ORAL ARGUMENT SCHEDULED FOR APRIL 23, 2012

Case No. 11-5241

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DR. JAMES L. SHERLEY, et al.,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, et al.,

Defendants-Appellees.

On Appeal From The United States District Court
For The District Of Columbia
1:09-cv-01575-RCL

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* Authorities upon which we chiefly rely are marked with asterisks.

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* Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, div. F,
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18B Charles Alan Wright et al., *Federal Practice and Procedure*
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Andrew Pollack, *Geron Is Shutting Down Its Stem Cell Clinical Trial*,
N.Y. Times, Nov. 14, 2011, *available at*

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Elizabeth Csaszar et al., *Rapid Expansion of Human Hematopoietic Stem Cells by Automated Control of Inhibitory Feedback Signaling*, 10 Cell Stem Cell 218 (2012) 16

James Gwartney et al., *Economics: Private and Public Choice* (2008) 27

NIH Human Embryonic Stem Cell Registry: Detailed Information for Line #147, *at* http://grants.nih.gov/stem_cells/registry/current.htm?id=490 29

Press Release, University of Michigan, *U-M Human Embryonic Stem Cell Line Placed on National Registry* (Feb. 14, 2012), *at* http://www.uofmhealth.org/news/human-embryonic-stem-cell-line-placed-on-national-registry 29, 30

Remarks of President Barack Obama—As Prepared for Delivery, Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (Mar. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/ 10

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GLOSSARY

APA	Administrative Procedure Act
hESC	Human Embryonic Stem Cells
NIH	National Institutes of Health

INTRODUCTION AND SUMMARY OF ARGUMENT

Defendants' brief is most notable for what it does *not* say. Preferring to mischaracterize this case as a replay of *Sherley II*, Defendants completely ignore the majority of Plaintiffs' arguments—especially with respect to two independent grounds for setting aside the Guidelines that were not addressed in *Sherley II*.

Perhaps most tellingly, Defendants dispute almost none of Plaintiffs' arguments that NIH violated the Administrative Procedure Act ("APA") in promulgating the Guidelines. It is *undisputed* that (1) the APA required NIH to address comments concerning the scientific and ethical merits of human embryonic stem-cell research unless the Executive Order excused it from doing so; (2) NIH failed to address thousands of such comments; and (3) the Guidelines must be vacated if NIH violated the APA in promulgating the Guidelines. Accordingly, this case involves a naked violation of the APA unless Defendants are correct that Executive Order 13,505 *required* NIH to fund human embryonic stem-cell research and somehow excused NIH from complying with its obligations under the APA. Because the Executive Order did not and could not direct NIH to ignore comments concerning the scientific and ethical merits of such research, the Guidelines must be vacated.

Additionally, Defendants essentially disregard Plaintiffs' claim—not addressed in *Sherley II*—that the Guidelines violate Dickey-Wicker because

Defendants and human embryonic stem-cell researchers knowingly subject embryos to risk of injury or death. The Guidelines violate this separate prong of Dickey-Wicker because Defendants know that federally funded human embryonic stem-cell research creates demand for additional embryonic stem-cell lines, which necessitates the destruction of more embryos, thereby subjecting those embryos to risk of injury or death. Defendants do not grapple with this argument, addressing it only in passing without citing a single case other than the decision below.

Defendants do address Plaintiffs' showing that the Guidelines unlawfully fund research in which an embryo is "destroyed." Despite asserting that *Sherley II*'s preliminary assessment of that claim is determinative, they concede that, at a minimum, their assertion contravenes the general rule that legal conclusions reached at the preliminary-injunction stage are not binding on the merits. This Court should therefore consider this issue anew, and hold that Defendants' artificial distinction between the derivation and use of human embryonic stem cells contravenes Dickey-Wicker.

For each of these three independent reasons, delineated in Plaintiffs' opening brief and discussed further below, reversal is required.

