAN SERVICES, DR. RUTH KIRSCHSTEIN, and NATIONAL INSTITUTES OF HEALTH,	)	
Defendants.	)	

MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

During the Clinton Administration, the National Institutes of Health ("NIH") embarked on a public, deliberate, and comprehensive process to develop substantive rules establishing a legal and ethical framework under which NIH would fund research involving human pluripotent stem cells ("HPSCs"). This process culminated in the publication of final regulations entitled the *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells* (hereinafter the "*Guidelines*") on August 25, 2000. See 65 Fed. Reg. 51975 (Exhibit 1).

At the start of the George W. Bush Administration, Department of Health and Human Services ("HHS") Secretary Tommy Thompson announced that the new Administration would conduct an internal review of the *Guidelines* but that, during the review, researchers' applications pursuant to the *Guidelines* would be processed. See Exhibit 2. In April 2001, however, HHS reversed course by unilaterally imposing a complete moratorium on implementation of the *Guidelines* pending the outcome of the Administration's internal review and canceling the April 25, 2001 meeting that was to evaluate the first set of applications under the *Guidelines*, including those submitted by plaintiffs Trounson, Pera, and Pedersen. See Exhibit 3.

Plaintiffs, who are seven of the world's leading HPSC researchers and three patients suffering from devastating conditions that are early therapeutic targets of that research, thereupon filed this case. Plaintiffs seek declaratory and injunctive relief requiring defendants to implement the *Guidelines* and to proceed in all other respects with funding of scientifically meritorious HPSC research.

According to HHS's own STEM CELL FACT SHEET, "[h]uman pluripotent stem cells are a unique scientific and medical resource. . . . Because pluripotent stem cells give rise to almost all of the cell types of the body, such as muscle, nerve, heart, blood, they hold great promise for both

research and health care. This advance in human biology continues to generate enthusiasm among scientists, patients suffering from a broad range of diseases, including cancer, heart disease and diabetes, and their families." Exhibit 4. This view is shared throughout the scientific community. *Science* magazine declared stem cells the scientific "breakthrough of the year" in 1999 (Exhibit 5), and over 100 leading university presidents wrote in January 2001 that "[t]he discovery of pluripotent stem cells may be the single most important scientific and medical breakthrough in the past decade or more." Exhibit 6.

As the American Association for the Advancement of Science has explained, "[f]ederal funding for stem cell research is necessary in order to promote investment in this promising line of research, to encourage sound public policy, and to foster public confidence in the conduct of such research." Exhibit 7, p. vi. This is so because, among other things, "[r]ealizing the potential health benefits of stem cell technology will require a large and sustained investment in research" and "[t]he federal government is the only realistic source for such an infusion of funds." *Id*. Thus, absent federal funding, both basic research and the development of useful therapies from HPSCs will be greatly hindered and delayed. See Thomson Dec. at 7-8 (Exhibit 33); Trounsen Dec. at 6-7 (Exhibit 34); Pera Dec. ¶ 14 (Exhibit 35); Pedersen Dec. ¶ 8 (Exhibit 38). In short, as 80 Nobel laureates recently wrote the Administration, "[f]ederal support for the enormous creativity of the US biomedical community is essential to translate this discovery into novel therapies for a range of serious and currently intractable diseases." Exhibit 8.

Defendants' unilateral moratorium, therefore, is inflicting severe harm on plaintiffs in particular[1] and on medical progress in general. That moratorium also is patently unlawful for the reasons

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[1] See, *e.g.*, Kaufman Dec. at 4 (Exhibit 36); Pera Dec. ¶¶ 16-20 (Exhibit 35); Pedersen Dec. ¶ 13 (Exhibit 38); Tyree Dec. (Exhibit 39); Cordy Dec. (Exhibit 40); Reeve Dec. (Exhibit 41).

discussed in this memorandum. First, the moratorium cannot be justified by reference to an appropriations rider that bars funding of research in which embryos are destroyed, since the *Guidelines* conform to that rider by prohibiting the use of federal funds for the destruction of embryos. Second, because the *Guidelines* are final, in-force regulations adopted through notice-and-comment rulemaking, defendants' unilateral suspension of the *Guidelines* violates the Administrative Procedure Act ("APA"), as the D.C. Circuit held in essentially identical cases arising from the transition from the Carter to Reagan Administrations. Third, defendants' moratorium violates the NIH Revitalization Act of 1993, which prohibits the executive branch of government from barring, or withholding funds for, this kind of research. Finally, the moratorium constitutes arbitrary and capricious agency action in contravention of the APA, since defendants have not provided, and cannot possibly provide, any reasoned basis for abandoning an area of research that is vital to achieving HHS's and NIH's statutory missions.

STATEMENT OF FACTUAL AND LEGAL CONTEXT

1. Historical Context. Since the early 1930s, U.S. biomedical research has utilized *ex utero* fetal tissue in federally funded research. For example, the 1954 Nobel Prize for medicine went to an American immunologist who used cell lines obtained from fetal kidney cells to grow polio virus in culture, a key step in the development of the polio vaccine. See National Bioethics Advisory Comm'n, *Ethical Issues in Human Stem Cell Research*, at 29 (Sept. 1999) (Exhibit 9).

In the early 1970s, with the Nation split over the morality of abortion and with the airing of certain troubling allegations about experiments on fetuses, research involving fetal tissue became a topic of Congressional interest. *Id.* In 1974, Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, with research using the human fetus at the top of the Commission's agenda. 88 Stat. 342, 348 (1974). The 1974 Act banned

research involving living fetuses until the Commission issued its report. The Commission's recommendations formed the basis for regulations issued by the Department of Health, Education and Welfare (predecessor to defendant HHS) in 1975 for research involving fetuses and human subjects. See 40 Fed. Reg. 33526 (Aug. 8, 1975).

2. The Bush I Moratorium. In the 1980s, Swedish scientists began transplanting tissue from aborted fetuses into the brains of Parkinson's patients. See Exhibit 10. Scientists then sought NIH funding for similar research in the United States. This generated a political controversy focusing on fetal tissue as a transplantation medium. In 1987, the HHS Assistant Secretary of Health -- in response to a request to NIH to fund a research protocol involving experimental implantation of fetal cells to treat Parkinson's Disease -- imposed a temporary moratorium on funding of fetal tissue transplantation research. See H.R. Rep. No. 103-28, at 59 (1993) (Exhibit 25). On November 2, 1989, contrary to the recommendations of an NIH advisory panel, the Secretary of HHS extended the moratorium indefinitely:

> "I am continuing indefinitely the limited moratorium on federal funding of research in which human fetal tissue from induced abortions is transplanted into human recipients. This action does not affect funding of other research involving fetal tissue." (Exhibit 11.)

This administratively-imposed moratorium lasted throughout the Presidency of George H.W. Bush. Toward the end of his Administration, Congress passed legislation to overturn the ban on federal funding of research on fetal tissue transplantation, but President Bush vetoed it and his veto was not overridden. See Exhibit 12.

3. The 1993 NIH Revitalization Act. The administrative moratorium was lifted on January 22, 1993, pursuant to an order to HHS from newly inaugurated President Clinton. See 58 Fed. Reg. 7457 (Feb. 5, 1993) (Exhibit 13). That order provided:

> "This moratorium has significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders, such as Parkinson's disease, Alzheimer's disease, diabetes, and leukemia. Accordingly, I hereby direct that you immediately lift the moratorium."

Shortly thereafter, Congress enacted the NIH Revitalization Act of 1993, Pub. L. No. 103-43, Title I(A), 107 Stat. 122, 126-33 (1993) (Exhibit 14), codified at 42 U.S.C. §§ 289g, 289g-1, 289g-1 note, 289g-2. As relevant here, the Act created statutory guidelines to ensure that research on fetal tissue transplantation is conducted ethically and appropriately by prescribing informed consent requirements (42 U.S.C. § 289g-1) and by prohibiting directed donations to specific transplant recipients (42 U.S.C. § 289g-2). Section 113 of the Act, which is entitled "Nullification of Moratorium," both (1) added statutory force and permanence to President Clinton's nullification of the first Bush Administration's moratorium on fetal tissue transplantation research, and (2) affirmatively prohibits the executive branch from interfering with NIH funding of research on the transplantation of human fetal tissue for therapeutic purposes.

As to the former, § 113(a) bars the executive branch of government from prohibiting HHS from research on the transplantation of fetal tissue for therapeutic purposes:

> "**(a) In General.** -- Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with [42 U.S.C. § 289g-1], without regard to any such policy that may have been in effect prior to the date of the enactment of this Act."

As to the latter, § 113(b) bars HHS from interfering with the funding of fetal tissue transplantation research projects that the NIH peer-review processes have found meritorious:

> "**(b) Prohibition against withholding of funds in cases of technical and scientific merit.** --
>
> **(1) In general.** -- Subject to [42 U.S.C. § 289a-1(b)(2)], in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if --
>
> (A) the research has been approved for purposes of subsection (a) of such section 492A;
>
> (B) the research will be carried out in accordance with section 498A of such Act (as added by section 111 of this Act); and
>
> (C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act (as added by section 112 of this Act)."

The reference in paragraph (A) is to the Department's normal peer review procedures for identifying scientifically meritorious research; paragraph (B) refers to the Act's informed consent requirements; and paragraph (C) refers to the Act's prohibition on the purchase of fetal tissue. Finally, the Act expressly defines "human fetal issue" to include cells obtained from both fetuses and embryos: "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." Act § 111(g), codified at 42 U.S.C. § 289g-1(g).

4. **The Appropriations Rider.** In the wake of the Revitalization Act, NIH convened an Human Embryo Research Panel. In 1994, the panel proposed allowing federal funding for the creation of the embryos for research purposes and for the derivation of cells from embryos. See *Ethical Issues in Human Stem Cell Research* at 34 (Exhibit 9).

In 1996, Congress reacted to the panel's recommendations by imposing a ban on the use of appropriated federal funds 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 46.208(a)(2) and 42 U.S.C. 289g(b)."

Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (Exhibit 42). That limitation on federal funding of embryo creation and of research in which embryos are destroyed has been repeated in each annual appropriations act. The current limitation is found in § 510 of the Consolidated Appropriations Act - FY 2001, Pub. L. No. 106-554 (Exhibit 15).

5. <u>The Discovery of Stem Cells and the Development of Ethics and Legal Opinions</u>. In 1998, plaintiff James Thomson derived HPSCs from embryos in the blastocyst stage and plaintiff John Gearhart derived HPSCs from germ cells found in fetal tissue. See Exhibit 23 at 8, 10. Embryonic stem cells do not exist naturally in embryos; they are derived from laboratory procedures. Thomson Dec. at 2-3 (Exhibit 33). Likewise, embryonic germ cells do not naturally exist in fetal tissue; they too are derived, and then stem cells are derived from them. Exhibit 23 at 11-12 (Gearhart testimony). Neither Dr. Thomson's nor Dr. Gearhart's research was supported by federal funding, but these breakthroughs put in play the issue of federal funding of research using HPSCs.

On January 15, 1999, the General Counsel of HHS (Harriet S. Rabb) provided a written opinion concluding that federal funding involving research using stem cells derived from embryos is lawful under the Appropriations Rider, so long as private funds were used to derive the cells from the embryos. See Exhibit 16.

Meanwhile, in November 1998, President Clinton had asked the National Bioethics Advisory Commission to conduct a thorough review of human stem cell research and the potential ground rules for its public funding. The Commission considered science, law, and ethics and commissioned reports from religious and ethical experts as well as scientists and lawyers. As particularly relevant

here, the Commission obtained an independent legal opinion from Covington & Burling, which concluded that the HHS General Counsel had correctly concluded that NIH is not barred from funding stem cell research as long as the actual derivation of stem cells from embryos is privately funded. See Exhibit 17. The Commission ultimately recommended in its September 1999 Report that federal funding of HPSC research should proceed under two conditions:

> "First, such research should be limited to using only two of the current sources of such cells; namely, cadaveric fetal material and embryos remaining after infertility treatments. Second, that such sponsorship be contingent on an appropriate and open system of national oversight and review." Exhibit 9 (transmittal letter)..

6. **The NIH Regulations.** The NIH then began a notice and comment procedure to develop regulations for federal funding of stem cell research. Draft regulations were published in the Federal Register on December 2, 1999. See Exhibit 18. On August 25, 2000, the final regulations, entitled *NIH Guidelines for Research Using Human Pluripotent Stem Cells*, were published in the Federal Register and made effective upon publication. See 65 Fed. Reg. 51975, with minor corrections published at 65 Fed. Reg. 69951 (Exhibit 1). With respect to embryos, the release expressly reaffirmed the prior interpretation of the appropriations rider (Exhibit 1 at 51976), and the *Guidelines* provide that NIH funds may be used for research using HPSCs after such cells have been derived from embryos, but that federal funds cannot be used for "[t]he derivation of pluripotent stem cells from human embryos." Exhibit 1 at § III; see also Exhibit 4 (HHS FACT SHEET) at 3. The *Guidelines* also require, among other things, that the cells have been derived from excess frozen embryos, that no inducements be given for the donation of the embryos, that the donors have provided informed consent, and that the donation not be directed to any particular recipient. See Exhibit 1 at § II.A.2. With respect to tissue from fetuses, the *Guidelines* allow funding of research to derive pluripotent stem cells from such tissue, as well as funding of research using such cells. See Exhibit

1 at § II.B. In a nutshell, the *Guidelines* authorize federally-funded researchers to pursue stem cell research, subject to specified conditions designed to ensure that such research is conducted in an ethical and legal manner.

On November 21, 2000, NIH announced the process it would follow to select stem cell research projects for funding in accordance with the *Guidelines*. See Exhibit 19. In essence, NIH said that its normal processes for reviewing funding applications by a peer-review study section and then by an Advisory Council would apply, but that separate applications showing compliance with the *Guidelines* also would be reviewed on a parallel track by a review group (the "HPSCRG") and then by a review advisory council (the "CSRAC"). NIH also established a timetable for these reviews, with the first group of applications to complete the special review process in May 2001.[2] On January 16, 2001, NIH issued similar compliance approval processes and timelines for intramural (within NIH) research. See Exhibit 20.

In response to the draft *Guidelines*, researchers such as plaintiffs Trounson and Pera began work to develop new cell lines that comply with the conditions specified therein. See Trounson Dec. at 7 (Exhibit 34); Pera Dec. at ¶ 11 (Exhibit 35). Once the final *Guidelines* were issued, plaintiffs Trounson and Pera submitted their compliance application on March 15, 2001. See Pera Dec. at ¶ 16

[2] The published schedule for receipt and review of HPSC applications by the HPSCRG and the CSRAC is as follows:

Submission Window of Applications (new, continuation, revised, supplements)	Materials received by Office of Science Policy	Review by HPSCRG	Consideration by CSRAC
January 10 to May 1	March 15	April	May
May 10 to September 1	July 15	August	September
September 10 to January 2	November 15	December	January

(Exhibit 35). Plaintiff Pedersen also submitted an application for approval using the Trounson-Pera cell line. See Pedersen Dec. ¶ 10 (Exhibit 38).

7. The Recent Suspension of the Guidelines. Despite the lengthy deliberations leading up to publication of the August 25, 2000 final *Guidelines* and the subsequent promulgation of approval processes, HHS Secretary Tommy G. Thompson announced in February 2001 that the new Administration was launching yet another review of the *Guidelines*. At that time, Secretary Thompson said that the funding and compliance applications should still be submitted to NIH and that the Administration's review would not delay the application process. See Exhibit 2.

On or about April 20, 2001, however, HHS instructed NIH to cancel the April 25, 2001 meeting of the NIH committee that had been scheduled to review the first compliance applications for human embryonic stem cell research. According to a contemporaneous press account:

> "The National Institutes of Health has canceled next week's inaugural meeting of a committee that was to review the first applications from scientists seeking federal funds for human embryo cell research. It did so, agency officials said, after officials of the Department of Health and Human Services told them to cancel the meeting." Exhibit 3.

In addition to canceling the April 25, 2001 meeting, HHS suspended the review and approval process of all funding and compliance applications for human embryonic stem cell research. This total suspension was confirmed in a stipulated stay filing made with this Court in the related *Nightlight Christian Adoption*s case, No. 1.01CV00502-RCL (D.D.C.) (Exhibit 21).[3]

[3] On May 2, 2001, plaintiffs herein filed a motion for leave to intervene as defendants and cross-claimants in the *Nightlight Christian Adoptions* case. Shortly thereafter, the plaintiffs and defendants in that case filed their agreed stay motion. Accordingly, plaintiffs filed this separate lawsuit.

SUMMARY OF ARGUMENT

1. Consistency with the Appropriations Rider. The General Counsel of defendant HHS in January 1999, and the law firm of Covington & Burling in its response to the request for an opinion from the National Bioethics Advisory Commission, and the NIH in issuing the *Guidelines*, all concluded that the appropriations rider does not bar funding of HPSC research as long as federal funds are not used for deriving the HPSCs from the embryos. That conclusion is clearly correct as a matter of law. As quoted above, the rider bars the use of federal funds for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death . . . ." Appropriations riders are to be narrowly construed and limited to their unambiguous terms. *Calloway v. District of Columbia*, 216 F.3d 1, 9 (D.C. Cir. 2000). The rider defines the term "embryo" to include an "organism," and the uniform congressional testimony and scientific evidence establishes that HPSCs are not "embryos" and are not "organisms" because, unlike an "organism," they are not, nor will they become, whole, independent entities that can carry out life functions.

Nor is the rider triggered by the fact that some HPSCs were -- prior to the project to be funded, and using non-federal funds -- derived from embryos. The rider unambiguously employs the present tense in barring funding only of research "in which" human embryos "are" destroyed, discarded or subjected to risk, and "Congress' use of a verb tense is significant in construing statutes." *United States v. Wilson*, 503 U.S. 329, 333 (1992); accord *Otte v. United States*, 419 U.S. 43, 49-50 (1974); *In re Arochem Corp.*, 176 F.3d 610, 623 (2d Cir. 1999). The *Guidelines* carefully hew to that distinction by prohibiting funding for "the derivation of pluripotent stem cells from human embryos" while authorizing funding of research using stem cells themselves.

This interpretation of the rider is confirmed by the fact that, *after* the HHS General Counsel's opinion was issued, and *after* Congress held a hearing on that opinion, Congress re-enacted the

rider without changing its terms. *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."); *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 194 (D.C. Cir. 1993). Thus, plaintiffs are entitled to a judgment declaring that the *Guidelines* are consistent with the appropriations rider.

2. Violation of the APA's Notice and Comment Procedures. Defendants' peremptory suspension of the *Guidelines*, which are final agency regulations adopted in accordance with the notice and comment requirements of the Administrative Procedure Act, directly violates that Act. First, the *Guidelines* are regulations subject to the APA's notice and comment provisions. "Any claim of exemption from APA rulemaking requirements will be narrowly construed and only reluctantly countenanced," and indeed "strict scrutiny" of such a claim is applied if the government tries to repeal a document that was adopted through notice and comment rulemaking without going through those procedures. *Environmental Defense Fund, Inc. v. Gorsuch*, 713 F.2d 802, 816-17 (D.C. Cir. 1983) (citations omitted). Given that presumption, and given that the *Guidelines* impose numerous new substantive eligibility requirements on the funding of HPSC research not found in any law or regulation, they clearly are subject to the APA's notice and comment processes. *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95-96 (D.C. Cir. 1997); *Chamber of Commerce v. DOL*, 174 F.3d 206, 211 (D.C. Cir. 1999); *World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61 (D.D.C. 2000).