ARGUMENT

I. THE GUIDELINES MUST BE VACATED BECAUSE THEY WERE ADOPTED IN VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT.

Plaintiffs' opening brief demonstrated that NIH promulgated the Guidelines in violation of the APA. *See* Pls.Br. 42-63. By admittedly refusing to confront tens of thousands of comments addressing issues central to the rulemaking, NIH directly contravened both the APA's command to provide the public a meaningful opportunity to comment on proposed rules, 5 U.S.C. §§ 553(b)-(c), 706(2)(D), and NIH's duty to consider all relevant factors and data before taking action, *see id.* § 706(2)(A); *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148 (D.C. Cir. 2011). The Guidelines therefore must be "h[eld] unlawful and set aside." 5 U.S.C. § 706(2); *see Petrol. Commc'ns, Inc. v. FCC*, 22 F.3d 1164, 1171-73 (D.C. Cir. 1994).[1]

In their terse response to this issue, Defendants dispute almost none of Plaintiffs' arguments. Their sole defense of NIH's ostrich-like approach is that Executive Order 13,505 supposedly *required* NIH to fund human embryonic stem-cell research and thus somehow excused NIH from addressing comments concerning the scientific and ethical merits of such research. Defs.Br. 46-51. As Plaintiffs' opening brief established, Defendants' argument is both factually and

[1] All relevant statutes and regulations are reproduced in the Addendum to Plaintiffs' opening brief.

legally incorrect. The Executive Order did *not* direct NIH to ignore such comments, nor *could* it have done so. Pls.Br. 53-62. Because Defendants' only purported basis for excusing NIH's action and opposing vacatur of the Guidelines fails, the district court's judgment upholding the Guidelines must be reversed.

A. The Guidelines Undisputedly Must Be Vacated Unless The Executive Order Authorized NIH To Disregard Comments Opposing Federal Funding Of Human Embryonic Stem-Cell Research.

In defending NIH's refusal to address thousands of comments it received concerning the scientific and ethical merits of human embryonic stem-cell research, Defendants do not dispute three key premises of Plaintiffs' argument.

First, Defendants do not dispute that NIH was required by the APA to address those comments unless the Executive Order excused it from doing so. *Cf.* Pls.Br. 44-47. They do not contest NIH's obligations under the APA to consider and respond to relevant comments and objections. And, aside from the Executive Order, Defendants offer no reason why the scientific and ethical merits of human embryonic stem-cell research were not relevant to the rulemaking. They do not argue that NIH had independent authority to render comments irrelevant simply by declining to invite them; instead, they rely solely on the Executive Order. Nor do Defendants dispute that some 30,000 comments that NIH received—but ignored—raised serious, substantial questions that cast doubt on the agency's approach and warranted a response.

Second, Defendants do not dispute that NIH made no effort whatsoever to consider or respond to those comments. *Cf.* Pls.Br. 47-48. They do not contend that anything in the final Guidelines can be construed as responding even obliquely to the commenters' objections. Nor do they suggest that NIH, in formulating the Guidelines, actually considered (but failed to discuss) those comments and the evidence they presented.

Third, Defendants do not dispute in this Court that if NIH did contravene the APA in adopting the Guidelines, then the Guidelines must be set aside. *Cf.* Pls.Br. 42, 62; *see, e.g.*, *Petrol. Commc'ns*, 22 F.3d at 1171-73 (remanding to agency with instructions to vacate rule adopted without adequately considering commenters' objections). They do not contend that NIH's failure to confront a fundamental aspect of the issue could be cured by any remedy short of vacatur.

By failing to dispute any of these premises in their brief, Defendants forfeited any argument regarding them. *See, e.g.*, *Roth v. U.S. Dep't of Justice*, 642 F.3d 1161, 1181 (D.C. Cir. 2011). As a result, unless Defendants can establish that the Executive Order excused NIH's actions, the Guidelines were adopted in violation of the APA and must be vacated.

B. The Executive Order Did Not And Could Not Excuse NIH's Deliberate Disregard Of Thousands Of Relevant Comments.

Defendants have staked their entire APA case on the theory that the Executive Order required NIH to adopt rules providing for the funding of human

embryonic stem-cell research, and thus by executive fiat eliminated NIH's obligation to comply with the APA. Defs.Br. 46-51. That wager was unwise. Defendants' theory fails for at least four reasons, each set forth in Plaintiffs' brief, and none of which Defendants' brief refutes.