D.C. Circuit precedent arising from the transition from the Carter to Reagan Administrations conclusively establishes that the APA is violated where, as here, the government suspends duly promulgated final regulations that were adopted pursuant to the APA. As those cases hold, "an agency decision which effectively suspends the implementation of important and duly promulgated standards . . . constitutes rulemaking subject to notice and comment requirements of 5 U.S.C. § 553."

Gorsuch, *supra*, 713 F.2d at 814-18; accord *Environmental Defense Fund, Inc. v. EPA*, 716 F.2d 915, 920 (D.C. Cir. 1983); *Natural Resources Defense Council, Inc. v. EPA*, 683 F.2d 752 (3d Cir. 1982). Those cases also make it clear that the APA's "good cause" exception to those requirements is "limited to emergency situations" (*Environmental Defense Fund, Inc.*, *supra*, 716 F.2d at 920) and does not apply simply because, as in those cases and here as well, a new Administration wants time to review (or even repeal) a prior Administration's duly promulgated regulation. Those cases are directly on point here, and they make it clear that defendants' peremptory suspension of the *Guidelines* contravenes the procedural requirements of the APA. Plaintiffs thus are entitled to a judgment declaring that defendants must implement the *Guidelines* and cannot suspend or change them other than in accordance with the APA's notice and comment procedures.

3. Violation of the 1993 NIH Revitalization Act. In the late 1980s, the first Bush Administration refused, over Congress' objections, to fund research using tissue and cells from fetuses and embryos. In 1993, when supporters of such research had gained control of the White House as well as Congress, they enacted their views into binding statutory law through a provision in the NIH Revitalization Act that expressly forbids the executive branch of government from imposing a policy barring support for research on fetal tissue transplantation and from withholding funds for such research.

Defendants' suspension of the *Guidelines* violates that law. First, stem cell research falls under the scope of research protected by the Act -- namely, "any research on the transplantation of human fetal tissue for therapeutic purposes." The Act defines "human fetal tissue" to include cells obtained from both embryos and fetuses, and thus both HPSCs derived from fetal tissue and HPSCs derived from embryos are "human fetal tissue" within the meaning of the Act. Likewise, the plaintiff researchers' work involves working with stem cells to develop specialized, functional cells and

tissue that can be used for transplantation into patients with conditions such as Type 1 diabetes, Parkinson's Disease, and spinal cord injury. Thus, such research constitutes research on transplantation protected by the Act.

Second, it is clear that defendants' conduct contravenes the Act. By suspending implementation of the *Guidelines*, defendants have imposed a policy prohibiting HHS from conducting or supporting the research in question. Likewise, defendants' unilaterally imposed moratorium unquestionably is withholding funding from projects that would be approved on their scientific merits if the defendants had not frozen the grant application process. Indeed, the 1993 Act was passed to ensure that similar conduct by the first Bush Administration -- namely, an administratively imposed moratorium on research -- would never be repeated. Thus, plaintiffs are entitled to a judgment declaring that the suspension of the *Guidelines* and other aspects of the moratorium imposed by defendants on HPSC research violates the Revitalization Act.

4. Arbitrary and Capricious Agency Action. Even if defendants' moratorium did not constitute the unlawful suspension of a final regulation and even if it was not expressly forbidden by the Revitalization Act, it still would be arbitrary and capricious action in violation of the APA. Under § 706(2)(A) of the APA, agency action must be set aside "[w]here the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion . . . ." *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) (citation omitted). Those twin grounds for review are applied with particular care where, as here, an agency reverses its position on an issue, because "an agency's change in direction from a previously announced intention is a danger signal that triggers scrutiny to ensure that the agency's change of course is not based on impermissible or irrelevant factors." *Robbins v. Reagan*, 780 F.2d 37, 48 (D.C. Cir. 1985).

As to the first ground for review, defendants' suspension of the *Guidelines* and the process for funding HPSC research plainly has not been attended by any reasoned explanation. To the contrary, defendants' unexplained moratorium has been accompanied only by widespread press reports that the moratorium is motivated by White House efforts to curry favor with voters of a particular religious faith. Exhibits 27-29.

In any event, as to the second ground for review, defendants' outright moratorium on HPSC research is wholly contrary to their statutory mission and wholly without any logical or evidentiary support. NIH has acknowledged, and others have agreed, that HPSCs constitute a "unique scientific and medical resource" and "hold great promise for both research and health care." See pages 1-2 *supra*. Likewise, it is beyond genuine dispute that federal funding of such research is vital to achieving that promise. See page 2 *supra*. As such, a failure to fund this research would constitute a grave disregard for defendants' statutory duty.

This is particularly true because the NIH Revitalization Act adopted a federal policy of authorizing the use of tissue obtained from fetal tissue so long as the abortion decision was made independent of the subsequent decision to donate the tissue to scientific research. The *Guidelines* adhere to the policy by authorizing the use of HPSCs so long as the embryos were derived from excess frozen embryos that were created for purposes of in vitro fertilization. Defendants' moratorium, by contrast, strikes a different balance -- forbidding all research -- that runs contrary to that statute. Moreover, defendants' refusal to proceed with research funding under the *Guidelines*, supposedly in order to avoid destroying embryos, is wholly irrational and wholly without evidentiary support. As explained above, the embryos from which cells can be obtained under the *Guidelines* are excess frozen embryos left over after in vitro fertilization procedures, and there is no basis in the record to dispute that those embryos will be discarded if they are not used for these scientific

purposes. As such, defendants' refusal to implement the *Guidelines* is unlawful for this further reason.

ARGUMENT

I. THE *GUIDELINES* DO NOT VIOLATE THE APPROPRIATIONS RIDER

The HHS General Counsel, Covington & Burling, and the NIH in the release publishing the final *Guidelines* were all correct in concluding that, consistent with the appropriations rider, federal funds may be used for research on HPSCs derived from embryos so long as the HPSCs were derived from embryos using non-federal funds. The rider reads as follows:

> "(a) 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 46.208(a)(2) 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." (Exhibit 15.)

We first demonstrate that, as an appropriations rider that limits NIH's general statutory authority, the rider must be narrowly construed. We then explain that HPSCs are not embryos as defined in the rider, and thus the rider on its face does not apply to HPSC research. Finally, we show that the fact that some HPSCs were derived (using private funds) from human embryos does not mean that § 510 bars federal funding of research that subsequently makes use of those HPSCs.

A. As An Appropriations Rider, § 510 Must Be Narrowly Construed.

The D.C. Circuit has recently observed that it is a "well-settled principle that 'while appropriation acts are "Acts of Congress" which can substantively change existing law, there is a very strong presumption that they do not.'" *Calloway v. District of Columbia*, 216 F.3d 1, 9 (D.C. Cir. 2000) (quoting *Building & Constr. Trades Dep't v. Martin*, 961 F.2d 269, 273 (D.C. Cir. 1992)). In light of that presumption, "'the established rule [is] that, when appropriations measures arguably conflict with the underlying authorizing legislation, their effect must be construed narrowly.'" 216 F.3d at 9 (quoting *Donovan v. Carolina Stalite Co.*, 734 F.2d 1547, 1558 (D.C. Cir. 1984)); see also 216 F.3d at 12 ("we must narrowly construe" an appropriations rider). Therefore, *Calloway* explained, the relevant question in a case such as this one is "has Congress unambiguously expressed an intent" to bar funding for the activity in question. *Id*. at 9. In this regard, the rider's effect will be limited to activities that are unambiguously covered, and the courts are not to consider whether "common sense" suggests that Congress might have desired to bar funding of other activities or whether the resulting narrow construction appears "incongru[ous]." *Id*. at 9-10.[4]

B. Stem Cells Are Not Embryos Within the Meaning of the Rider.

As quoted above, the rider applies to research in which "a human embryos or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." As the *Guidelines* observe, "[a]lthough human pluripotent stem cells may be derived from embryos . . ., such stem cells are not

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[4] See also, *e.g.*, *TVA v. Hill*, 439 U.S. 153, 189-93 (1978) ("The doctrine disfavoring repeals by implication 'applies with full vigor when the subsequent legislation is an *appropriations* measure.'") (citations omitted, emphasis in original); *Firebaugh Canal Co. v. United States*, 203 F.3d 568, 575-76 (9th Cir. 2000) (an appropriations bill will be interpreted to limit an agency's statutory authority only to the extent that they "irreconcilably conflict"); *Environmental Defense Center v. Babbitt*, 73 F.3d 867, 871 (9th Cir. 1995) ("Only a 'clear repugnance' between the previous legislation and the appropriations bill warrants a finding that Congress intended to repeal the previous legislation.") (citation omitted).

themselves embryos." Exhibit 1 at § I. Instead, as explained in NIH's STEM CELL PRIMER, HPSCs are isolated from the inner cell mass of embryos. See Exhibit 24. The point that HPSCs are not themselves embryos is also confirmed in the accompanying researcher declarations. See Thomson Dec. at 3 (Exhibit 33); Trounson Dec. at 4 (Exhibit 34); Pera Dec. at ¶ 7 (Exhibit 35).

Subsection (b) of the rider provides that "[f]or 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." We now show that HPSCs are not "organisms" either, and that research on HPSCs is therefore not covered by the rider.

1. Defining the Term "Organism". The statute does not define the term "organism." Thus, as the HHS General Counsel's opinion recognizes, the proper course is to review dictionary definitions. Because the statute involves a scientific context, it is appropriate to employ a scientific dictionary for this purpose.[5] The HHS General Counsel consulted the MCGRAW-HILL DICTIONARY OF SCIENCE AND TECHNICAL TERMS, which defines an organism as "[a]n individual constituted to carry out all life functions."[6] Likewise, the ACADEMIC PRESS DICTIONARY OF SCIENCE AND TECHNOLOGY states that an organism is "a living being; any form in which mutually interde-

[5] Courts employ specialized dictionaries when words in a statute are used in scientific or an otherwise specialized context. See *Stenberg v. Carhart*, 530 U.S. 914, 944 (2000) (using OBSTETRICS: NORMAL & PROBLEM PREGNANCIES and MEDICAL DICTIONARY FOR LAWYERS, as well as general purpose dictionaries, to define "delivery" in a Nebraska abortion statute); *Wint v. Yeutter*, 902 F.2d 76, 82 (D.C. Cir. 1990) (utilizing MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS, the HAMMOND BARNHARDT DICTIONARY OF SCIENCE, and others, to evaluate the Department of Agriculture's interpretation of "vegetable" in statute); *Lake Med. Ctr. v. Thompson*, 243 F.3d 568, 569 (D.C. Cir. 2001) (using INTERMEDIATE ACCOUNTING text to explain "depreciation" in a federal Medicare regulation).

[6] MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 1408 (5th ed. 1994) (Exhibit 22).

pendent parts maintain the various vital processes necessary for life to exist."[7] Scientifically, then, an "organism" is a entire being, one that can itself carry out all the functions necessary to life.

This conclusion also follows from general purpose dictionaries. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, which is frequently utilized by both the Supreme Court and the D.C. Circuit for construing statutes,[8] defines an organism as "an individual constituted to carry on the activities of life by means of parts or organs more or less separate in function but mutually dependent: a living being."[9] Thus, both the scientific and non-scientific dictionaries are in agreement that an "organism" constitutes an entire being that can carry out the functions of life on its own.

2. Applying the Definition. The conclusion that stem cells are not "organisms" within that definition is supported by overwhelming undisputed evidence. As the HHS General Counsel opinion observed, at a December 2, 1998 hearing before a subcommittee of the Senate Appropriations Committee, the NIH Director, four other scientists, a bioethicist, and a theologian were asked if stem cells are organisms, and all of them responded that human pluripotent stem cells are not organisms.[10] Specifically:

! Dr. Harold Varmus, Director, National Institutes of Health (p. 7): "There are many issues to be raised about the cells that we're talking about today, but one of those questions is whether these cells have the ability to give rise to a complete human

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[7] Exhibit 22; see also STEDMAN'S MEDICAL DICTIONARY (25th ed. 1990) (defining organism as "[a]ny living individual, whether plant or animal, considered as a whole") (Exhibit 22).

[8] See, *e.g.*, *Miller v. French*, 530 U.S. 327, 359 (2000) (using that dictionary); *Diamond Game Enters. v. Reno*, 230 F.3d 365, 370 (D.C. Cir. 2000) (same).

[9] WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1590 (1986). Essentially the same definition is contained in WEBSTER'S NEW COLLEGIATE DICTIONARY, which is also frequently used for these purposes. See, *e.g.*, *Kay v. Ehrler*, 499 U.S. 432, 436 (1991).

[10] See *Stem Cell Research: Hearings Before the Subcomm. on Labor, Health and Human Services, and Education of the Senate Comm. On Appropriations*, 105th Cong. (Dec. 2, 1998) (Exhibit 23 hereto) (hereinafter *Stem Cell Hearing*).

being. The answer to that from a scientific perspective is no. . . . [C]ells removed from the inner cell mass or grown as cultured pluripotent stem cells if reintroduced into a uterus do not give rise to a new human being. Hence these pluripotent cells cannot be considered organisms and cannot be considered to be embryos."[11]

- Dr. John Gearhart, Johns Hopkins University School of Medicine (p. 29): "No; they are not. They are not organisms."

- Dr. James Thomson, Wisconsin Regional Primate Research Center, University of Wisconsin (p. 29): "They are not organisms and they are not embryos."

- Dr. Michael West, President and CEO, Advanced Cell Technology (p. 29): "The cultured cells I would say are not. If they are, for instance, grown in a laboratory dish or transplanted into a uterus, they will not form a human being."

- Dr. Thomas Okarma, Vice President, Geron Corporation (p. 71): "My view is that these cells are clearly not organisms. They are highly derived by a laboratory process that took years to develop, and, in fact, as we have said, are not the cellular equivalent of an embryo. Were these cells to be implanted, they would not form a conceptus nor develop."

- Dr. Arthur Caplan, Director, Center for Bioethics, University of Pennsylvania (p. 71): "Absolutely not an organism. Stem cells lack the capacity to become viable, independent, interrelated, functioning entities, so they are not organisms."

- Mr. Richard Doerflinger, Associate Director for Policy Development, Secretariat of Pro-Life Activities, National Conference of Catholic Bishops (p. 71): "Stem cells are not organisms."

The Covington & Burling opinion noted that similar scientific evidence was presented to the National Bioethics Advisory Commission. Exhibit 17 at D-8. The attached declarations from several of the world's leading HPSC researchers also confirm that stem cells or cell lines are not organisms: they are not whole entities, they cannot carry out life's functions, and they would not implant if placed in a uterus. See Thomson Dec. at 3 (Exhibit 33); Trounson Dec. at 3 (Exhibit 34); Pera Dec. at ¶ 7 (Exhibit 35).

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[11] See also (p. 29): "As a scientist, as I have testified here today from the perspective that I bring to this from my professional background, I agree that these are not organisms."

NIH's own May 2000 document entitled STEM CELLS: A PRIMER agrees that stem cells "cannot form an organism because they are unable to give rise to the placenta and supporting tissues necessary for development in the human uterus. These inner cell mass cells are pluripotent -- they can give rise to many types of cells but not all types of cells necessary for fetal development. Because their potential is not total, they are not totipotent and they are not embryos." Exhibit 24 at 1.

In sum, the HHS General Counsel and the Covington & Burling opinions indisputably were correct in concluding that HPSCs are not "embryos" within the meaning of the rider. As such, the rider on its face does not apply to research involving HPSCs.

C. The Rider Does Not Apply Simply Because Certain HPSCs Previously Were Derived From Embryos.

Opponents of research funding argue that, although HPSCs are not embryos, the rider applies because the HPSCs on which the research is to be conducted were previously derived directly or indirectly through privately-funded research in which embryos are destroyed.[12] That argument, however, ignores the specific words employed in the rider. As quoted above, the rider only forbids funding of "research *in which* a human embryo or embryos *are* destroyed, discarded, or knowingly subjected to risk of injury or death . . ." (emphasis added). Under those plain words, the rider applies only if embryos "are" -- present tense -- destroyed "in" the federally-funded research. As NIH Director Varmus correctly explained in Congressional testimony, "our view is that there is a very clear distinction to be made between research in which stem cells that have been developed in one laboratory by one procedure are then used by other investigators to support other kinds of research

[12] The cell lines may be generated from other cell lines without involving additional embryos. They may also be derived from germ cells obtained from fetal tissue. Exhibit 23 at 11-12.

that is not research in which an embryo, an organism, is subjected to risks greater than those that are dictated by other statutes." *Stem Cell Hearing* at 147 (Exhibit 23).

The fact that the rider employs the present tense -- research "in which" embryos "are" destroyed -- is dispositive here. As the Supreme Court has held, "Congress' use of a verb tense is significant in construing statutes." *United States v. Wilson*, 503 U.S. 329, 333 (1992) (relying on use of past tense to construe statute); see also, *e.g.*, *In re Arochem Corp.*, 176 F.3d 610, 623 (2d Cir. 1999) (relying on use of present tense to interpret and apply statute); *United States v. Valentine*, 63 F.3d 459, 463 (6th Cir. 1995) (same); *Otte v. United States*, 419 U.S. 43, 49-50 (1974) (noting that statute "speaks in the past tense as well as the present" in construing statute to cover both). The rider, therefore, must be construed to apply only where embryos "are" destroyed "in" the federally-funded research itself.

This conclusion is further confirmed by the fact that Congress was well aware of how to write a law that would have applied to cells obtained from embryos, if it had wanted to do so. Specifically, the 1993 NIH Revitalization Act expressly *protects* funding of research on transplantation of "cells obtained from a dead human embryo or fetus." 42 U.S.C. § 289g-1(g). As we show later, this provision affirmatively bars NIH from adopting a policy of refusing to fund stem cell research. But the point for present purposes is this: when Congress wanted to legislate about the funding of research involving cells that had been obtained from embryos, it knew how to do so. Because Congress did not employ such language in the rider, the rider cannot be construed as if Congress had done so. See, *e.g.*, *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993).

This construction of the rider is also supported by the historical context within which it was enacted. As explained above, federal law authorizes federally-funded research using cells derived from aborted fetuses (42 U.S.C. § 289g) while simultaneously (in the Hyde Amendment) barring the

use of federal funds to abort fetuses.[13] Our interpretation of the rider produces the parallel situation for embryos: federal funds can support research using HPSCs derived from embryos but cannot be used to destroy embryos. Accordingly, interpreting the rider as limited to the destruction of embryos is consistent with the historical context in which the rider was enacted.