1. Defendants Cannot Justify NIH's Action On A Basis That NIH Did Not Rely Upon During The Rulemaking.

Defendants do not even address a threshold obstacle to their argument: They cannot argue here that the Executive Order excused NIH from addressing the comments at issue, because NIH undisputedly did not make that argument in the rulemaking. Pls.Br. 49. It is a "fundamental rule of administrative law" that "a reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). Thus, where an agency fails to address comments in adopting a rule, its litigation counsel cannot excuse that failure by asserting that the ignored comments were irrelevant, if the agency *itself* did not justify its action on that basis during the rulemaking. *See Canadian Ass'n of Petrol. Producers v. FERC*, 254 F.3d 289, 298-99 (D.C. Cir. 2001) (agency counsel could not assert reason why comments were irrelevant that was neither offered during rulemaking nor established by agency precedent). So too here, having elected (without *any* stated explanation) to disregard thousands of comments challenging the scientific

and ethical merits of human embryonic stem-cell research, NIH cannot now claim through its counsel that the Executive Order excused it from addressing those comments. Defendants offer no argument or authority to the contrary.

2. The Executive Order's Text Forecloses Defendants' Argument.

Defendants likewise fail to confront the fact that, even if their argument were properly before this Court, it is contradicted by the Executive Order's text. Pls.Br. 54-57. The Order states that NIH "*may* support and conduct *responsible*, *scientifically worthy* human stem cell research, including human embryonic stem cell research"—not that NIH "must" or "shall" support such research, or that such human embryonic stem-cell research must be deemed "responsible" and "scientifically worthy." J.A.493, §2 (emphases added). That text disproves Defendants' sole argument that the Order *required* NIH to fund human embryonic stem-cell research and that NIH would have disobeyed the Order by failing to do so. *See* Defs.Br. 46-51. An agency's decision not to fund certain research would not contravene a directive expanding its authority to *consider* funding such research. Indeed, the only affirmative command the Order *did* give NIH—directing it to issue guidance consistent with the Order's ethical-responsibility and scientific-worthiness criteria (J.A.493, §3)—shows that NIH had not only the ability, but the obligation, to assess whether human embryonic stem-cell research satisfied those criteria before deciding to fund it.

Far from refuting this straightforward textual analysis, Defendants do not even respond to it. They do not dispute that their reading of the Order requires replacing "*may*" with "must" or "shall."

Defendants' failure to reconcile their interpretation of the Order with its text is fatal, for where the text of an Executive Order is clear, it controls. *See Sea-Land Serv., Inc. v. ICC*, 738 F.2d 1311, 1314 (D.C. Cir. 1984) (holding "plain language" of Executive Order was "clear" and thus left no room for application of interpretive canon). Defendants offer no authority allowing an agency to rewrite an Executive Order's text in the guise of interpreting it in any circumstance—let alone allowing agency counsel to fabricate their own interpretation after the fact to save the agency's action from invalidity under the APA.

Even if an Executive Order's text *could* be trumped by other factors, moreover, Defendants offer no compelling reason to ignore the Order's plain language here. They do *not* defend the district court's reasoning (J.A.688) that the interpretation of the Order now advanced by NIH's counsel deserves deference under *Udall v. Tallman*, 380 U.S. 1 (1965). Indeed, they claim no deference at all. And for good reason: As Plaintiffs' brief demonstrated, even if NIH's counsel's interpretation were a plausible reading of the Order's text (and it is not), the theory of deference applied in *Udall* has no application here, and in any event *no* doctrine of deference would extend to NIH's *post hoc* rationalization offered for the first

time in litigation. Pls.Br. 58-62; *see Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988).[2]

Defendants do rely on the Executive Order's purpose, but they distort the Order's stated aim. Contrary to Defendants' description, the Order's goal was not to take the scientific and ethical merits of human embryonic stem-cell research off the table and foreclose further debate. *See* Defs.Br. 46-48, 51. Quite the opposite, it sought to eliminate political interference in the analysis of stem-cell research. *See* J.A.493, §1. To that end, it removed restrictions imposed by the prior Administration and freed NIH to determine for itself which types of stem-cell research are sufficiently "responsible" and "scientifically worthy" to merit federal funding. *Id.* §2.

It therefore makes no sense to interpret the Executive Order as imposing yet another presidential limitation—here, a mandate that one type of stem-cell research *must* receive funding because this President believes it worthwhile. Yet that is

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[2] The President's memorandum of July 30, 2009, mentioned by Defendants' *amici* has no bearing. *See* Brief of Coalition for Advancement of Medical Research *et al.* ("CAMR Br.") 25 & n.50 (discussing 74 Fed. Reg. 38,885 (July 30, 2009)). Nothing in that memorandum even purports to ratify the countertextual interpretation of the Executive Order that Defendants now advocate. And even if the memorandum *had* endorsed that interpretation and effectively modified the original Order, it could not justify NIH's action here because the memorandum was issued only *after* NIH promulgated the Guidelines (and because the President cannot authorize an agency to violate the APA).

precisely the way Defendants ask this Court to read the Order. The Order's explicit objective was to take the President's thumb *off* of the scales in NIH's assessment of the merits of various forms of stem-cell research. But in Defendants' view, the Order merely moved that thumb to the other side. Defendants' reading would thus defeat, not further, the Order's purpose.