This conclusion, finally, is confirmed by the rule that "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Amfac Resorts, LLC v. United States DOI*, 2001 U.S. Dist. LEXIS 6699, at *58 (D.D.C. May 23, 2001) (Lamberth, J.), quoting *Lorillard v. Pons*, 434 U.S. 575, 580 (1978); accord *Faragher v. Boca Raton*, 524 U.S. 775, 792 (1998); *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 194 (D.C. Cir. 1993). That rule is *doubly* applicable here. First, after the HHS General Counsel construed the rider in her January 1999 opinion as permitting funding for HPSC research (Exhibit 16), and after Congress held a hearing concerning that opinion (Exhibit 23), Congress re-enacted the rider in the FY 2000 appropriations act without changing its terms. Then, after NIH reaffirmed that interpretation in issuing the final *Guidelines* (Exhibit 1), Congress again re-enacted the rider with its terms unchanged in the FY 2001 appropriations act (Exhibit 15).

In sum, the D.C. Circuit has instructed that appropriation riders are to be "narrowly construed" by limiting them to their unambiguous scope, and that courts are not to seek to expand that scope by speculating as to whether a broader interpretation might make sense or might resolve alleged incongruities. When the rider is construed in light of that basic principle and in accordance with the other applicable, well-settled rules of statutory construction as discussed above, it is abun-

[13] The Hyde Amendment appears in the two sections of the Appropriations Act that immediately precede the Rider at issue here. See Exhibit 15 at §§ 508-509.

dantly clear that the rider must be interpreted as only applying where embryos will be destroyed or discarded in the research project itself.

Once the scope of the rider is properly recognized, it is apparent that the *Guidelines* adhere to the rider by denying federal funding for "the derivation of pluripotent stem cells from human embryos" while authorizing funding of research using the stem cells themselves. See Exhibit 1 at § III. As such, plaintiffs are entitled to summary judgment declaring that the *Guidelines* are consistent with the appropriations rider.

II. DEFENDANTS' SUSPENSION OF THE *GUIDELINES* VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

A line of Court of Appeals decisions holding that the unilateral suspension of various final regulations following the transition from the Carter to Reagan Administrations violated the APA makes it indisputably clear that defendants are violating the APA here.

A. The APA Applies to the *Guidelines.*

Section 553 of the APA requires federal agencies to provide advance notice and an opportunity for public comment prior to rulemaking. See 5 U.S.C. § 553.[14] Agency action that is subject to the APA but does not comply with the notice and comment requirements is unlawful and must be set aside. See, *e.g.*, *Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001).

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[14] Specifically, § 553(b) provides that "[g]eneral notice of proposed rule making shall be published in the Federal Register . . ."; § 553(c) provides that "[a]fter notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission or written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose"; and § 553(d) provides that "[t]he required publication or service of a substantive rule shall be made not less than 30 days before its effective date" unless an enumerated exception applies.

For these purposes, "rulemaking" includes any agency processes for "formulating, amending, or repealing" legislative rules that are substantive -- as opposed to purely interpretative or procedural -- in nature. See 5 U.S.C. §§ 553, 551(5). The D.C. Circuit has explained that "[a]ny claim of exemption from APA rulemaking requirements will be narrowly construed and only reluctantly countenanced." *Environmental Defense Fund, Inc. v. Gorsuch*, 713 F.2d 802, 816 (D.C. Cir. 1983) (citations omitted). Cases in this Circuit explain that a rule is substantive, not interpretative, if it "adds to or modifies a legal norm" (i.e., a statute or regulation) based on the agency's own authority. See *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997); *World Duty Free Americas, Inc. v. Summers*, 94 F. Supp 2d 61 (D.D.C. 2000). Likewise, courts distinguish substantive rules from procedural rules by examining whether the rule "alter[s] the rights or interests of [private] parties." *Chamber of Commerce of the United States v. DOL*, 174 F.3d 206, 211 (D.C. Cir. 1999) (citation omitted). A substantive rule is one that has a "substantial impact" upon private parties and "puts a stamp of [agency] approval or disapproval on a given type of behavior." *Id.* (citation omitted).

Tested against these standards, it is clear that the *Guidelines* are substantive regulations that are subject to the APA's rule-making procedures and that do not fall within the APA exceptions for purely interpretative or procedural rules. First, the *Guidelines* contain numerous substantive provisions that are not found in any statute or other regulation. For example, they prohibit embryo donors from benefitting financially from donations; prohibit donations directed to particular transplant recipients; require assurances that the HPSCs used in NIH-funded research were obtained free or through a reimbursement of reasonable costs in transporting and storing the HPSCs; make certain kinds of research ineligible for NIH funding, including somatic cell nuclear transfer; and impose numerous conditions to separate the decision to have an abortion or to discard a fertilized egg from

the subsequent decision to donate cells or tissue to research. See Exhibit 1.[15] Thus, the *Guidelines* go beyond mere construction of existing law to add content to governing legal norms based on NIH's own authority.

Likewise, the *Guidelines* will have a substantial impact on the rights of private parties and place NIH's stamp of approval on certain kinds of research and other conduct. For example, the *Guidelines'* substantive provisions (as just described) will enable researchers to use cell lines that were derived in compliance with those rules but will prohibit funding research involving cells that do not satisfy all of those requirements.[16] Those various substantive provisions also place NIH's "stamp of approval" on certain forms of conduct as being ethical and appropriate. In short, there can be no genuine doubt that the *Guidelines* constitute substantive rulemaking subject to the APA's notice and comment requirements.

The conclusion that the *Guidelines* are subject to the APA's rule-making procedures is confirmed by the fact that NIH followed those procedures in developing and approving the *Guidelines*. From the beginning of the *Guidelines* process, NIH carefully adhered to § 553's requirements, publishing the draft *Guidelines* in the *Federal Register* and soliciting public comments. See 64 Fed. Reg. 67576 (Dec. 2, 1999) (Exhibit 18). That process resulted in some 50,000 comments, which

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[15] Existing caselaw makes it clear that an embryo's progenitors have the right to decide its disposition. See, *e.g.*, *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992) (given constitutional right to procreational autonomy, husband had right to have frozen embryo discarded rather than donated to childless couple); *J.B. v. M.B.*, 751 A.2d 613 (N.J. App. 2000) (husband entitled to order requiring destruction of frozen embryos); *A.Z. v. B.Z.*, 725 N.E.2d 1051 (Mass. 2000) (prohibiting use of frozen embryo that is not accepted by both donors, because person cannot be required to become a parent against his or her will).

[16] For example, one of the requirements of the *Guidelines* – that excess embryos must have been frozen – made every HPSC cell line in existence at the time of the *Guidelines*' adoption ineligible for use in NIH funded research. Researchers such as plaintiffs Dr. Trounson and Dr. Pera accordingly spent months developing new cell lines to be compliant with the *Guidelines*. See Pera Dec. at ¶ 15 (Exhibit 35).

NIH took into account in generating the final *Guidelines*. See 65 Fed. Reg. 51975 (Aug. 25, 2000); minor corrections at 65 Fed. Reg. 69951 (Nov. 21, 2000) (Exhibit 1).[17]

This conclusion is strongly supported by the D.C. Circuit's 1983 decision in *Gorsuch*, *supra*, 713 F.2d 802. In that case, the Carter Administration had published regulations setting standards for granting certain permits, and the Reagan Administration suspended those standards. Rejecting the government's argument that the rules constituted mere agency procedures exempt from notice-and-comment rulemaking, the D.C. Circuit emphasized that "[s]crutiny of a claimed exemption [from the APA's notice and comment procedures] should be exacting where an agency seeks, as EPA does here, to undo all it accomplished through its rulemaking without giving all parties an opportunity to comment on the wisdom of repeal." *Id*. at 816-17 (citation omitted). Applying that "strict scrutiny," the court held that the regulations were subject to notice and comment procedures because they had substantive impacts both on the persons directly needing permits and the general public. *Id*. at 817-18.[18]

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[17] In fact, Congress in 1993 recognized that the first Bush Administration's fetal tissue transplantation moratorium had been unlawfully imposed without complying with applicable notice and comment rulemaking procedures:

> "[M]ore troubling than the delay was the dubious procedural nature of the Bush Administration's final decision-making. No steps were taken to allow public participation. No review was allowed, no comment, and no appeal. No regulations were issued and no rule-making was undertaken. The Department's own attorneys pointed out to the Secretary that such a procedure was unorthodox and legally vulnerable."

H.R. Rep. No. 103-28, at 73 (1993) (Exhibit 25); see also Opinion of Crowell & Moring, *id*. at 211-13 (Exhibit 25).

[18] Section 553(a)(2) of the APA also exempts "a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts" from the rulemaking procedures. Section 553(a)(2) is, however, not applicable to HHS or NIH. On January 28, 1971, the Secretary of the Department of Health, Education, and Welfare (presently HHS) published a "Statement of Policy" in the *Federal Register* that waived this exception to the APA's rulemaking procedures and

In short, the *Guidelines* at issue here were and are subject to the APA's notice and comment requirements.

B. Defendants' Suspension of the *Guidelines* Violates the APA.

Given that the *Guidelines* constitute final agency regulations promulgated in accordance with the APA, defendants have violated the APA by unilaterally suspending the *Guidelines* rather than enforcing the *Guidelines* while going through the notice-and-comment rulemaking process to seek their amendment or repeal. This conclusion, indeed, is mandated by controlling precedent arising from the transition from the Carter to the Reagan Administrations.

In *Environmental Defense Fund, Inc. v. EPA*, 716 F.2d 915 (D.C. Cir. 1983), the EPA issued final environmental reporting regulations in 1980 and required submission of the first reports in March of 1981. *Id*. at 917. Upon taking office, however, the Reagan Administration suspended the regulation and deferred the date for implementing the rule, determining that "good cause" existed for dispensing with the normal notice-and-comment procedures. *Id*. The plaintiffs then filed suit, seeking an order compelling the EPA to put the regulations back into effect. Prior to any ruling, EPA in fact put the regulations back into effect, but the plaintiffs moved for attorneys' fees and expenses as the prevailing party under the Equal Access to Justice Act, 28 U.S.C. § 2412(d)(1)(A).