The signing statement discussed by Defendants' *amici* does not prove otherwise. *See* CAMR Br. 24-25. Whether the President personally believes that human embryonic stem-cell research should receive support is beside the point. As the signing statement itself underscored, the Order sought to take politics out of the equation and to free agency experts to assess scientific research on its merits, unhindered by artificial limitations. *See* Remarks of President Barack Obama—As Prepared for Delivery, Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (Mar. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/ ("[P]romoting science . . . is . . . about letting scientists like those here today do their jobs, free from manipulation or coercion, and listening to what they tell us, even when it's inconvenient—especially when it's inconvenient. It is about ensuring that scientific data is never distorted or concealed to serve a political agenda—and that we make scientific decisions based

on facts, not ideology.").

For the same reason, Defendants' reliance on prior Administrations' policies is misplaced. Defs.Br. 48. The Order swept those policies aside precisely to prevent the White House's views from skewing NIH's analysis. And Defendants offer no proof that the current Administration *mandated* what past Administrations merely purported to *permit*.

Defendants' remaining argument for ignoring the Executive Order's text—that the Order left in place NIH's peer-review process for assessing individual research proposals (Defs.Br. 50)—is equally baseless. The Order did not even *mention* that process (J.A.493-94), precluding any inference that the Order itself compelled NIH to resolve all disputes concerning the merits of specific forms of stem-cell research exclusively through that process.

Defendants seize on language in the Order's boilerplate provision disclaiming any intent to alter agencies' authority or functions, but that language provides them no support. Defs.Br. 50 (quoting J.A.493, §4(b)). The provision states that "[n]othing in this order shall be construed to impair or otherwise affect" "authority granted by law to an executive department, agency, or the head thereof." J.A.493, §4(b). To the extent this provision pertains at all to NIH's ability to decline to fund certain types of stem-cell research, it shows that the Order itself had no effect, but instead left NIH's preexisting authority unchanged.

To prevail, therefore, Defendants must prove that before the Executive Order was issued, the peer-review process *already* prevented NIH from withholding support for a specific category of stem-cell research. As Plaintiffs' opening brief explained, nothing about the peer-review process deprived NIH of that authority; there is no conflict between prescribing categorical eligibility criteria up front and deciding through peer review which eligible proposals to prioritize. Pls.Br. 57. Nor can NIH plausibly argue otherwise, having exercised that authority *in this rulemaking* by deeming certain types of stem-cell research categorically ineligible for funding on ethical grounds. *Id.*; J.A.48-49. In short, neither the Order nor the existing peer-review process prevented NIH from assessing for itself the scientific and ethical merits of human embryonic stem-cell research.

3. The Guidelines Themselves Contradict Defendants' Interpretation Of The Executive Order.

Defendants also ignore the fact that NIH's own actions prove that the Executive Order left it free to consider the scientific and ethical merits of human embryonic stem-cell research notwithstanding the Executive Order. Pls.Br. 45, 57. As noted above, NIH proposed (J.A.496-97), and ultimately adopted (J.A.48-49), provisions categorically forbidding certain types of human embryonic stem-cell research on ethical grounds—including projects that involve cloning or breeding of animals, or that make use of stem cells derived from embryos for which payments

were offered. *Id.* If the President had "already made the determination to fund [human embryonic stem-cell] research" (Defs.Br. 51), those limitations would be impermissible. Plainly, therefore, NIH recognized that the Executive Order left it with discretion to determine which forms of stem-cell research should be funded as ethically responsible and scientifically worthy, and which should not.

4. If Defendants' Interpretation Of The Executive Order Were Correct, The Order Would Be Unlawful And Could Not Bind NIH.