The D.C. Circuit held that plaintiffs were entitled to fees and expenses because the EPA's position in suspending the regulations was not "substantially justified." The court explained that

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directed all subordinate agencies (including NIH) to utilize the rulemaking provisions of the APA when issuing rules relating to "grants, benefits or contracts." 36 Fed. Reg. 2532 (Feb. 5, 1971); see also *Abbs v. Sullivan*, 756 F. Supp. 1172, 1188 (W.D. Wis. 1990) (stating that as a result of this voluntary election by the HHS Secretary to abide by the rulemaking provisions of the APA, "courts have held the Department of Health and Human Services to strict compliance with the notice and comment requirements when promulgating regulations") (also citing other cases), *vacated on other grounds*, 963 F.2d 918 (7th Cir. 1992).

"[t]he suspension or delayed implementation of a final regulation normally constitutes substantive rulemaking under APA § 553." 716 F.2d at 920. "Thus, on its face, the suspension of the [regulation] was subject to APA notice and comment provisions." *Id.* The court then rejected EPA's argument that the "good cause" exception to the notice-and-comment requirements was met because immediate action was needed to avoid purported harms from regulations that the new Administration intended to eliminate. The court reiterated that "such exceptions to notice and comment procedures will be narrowly construed and only reluctantly countenanced," and held that "[t]he justifications for the exception are not 'escape clauses' that may be arbitrarily utilized at the agency's whim" and that "use of the exception should be limited to emergency situations." *Id.* (citations omitted). Gauged against those standards, the court found that the exception did not apply. *Id.* at 921.

The D.C. Circuit also reached the same conclusion in the *Gorsuch* case. As explained above, *Gorsuch* involved regulations that President Carter's EPA had issued in January 1981, to take effect six months later, containing performance standards for the issuance of permits for incinerators and storage surface impoundments. 713 F.2d at 807. Upon taking office, the Reagan Administration unilaterally suspended implementation of the regulations and refused to process any permits under their standards. *Id.* at 808. Rejecting the new Administration's position, the court held that "an agency decision which effectively suspends the implementation of important and duly promulgated standards . . . constitutes rulemaking subject to notice and comment requirements of 5 U.S.C. § 553." *Id*. at 814-18. And the court approvingly discussed the Third Circuit's opinion in *Natural Resources Defense Council, Inc. v. EPA*, 683 F.2d 752, 761 (3d Cir. 1982), which held that any agency's "action in indefinitely postponing the effective date of [certain amendments to regulations] fit the

definition of 'rule' in the APA, and, as such, was subject to the APA's rulemaking requirements."[19] See also *National Family Planning & Reproductive Health Ass'n v. Sullivan*, 1992 U.S. Dist. LEXIS 9421, at *7-9 (D.D.C. July 1, 1992) (suspension of published regulations violated APA notice and comment requirements); *National Wildlife Fed'n v. Mosbacher*, 1989 U.S. Dist. LEXIS 9748 (D.D.C. Aug. 11, 1989) (same); Congressional Testimony of University of Texas Law Professor Tom McGarity (Exhibit 43).

In short, the D.C. Circuit has ruled that a new Administration cannot simply suspend a final regulation that was promulgated through notice and comment rulemaking -- and, indeed, that such a course lacks any substantial legal justification and will subject the government to an award of attorney's fees under the EAJA. That principle is dispositive here. The *Guidelines* were published in final form following completion of notice and comment rule-making procedures under the APA. Rather than implementing the *Guidelines*, however, the defendants unilaterally suspended all activity under the *Guidelines*, canceling the scheduled meeting at which the first set of applications were to be reviewed and refusing to undertake any other steps to process applications. Because the *Guidelines* can be changed or repealed only through the APA notice and comment process, and because that process has not been performed (or even begun), defendants' failure to implement the *Guidelines* plainly violates the APA.[20]

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[19] Like the D.C. Circuit in *EDF v. EPA*, the Third Circuit's *NRDC* opinion rejected the government's argument that "good cause" existed for suspending the regulations while the new Administration reviewed the regulations' impact. See 683 F.2d at 764-67.

[20] As the D.C. Circuit's decisions in *EDF v. EPA* and *Gorsuch* make clear, the "good cause" exception in § 553(b)(3)(B) of the APA, which is "limited to emergency situations," does not apply simply because a new Administration intends to repeal its predecessor's published rule. Moreover, § 553(b)(3)(B) provides that an agency purporting to act under the good cause exception must publish a reasoned finding of good cause, which defendants have not done here either.

For these reasons, plaintiffs are entitled to summary judgment declaring that NIH's suspension of the *Guidelines* is unlawful under the APA.

III. DEFENDANTS' IMPOSITION OF A MORATORIUM ON HPSC RESEARCH VIOLATES THE NIH REVITALIZATION ACT

As described above, the NIH Revitalization Act of 1993 bars the executive branch from (1) imposing any policy prohibiting support for research on the transplantation of human fetal tissue or (2) withholding funding for any such research that has technical and scientific merit. The moratorium on HPSC research imposed by defendants violates both aspects of this law.

A. The Origin and Terms of the Revitalization Act.

The current dispute over the Administration's unilateral refusal to fund HPSC research brings to mind one of Yogi Berra's aphorisms, "it's deja vu all over again." As described at pages 4-6 above, the NIH Revitalization Act of 1993 was the culmination of a long debate over government funding for research relating to the transplantation of human fetal tissue. The first Bush Administration had ordered a moratorium on such research. After President Clinton took office, however, supporters of such research controlled both the White House and the Congress, and they enacted their views of this subject into statutory law. In doing so, moreover, they contemplated that the day might come when the executive branch would again be directed by a President opposed to such research, and they explicitly addressed that eventuality by prohibiting the executive branch of government from unilaterally (*i.e.*, other than with the consent of Congress by way of a new statute) imposing a new moratorium or withholding funds on such research.

Specifically, § 113(a) of the Act commands that "no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes.

Such research shall be carried out in accordance with [42 U.S.C. § 289g-1], without regard to any such policy that may have been in effect prior to the date of the enactment of this Act." Further, § 113(b), which is entitled "Prohibition against withholding of funds in cases of technical and scientific merit," directs that "in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if" the research has been approved by the normal peer-review process and will satisfy the Act's provisions requiring informed consent and prohibiting the purchase of fetal tissue. Finally, the Act defines the protected research to include cells derived from both fetuses and embryos.

By enacting these provisions, Congress and the President established an agreed status quo under which (1) the research will be funded as long as it meets the ethical limitations spelled out in the Act, and (2) neither the Congress (because of the President's veto power) nor the President (because of the § 113 provisions) can unilaterally change that status quo. As we now show, HPSC research is protected by the Act, and the defendants' unilaterally-imposed moratorium on that research therefore violates the Act.

B. HPSC Research Proposed to be Conducted by Plaintiff Researchers is Protected by the Revitalization Act

The HPSC research at issue in this case is covered by the Revitalization Act, as it (1) involves "human fetal tissue" and (2) is designed to develop and deploy transplantation therapies.

1. Human Fetal Tissue. In the Act, Congress defined "human fetal tissue" as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." 42 U.S.C. § 289g-1(g). The human pluripotent stem cells at issue in this case fall within that definition. As noted above, the pluripotent stem cell lines used by the plaintiff

researchers are based on either embryonic germ cells or embryonic stem cells, each of which is derived from a different source.

a. Embryonic germ cells. Embryonic germ cells are derived from non-living fetuses that result from terminated first trimester pregnancies. See Exhibit 23 at 10-12. Thus, they are "cells obtained from a . . . fetus after a spontaneous or induced abortion . . . ." *Id*. The HHS General Counsel specifically concluded that stem cells derived from the primordial germ cells of non-living fetuses -- such as in plaintiff Gearhart's work -- "would be considered human fetal tissue" for purposes of the Revitalization Act. Exhibit 16 at 4. Then-NIH Director Varmus testified before Congress in January 1999 that "Dr. Gearhart's work could have been supported with federal funds." Exhibit 23 at 121. The *Guidelines* agree. See Exhibit 1 at § B.2.a. And the legislative history underlying the 1993 Act looked forward to the derivation of cells from fetal tissue:

> "It is likely that alternative uses of fetal tissue for transplantation will be developed, such as established cell lines, that might obviate the need for tissue obtained directly from the fetus. . . . It is estimated that the development of these alternatives, if they are indeed possible, would take at least 10 years." S. Rep. No. 103-2 at 14 (1993), *reprinted in* 1993 U.S. Code Cong. & Admin. News 196, 210 (Exhibit 26).

In short, there is no doubt that research on stem cells derived from germ cells obtained by non-living fetuses (such as the stem cells that plaintiff Dr. Gearhart has derived and uses) falls within the Revitalization Act.

b. Embryonic stem cells. Embryonic stem cells are derived from cells obtained from excess frozen embryos. Trounson Dec. at 3 (Exhibit 34). As explained above, the Act explicitly applies to cells obtained from embryos as well as fetuses, because it defines "human fetal tissue" covered by the Act as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." That reference to embryos is, for several

reasons, properly construed to include frozen embryos that have never been implanted, such as the ones from which HPSCs are derived.

First, when the Revitalization Act was passed (and still today), HHS's human subject regulations defined "fetus" as the "product of conception from the time of implantation." 45 C.F.R. § 46.203(c). When Congress uses a term with an established regulatory meaning in place, it is presumed to intend that meaning (*Republic of Argentina v. Weltover*, 504 U.S. 607, 612-13 (1992)), and hence the word "fetus" in the Revitalization Act should be given that same meaning. And because "fetus" means everything from the time of implantation onward, it is clear that the word "embryo" must -- in order to give it meaning separate from the word "fetus"[21] – be construed to include the product of conception prior to implantation. That, in turn, means that the phrase "after a spontaneous or induced abortion, or after a stillbirth" must be read as applying only to the word "fetus," because an embryo that has never been implanted cannot be the subject of either an abortion or a stillbirth without distorting the normal meaning of the words.[22]

This interpretation is also supported by the canon of the last antecedent, under which "a subsequent modifying phrase refers solely to the last antecedent, which consists of the last word, phrase, or clause." *Murphy Exploration & Prod. Co. v. DOI*, 2001 U.S. App. LEXIS 13499, at *22 (D.C. Cir. June 19, 2001). Under that canon, the subsequent modifying phrase "after a spontaneous or induced abortion, or after a stillbirth" is properly read as applying only to the adjacent word "fetus,"

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[21] It is an "elementary canon of construction that a statute should be interpreted so as not to render one part inoperative." *Dep't of Revenue v. ACF Indus.*, 510 U.S. 332, 340 (1994) (citations omitted); see also, *e.g.*, *Colautti v. Franklin*, 439 U.S. 379, 392 (1979); *Edison Elec. Inst. v. EPA*, 996 F.2d 326, 335 (D.C. Cir. 1993).

[22] Indeed, a "stillbirth" is defined as "the birth of a dead fetus," and thus by definition applies only to fetuses, not embryos. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2243 (1986). This further confirms that the phrase applies only to fetuses.

and not to the distant word "embryo."[23] For these reasons, the Act should be construed as covering research involving cells obtained from frozen embryos that have never been implanted.[24]

This conclusion that the Revitalization Act protects research involving cells obtained from excess frozen embryos also follows from the overall purposes of the Act. Given that the Act unambiguously permits research on cells obtained from induced abortions, and given that most Members of Congress and most other people see abortion as much more controversial or problematic than discarding an excess frozen, unimplanted embryo,[25] it would be absurd to interpret the Act as protecting only cells derived from aborted fetuses and not cells derived from excess unimplanted embryos. See, *e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 429 (1998) (rejecting interpretation that "would produce an absurd and unjust result which Congress could not have intended") (citation omitted).

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[23] This conclusion is further supported by the absence of a comma between the words "fetus" and "after," since "[e]vidence that a qualifying phrase is supposed to apply to all antecedents instead of only to the immediately preceding one may be found in the fact that it is separated from the antecedents by a comma." 2A Norman J. Singer, STATUTES AND STATUTORY CONSTRUCTION § 47.33 (6th ed. 2000).

[24] Having established that the word "embryo" as used in the Act must include a frozen, unimplanted embryo, one might ask if stem cells are derived from "cells obtained from a dead human embryo" within the meaning of the Act. The answer is that they are. First, the *Guidelines* provide that the embryonic stem cells eligible for use in federally-funded research must have been derived (without federal funds) from a frozen embryo that has been previously determined by the embryo's progenitors to be in excess of any clinical need and to be slated for disposition. See Exhibit 1, § II.A.2. Because the embryo's progenitors have the sole right to determine that it will never be implanted (see note 15 *supra*), their determination to that effect -- made prior to being asked to consider donation for stem cell research -- means that the statutory definition is satisfied. Second, as a technical matter, the embryo is dead prior to the time the cells are obtained for use in the federally-funded research. The process of isolating the cells from the inner cell mass of a blastocyst is preceded by the destruction of the blastocyst's outer shell, which destroys the embryo's possible viability (even if implanted). See, *e.g.*, Trounson Dec. at 3 (Exhibit 34).

[25] For example, Medicaid does not pay for abortions but does pay for the IUD form of birth control, which is believed to work by preventing a fertilized egg from becoming implanted. See Exhibit 30. More directly, as Senator Orrin Hatch recently said, "I just cannot equate a child living in the womb, with moving toes and fingers and a beating heart, with an embryo in a freezer." NEW YORK TIMES, July 1, 2001.

2. Transplantation for Therapeutic Purposes. Given that HPSCs qualify as "human fetal tissue" under the Act, the remaining question is whether HPSC research covered by the *Guidelines* constitutes "any research on the transplantation of human fetal tissue for therapeutic purposes." The answer plainly is that it does. The HHS FACT SHEET on the *Guidelines* explains that "further research using human pluripotent stem cells may help [g]enerate cells and tissue for transplantation." Exhibit 4 at 1. Specifically, "[p]luripotent stem cells have the potential to develop into specialized cells that could be used as replacement cells and tissues to treat many diseases and conditions, including Parkinson's disease, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis." *Id*. Likewise, the NIH STEM CELL PRIMER explains that "[p]erhaps the most far-reaching potential application of human pluripotent stem cells is the generation of cells and tissue that could be used for so-called 'cell therapies,'" such as "[t]ransplant of healthy heart muscle" to treat heart disease and "transplantation of either the entire pancreas or isolated islet cells" to treat diabetes." Exhibit 24 at 3. See also, *e.g.*, Thomson Dec. at 4 (Exhibit 33) (describing potential transplantation therapies arising from stem cell research); Kaufman Dec. at 2 (Exhibit 36) (same); NIH Institute Directors testimony on April 26, 2000, at 2 (Exhibit 31) ("Pluripotent stem cells, stimulated to develop into specialized cells and tissue, offer real hope for the possibility of a renewable source of replacement cells and tissues to treat a myriad of diseases, conditions and disabilities . . . ."); NIH Institute Director letters dated May 22, 2001 (Exhibit 32) (discussing potential uses of stem cells for transplantation therapies).

Stem cell research, therefore, plainly is encompassed by the Revitalization Act's broad protection for "*any* research on the transplantation of human fetal tissue for therapeutic purposes" (emphasis added). It makes no difference that scientists are not ready to actually transplant stem cells or their products into patients today, since research "on transplantation" certainly includes the pre-

liminary research targeted at developing safe and effective transplantation therapies.[26] See Kaufman Dec. at 3-4 (Exhibit 36) (explaining why initial embryonic stem cell research is necessary to enable later transplantations). Of course it would be wholly irrational to interpret the Act as protecting the funding of actual transplantation but not the funding of the preliminary research essential to ensure that the transplants will help, not harm, patients.[27]

In sum, HPSC research constitutes "research on the transplantation of human fetal tissue for therapeutic purposes" subject to the protections of the Revitalization Act.

C. Defendants are Violating the Revitalization Act.

Given that HPSC research is protected by the Revitalization Act, it inexorably follows that defendants' suspension of the *Guidelines* and imposition of a *de facto* moratorium on stem cell research funding violates the Act in two respects. First, that suspension and moratorium constitute a "policy" under which HHS and its subordinate agencies are "prohibited from conducting or supporting" fetal tissue research -- which is precisely what § 113(a) of the Act bars the executive branch from doing. See page 5 above. Although styled as an open-ended "review" of the *Guidelines* by defendants, there can be no genuine dispute that defendants' current policy is to prohibit funding for HPSC research. Indeed, in the Stipulated Motion to Stay filed in the case of *Nightlight*

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[26] The NIH STEM CELL PRIMER explains that, prior to actual transplantation of stem cells into patients, scientists must first do further research to understand stem cell specialization and must overcome problems of immune rejection. Exhibit 24 at 3. Indeed, the Act's legislative history shows that Congress understood that transplantation therapies would require years of preliminary research and fully intended to protect that research. See S. Rep. No. 103-2, at 14 (Exhibit 26).

[27] See, *e.g.*, *RCA Global Commun., Inc. v. FCC*, 758 F.2d 722, 731-33 (D.C. Cir. 1985) (holding that "the most fundamental principles of statutory construction" forbid construing a statute to "deprive it of all substantive effect"); *Helverson v. Slater*, 129 F.3d 180, 189 (D.C. Cir. 1997) (agency is barred from adopting interpretation of section that would "deprive [it] of virtually all effect").

Christian Adoptions v. Thompson, No. 1.01CV00502-RCL in this Court (Exhibit 21), the defendants in this case explicitly agreed to

> "continue their present policy of not funding any research involving use of pluripotent stem cells derived from human embryos, including all independent investigator and intramural research. During the Review period Defendants will not evaluate the scientific merits of any applications for funding of embryo stem cell research. Similarly, during the period of Review Defendants will continue their present policy of postponing the review of compliance packages under the Guidelines. Even if the Review results in consideration of funding for pluripotent stem cell research, Defendants will not fund any such research for a period of thirty (30) days following conclusion of the Review."

This policy of prohibiting support for stem cell research plainly violates § 113(a) of the Act.[28]

Second, defendants are in violation of § 113(b) of the Act, which prohibits defendants from withholding funding for fetal tissue research that meets the Act's requirements. As noted above, defendants have terminated the entire funding process under the *Guidelines*. This is a blanket suspension of funding, without regard to whether the applications evince technical and scientific merit or not. As such, defendants are unlawfully withholding funds for research subject to the Act on grounds other than those specified in § 113(b)(1)(A)-(C).

This conclusion, finally, is confirmed by recalling that § 113 was enacted in direct response to a moratorium on research imposed administratively by the first Bush Administration. The repetition of that conduct by the new Bush Administration is, thus, unmistakably just what § 113 was enacted to prohibit.

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[28] Both the moratorium imposed during the "Review" and the additional 30 day moratorium agreed to by defendants after the conclusion of the "Review" constitute violations of the Revitalization Act.