Defendants also sidestep the fact that the Executive Order *could not* excuse NIH from considering and responding to comments addressing the merits of human embryonic stem-cell research. Pls.Br. 55. Defendants have not disputed, in this Court or below, that the President could not authorize NIH to flout the APA. *See* Defs.Br. 50; Defs.' Mot. Summ. J. 36. They assert instead that the APA does not dictate the issues relevant to a particular rulemaking, and that here the Executive Order limited those issues to bar further consideration of the merits of human embryonic stem-cell research. Defs.Br. 48, 50-51. But what the President cannot do directly, by explicitly instructing an agency to disobey the APA and disregard relevant comments, *see* 5 U.S.C. §§ 553(b)-(c), 706(2)(D), he assuredly cannot do *indirectly* by declaring an otherwise relevant threshold question closed to further debate.

Nor can the President direct an agency to act arbitrarily or capriciously. *See* 5 U.S.C. § 706(2)(A). If the President had ordered NIH to decide which research proposals to fund with a coin toss, his imprimatur would not insulate NIH's action from judicial review; the agency would be obligated to ignore his directive, and to answer to a court if it did not. *Cf. Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327-28 (D.C. Cir. 1996). So too, having instructed NIH to issue guidance addressing which types of stem-cell research satisfy the scientific-worthiness and ethical-responsibility criteria, the President could not command the agency to turn a blind eye to evidence and objections directly relevant to those criteria—action that would be equally arbitrary and capricious. *See Tesoro Alaska Petrol. Co. v. FERC*, 234 F.3d 1286, 1294 (D.C. Cir. 2000) ("The Commission's failure to respond meaningfully to the evidence renders its decisions arbitrary and capricious. Unless an agency answers objections that on their face appear legitimate, its decision can hardly be said to be reasoned."); *see also Canadian Ass'n*, 254 F.3d at 298-99; *Petrol. Commc'ns*, 22 F.3d at 1172-73.

As Defendants' counsel construe the Order, that is exactly what it purported to do. Under their interpretation, although the Order directed NIH to assess the scientific worthiness and ethical responsibility of stem-cell research projects generally, it commanded the agency to ignore those issues for one type of research—human embryonic stem-cell research—and to assume that such research

satisfied the Order's own criteria *regardless* of evidence or objections to the contrary. If the APA could be circumvented so easily, there would be nothing left of either its mandate that agencies consider and respond to relevant comments or its ban on arbitrary and capricious action. An agency's failure to assess a rule's costs and benefits seriously, *cf. Bus. Roundtable*, 647 F.3d at 1149-56, or to confront relevant objections commenters raise, *cf. Canadian Ass'n*, 254 F.3d at 298-99, could be excused simply by the President's advance permission. That is not and cannot be the law. If the Executive Order *did* direct NIH to ignore comments objecting to human embryonic stem-cell research, as Defendants contend, then it was unlawful, and NIH (which has no rulemaking authority beyond that delegated to it by Congress, and subject to the APA) was duty-bound to disobey it.

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It is undisputed that 30,000 public commenters who challenged the central premises of the Guidelines were completely shut out of the agency's notice-and-comment decision-making process. If the Guidelines are allowed to stand on the ground that the Executive Order excused NIH from complying with the APA, that statute—which is a crucially important limitation on the exercise of delegated legislative authority—will be a dead letter. And permitting NIH's litigation

counsel to rewrite the Executive Order long after the fact would set a dangerous precedent that would undermine agencies' public accountability.

That result can be easily avoided: If the Court considers Defendants' argument based on the Executive Order at all, it should interpret the Order according to its plain text and hold that it did not absolve NIH from confronting the serious objections to the scientific and ethical merits of human embryonic stem-cell research that thousands of commenters raised. And because NIH undisputedly failed to consider and respond to those objections, the Guidelines must be vacated.[3]