IV. DEFENDANTS' REFUSAL TO FUND HPSC RESEARCH ALSO CONSTITUTES ARBITRARY AND CAPRICIOUS AGENCY ACTION IN VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

Even if defendants' refusal to proceed with HPSC research funding did not constitute the unlawful suspension of a published regulation -- which it does -- and even if the Revitalization Act did not flatly bar defendants from withholding funds for such research -- which it does -- defendants' refusal to fund HPSC research constitutes arbitrary and capricious action in violation of the APA and in derogation of defendants' obligations as stewards of American scientific research in support of the public health.

A. The Standards for Review of Defendants' Actions.

Section 706(2)(A) of the Administrative Procedure Act provides that agency action is to be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). There are two components to review under the "arbitrary and capricious" standard of § 706(2)(A).

First, the court must determine whether the agency has "articulated a satisfactory explanation for its action." *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) (quoting *State Farm*); *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) ("an agency must cogently explain why it has exercised its discretion in a given manner") (quoting *State Farm*, 463 U.S. at 48). More particularly, agencies are required "to explain the relationship between their action, the decisional standards in their statutes, and the data on which they base their predictions concerning the effects of their action." 1 Kenneth Culp Davis & Richard J. Pierce, Jr., ADMINISTRATIVE LAW TREATISE 316 (3d ed. 1994).

Second, the court must examine the agency's reasoning to see if it "runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. In other words, rules that are not supported by an adequate foundation should be invalidated by a court. *See Robbins v. Reagan*, 780 F.2d 37, 48 (D.C. Cir. 1985).

The court's review of these questions is particularly searching in a case like this one, because the D.C. Circuit "has long held that an agency's change in direction from a previously announced intention is a danger signal that triggers scrutiny to ensure that the agency's change of course is not based on impermissible or irrelevant factors." *Robbins, supra*, 780 F.2d at 48; *National Black Media Coalition v. FCC*, 775 F.2d 342 (D.C. Cir. 1985). NIH, as well as the National Bioethics Advisory Commission, have previously concluded that HPSC research is extraordinarily important and can be conducted in a manner that satisfies all significant ethical concerns. Defendants' reversal of that course calls for heightened scrutiny here.

In short, "[w]here the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, we must undo its action." *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) (citation omitted); accord *Independent Petroleum Ass'n of America v. Babbitt*, 91 F. Supp. 2d 117, 124 (D.D.C. 2000) (Lamberth, J.). As we now show, and particularly given the close scrutiny applicable here, the moratorium imposed by defendants must be undone for both of those reasons.[29]

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[29] In addition to setting aside agency action that is arbitrary and capricious, courts are required under the APA to set aside agency action that is not based on a permissible interpretation of the relevant statutes. See generally *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). As this Court recently wrote, "Chevron review and arbitrary and capricious review overlap at the margins." *Independent Petroleum Ass'n, supra*, 91 F. Supp. 2d at 124 (Lamberth, J.) (citation omitted). That is the case here because, under the same analysis presented

B. The Moratorium Imposed by Defendants Constitutes Arbitrary and Capricious Agency Action in Violation of the APA.

It is immediately apparent that defendants have not supplied any reasoned explanation for their refusal to implement the *Guidelines* and otherwise proceed with the funding of HPSC research. Unlike the *Guidelines*, which were accompanied by a detailed explanation, the moratorium is unexplained except for widespread press accounts that the White House has ordered the research suspended in an effort to curry political support from adherents to a particular religious faith. See Exhibits 27-29.[30] It would be hard to conceive of a more arbitrary or capricious, and otherwise unlawful, rationale for defendants' action.

It is also evident, however, that no volume of explanatory reasoning could ever justify a decision by NIH not to fund plaintiffs' HPSC research pursuant to the *Guidelines*. "[T]he starting point for this court's review of the validity of the [agency action] must begin with the relevant governing statutes" (*Independent Petroleum Ass'n*, *supra*, 91 F. Supp. 2d at 124 (Lamberth, J.)), and there are two sets of statutes that govern defendants' actions in funding scientific research. First, under the HHS and NIH authorizing statutes, defendants' statutory duty is to fund research that,

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below, defendants' conduct also can be seen as agency action that is not based on a permissible interpretation of the NIH's authorizing statute and the 1993 Revitalization Act. This constitutes, therefore, another basis for invalidating defendants' actions at issue here.

[30] The NEW YORK TIMES reports that opposition to implementing the *Guidelines* comes from "some top presidential advisers led by Karl Rove who worry that federal support for such research will alienate conservative voters, anti-abortion groups, and the hierarchy of the Roman Catholic Church" and quotes Mr. Doerflinger as saying that "I've talked a little with Karl Rove. He is concerned about the views of the Catholic Church on these issues because Catholic voters are seen as such a swing vote in the elections." Exhibit 27. The WASHINGTON POST quoted Secretary Thompson as replying "[t]here is, you're right" when asked whether there were "strong political cross-pressures" within the Administration on proceeding with HPSC funding; and also reported that "top political adviser Karl Rove, voicing concern about the Catholic vote, has led the camp that [opposes] spending federal money on the research." Exhibit 29. The Post further quoted Secretary Thompson as saying that the Administration is looking at "of course the political questions" as well as the legal, scientific, and ethical ones. Exhibit 28.

based on scientific considerations, is best designed to understand, treat, and cure disease. Specifically, federal law provides that the Secretary of HHS and the Director of the NIH

> "shall conduct in [NIH], and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man . . . ."

42 U.S.C. §§ 241 and 282. In carrying out that mission, the Secretary and Director are authorized to "make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects . . . ." *Id.*

Under this enabling statute, it would be arbitrary and capricious -- to put it mildly -- for defendants to refuse to fund HPSC research, given the extraordinary importance and promise of that research to NIH's mission and the vital need for federal funding to fulfill that promise. As to the former point, as quoted above, the NIH's published materials acknowledge that "[h]uman pluripotent stem cells are a unique scientific and medical resource" and "hold great promise for both research and health care"; *Science* magazine called them the scientific "breakthrough of the year" in 1999; and over 100 major university presidents recently said that their discovery "may be the single most important scientific and medical breakthrough in the past decade or more." See page 2 *supra*; see also Thomson Dec. at 3-4 (Exhibit 33) (detailing therapeutic potential of stem cells); Trounson Dec. at 4-5 (Exhibit 34) (same); NIH Institute Directors testimony on April 26, 2000 (Exhibit 31) ("Research using human pluripotent stem cells holds enormous promise for advances in the prevention, treatment, and diagnosis of a vast array of diseases. Virtually every realm of medicine might be touched by this innovation."); NIH Institute Directors letters of May 22, 2001 (Exhibit 32).

As to the latter point, the AAAS has explained that "[f]ederal funding for stem cell research is necessary in order to promote investment in this promising line of research, to encourage sound public policy, and to foster public confidence in the conduct of such research" because "[r]ealizing the potential health benefits of stem cell technology will require a large and sustained investment in research" and "[t]he federal government is the only realistic source for such an infusion of funds." See page 3 *supra*. Likewise, some 80 Nobel winners recently wrote that "[f]ederal support for the enormous creativity of the US biomedical community is essential to translate this discovery -- into novel therapies for a range of serious and currently intractable diseases," and the accompanying declarations from some of the world's leading HPSC researchers make it clear that federal support is vital to HPSC research. See page 3 *supra*; see also Thomson Dec. at 5-7 (Exhibit 33); Trounson Dec. at 6-7 (Exhibit 34); Pera Dec. at ¶¶ 13-15 (Exhibit 35); Kaufman Dec. at 4 (Exhibit 36); Pedersen Dec. at ¶ 8 (Exhibit 38). In sum, defendants' refusal to fund HPSC research is contrary to the agencies' fundamental statutory missions and thus is plainly unlawful under the APA.[31]

This conclusion is further supported by the other relevant statute that should guide defendants in their actions, which is the NIH Revitalization Act. As explained above, even putting aside the point that that Act expressly forbids what defendants have done, that Act embodies a statutory policy that balanced, in the context of research using fetal tissue, the goals of promoting scientific research and avoiding incentives for increased abortions. Under that policy, Congress determined that research using fetal tissue should proceed subject to reasonable safeguards to avoid encouraging further abortions. See pages 4-6 *supra*. The *Guidelines* adopted by NIH comport with that Con-

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[31] See, *e.g.*, *American Historical Ass'n v. Peterson*, 876 F. Supp. 1300, 1320 (D.D.C. 1995) (holding that Archivist violated the APA by entering into an agreement that, contrary to the Archivist's basic statutory mission of preserving Presidential documents, transferred control of such documents to a former President).

gressional guidance by authorizing the use of HPSCs while imposing conditions to ensure that the decisions to create, and subsequently to discard, the embryo are not related to the use of the stem cells that might be derived from the embryo. See pages 8-9 *supra*.

Defendants' moratorium on HPSC research, by contrast, runs directly contrary to that statutory balance. Moreover, a moratorium on HPSC research under the *Guidelines* is wholly irrational because it will not promote the supposed goal of preventing the destruction or discarding of embryos (even assuming arguendo that were a permissible goal under the applicable statutes). As explained above, the *Guidelines* expressly require the cells to have been obtained from embryos that were created for the purpose of in vitro fertilization procedures and that have been determined to be excess of the need for which they were created, in a decisionmaking process wholly divorced from the decision to donate the embryos to research. Indeed, as observed above (note 15 *supra*), courts have held that the progenitors have the right to choose to dispose of any excess frozen embryos. Thus, there is absolutely no evidentiary (or any other) basis upon which defendants could conclude that the embryos are not simply going to be thrown away if these stem cells are not used for research. Any moratorium based on the purported goal of avoiding the destruction of embryos would therefore be unsupported by any evidence and simply irrational. Thus, for this additional reason, defendants' suspension of the *Guidelines* should be set aside as arbitrary and capricious under the APA.

CONCLUSION

Judgment should be entered in favor of plaintiffs.

Respectfully submitted,

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