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[3] Defendants' counsels' effort to do what NIH neglected to do—namely, address the relative scientific merits of different types of stem-cell research—is not only too late but also is inaccurate. Although counsel refer to "[t]wo studies" in which human embryonic stem cells were used to treat "patients with serious eye diseases" (Defs.Br. 9), these studies involved only two patients, and the cited report conceded that "we do not know . . . whether any of the visual gains we have recorded were due to the transplanted cells, the use of immunosuppressive drugs, or a placebo effect." Steven D. Schwartz et al., *Embryonic Stem Cell Trials for Macular Degeneration: A Preliminary Report*, The Lancet, Jan. 23, 2012, at 1, 2, 7, *available at* http://download.thelancet.com/flatcontentassets/pdfs/S0140673612600282.pdf. And, contrary to the assertion that it has "been difficult to grow large quantities of adult stem cells in cell culture" (Defs.Br. 5), a laboratory has successfully expanded human hematopoietic stem cells. Elizabeth Csaszar et al., *Rapid Expansion of Human Hematopoietic Stem Cells by Automated Control of Inhibitory Feedback Signaling*, 10 Cell Stem Cell 218, 218-29 (2012). Moreover, "[t]he company conducting the world's first clinical trial of a therapy using human embryonic stem cells" has announced it is "halting that trial and leaving the stem cell business entirely." Andrew Pollack, *Geron Is Shutting Down Its Stem Cell Clinical Trial*, N.Y. Times, Nov. 14, 2011, *available at* http://www.nytimes.com/2011/11/15/business/geron-is-shutting-down-its-stem-cell-clinical-trial.html. Meanwhile, Defendants have

II. THE GUIDELINES VIOLATE THE DICKEY-WICKER AMENDMENT BY FUNDING RESEARCH IN WHICH AN EMBRYO IS DESTROYED OR KNOWINGLY SUBJECTED TO RISK OF INJURY OR DEATH.

A. The Panel Is Not Bound By *Sherley II's* Preliminary Assessment Of Plaintiffs' Claim That The Guidelines Fund Research In Which An Embryo Is "Destroyed."

It is black-letter law that a court's assessment of likelihood of success at the preliminary-injunction stage is not binding in future phases of the case. *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981) ("[C]onclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits."). Consequently, the divided *Sherley II* ruling, which vacated a preliminary injunction, does not prevent this Court from holding now that the Guidelines violate Dickey-Wicker's "destroyed" prong.

To circumvent this basic rule of law, Defendants first distort the issues before this Court. Defendants claim that "Plaintiffs offer no arguments or evidence not previously presented to this Court." Defs.Br. 38. This is simply inaccurate. Plaintiffs present two separate Dickey-Wicker arguments in this appeal: one regarding Dickey-Wicker's "destroyed" prong, and one regarding its "knowingly subjected to risk" prong. *Sherley II* explicitly declined to adjudicate the

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[Footnote continued from previous page]

completely failed to rebut Plaintiffs' showing about the ever-growing successes for thousands of patients provided by ever-expanding adult-stem-cell treatments. Pls.Br. 7-8; J.A.59; J.A.132.

"knowingly subjected" argument (J.A.525), and Plaintiffs present a fuller version of that argument here, buttressed by new evidence offered in supplemental briefing in the district court following *Sherley II*. *See* Pls.Br. 24-32 (citing J.A.543-47). Even if law-of-the-case principles were applicable to Plaintiffs' arguments on the "destroyed" prong, which they are not, they could not possibly apply to Plaintiffs' arguments on the "knowingly subjected to risk" prong, which were never addressed by this Court.

Defendants' legal arguments are red herrings. Defendants quote this Court's observation in *LaShawn A. v. Barry* that "the same issue presented in a later case in the same court should lead to the same result." 87 F.3d 1389, 1393 (D.C. Cir. 1996) (en banc) (emphases omitted). But *LaShawn* was not a preliminary-injunction case; it held only that a panel's jurisdictional holding in an appeal from a *final* judgment bound a subsequent panel hearing a subsequent appeal in the same case. Defendants' reliance on *Pepper v. United States*, 131 S. Ct. 1229 (2011), is also misplaced; that criminal case held that when a sentence imposed by a trial judge is completely overturned on appeal, the trial judge on resentencing is not bound by any prior determinations made with respect to departures from the Sentencing Guidelines. These cases cast no doubt on the Supreme Court's clear

statement in *Camenisch* that a ruling in a preliminary-injunction appeal is not binding in a subsequent appeal on the merits.[4]

Tellingly, by admitting that "the law of the case doctrine generally does not preclude reconsideration of a decision rendered on a preliminary injunction appeal" (Defs.Br. 39), Defendants effectively concede that, at a minimum, their position contravenes the general rule. And the authority Defendants cite for their characterization that this is only "generally" the rule, *Berrigan v. Sigler*, did not qualify its conclusion with the term "generally." 499 F.2d 514 (D.C. Cir. 1974). Instead, this Court stated categorically that "[t]he decision of a trial or appellate court whether to grant or deny a preliminary injunction does not constitute the law of the case for the purposes of further proceedings and does not limit or preclude the parties from litigating the merits." *Id.* at 518. *Berrigan* thus supports Plaintiffs' position, not Defendants'. Nor does Defendants' qualification draw any support from *Camenisch*'s statement that "'it is *generally* inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the

[4] The same flaw plagues Defendants' invocation of *LaShawn*'s discussion of "law of the circuit." In addition, the "law of the circuit" principle is motivated merely by the rule that "only the en banc court can overrule circuit precedent." 18B Charles Alan Wright et al., *Federal Practice and Procedure* § 4478.2, at 727 (2d ed. 2002). That is not a concern here, because, as stated above, the preliminary-injunction ruling is not binding.

merits.'" Defs.Br. 41 (quoting *Camenisch*, 451 U.S. at 395 (emphasis added by Defendants)). That statement addresses only the appropriate *remedy*.

Defendants next provide a lengthy string-cite of cases purporting to apply law-of-the-case doctrine in preliminary-injunction cases. Notably, however, they do not cite a single D.C. Circuit case. That is because this Court has consistently followed *Camenisch*'s clear statement that "conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits." 451 U.S. at 395; *Cmty. Nutrition Inst. v. Block*, 749 F.2d 50, 56 (D.C. Cir. 1984) ("[A] tentative assessment made to support the issuance of a preliminary injunction pending resolution of the issue . . . is not even law of the case, much less res judicata in other litigation.") (Scalia, J.); *see Belbacha v. Bush*, 520 F.3d 452, 458 (D.C. Cir. 2008) ("An order denying preliminary relief, however, does not constitute the law of the case, although it can be persuasive.") (quotation marks omitted); *Berrigan*, 499 F.2d at 518 (rulings have effect only to the extent they are "persuasive").[5]

Defendants ultimately fall back on the argument that this Court should apply law-of-the-case principles because this Court's earlier decision is "'persuasive'"—

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[5] Indeed, even some of the cases cited in Defendants' lengthy string-cite recognize that determinations at the preliminary-injunction stage are not always law of the case. *E.g.*, *ACLU v. Mukasey*, 534 F.3d 181, 187-88 (3d Cir. 2008).

the standard stated in *Berrigan*. Defs.Br. 41 (quoting *Berrigan*, 499 F.2d at 518). But that means that *Sherley II* controls only to the extent the panel concludes it is "persuasive"—and, as explained in Plaintiffs' opening brief and below, it is not. The law-of-the-case doctrine thus does not bar consideration of any of Plaintiffs' arguments.

B. The Guidelines Violate The Dickey-Wicker Amendment By Funding Research In Which Embryos Are Destroyed.

Defendants labor mightily to distort the plain language of the Dickey-Wicker Amendment, but cannot escape the fact that human embryonic stem-cell research involves the destruction of human embryos. Without addressing most of Plaintiffs' arguments, Defendants urge this Court to divorce the experimental use of stem cells from the antecedent and inextricably linked act of stem-cell derivation—in which human embryos are destroyed—by defining "research" in a way that defies both common practice and common sense.

Defendants' arguments reduce essentially to the following: (1) Although Dickey-Wicker proscribes "research in which . . . embryos are destroyed," the term "research" refers only to the immediate use of stem cells funded by NIH, not to any preparatory research, such as stem-cell derivation; and (2) human embryonic stem-cell research itself does not offend the statute because "an embryonic stem cell is not an 'embryo.'" Defs.Br. 31-32. These arguments ignore the realities of human embryonic stem-cell research and the critical fact—which Defendants

concede—that "all embryonic stem cell research involves the destruction of embryos at some point in the cells' derivation." *See* Defs.Br. 41, *Sherley I*.

To avoid a common-sense reading of the statute, Defendants suggest that Congress's use of the present tense—prohibiting "research *in which* a human embryo or embryos *are* destroyed"—means that Dickey-Wicker does not bar funding for research on previously derived stem-cell lines and that derivation is simply not a part of the "research" process. Defs.Br. 36-37, 42-43 (emphasis added by Defendants). But this ignores Plaintiffs' extensive arguments addressing these very issues—namely, that (1) Defendants' present-tense theory rests on the false premise that derivation of human embryonic stem cells occurs prior to *commencing* "research"; (2) where "the context indicates otherwise," present-tense usage does not exclude past conduct; and (3) Defendants' own regulations treat stem-cell derivation as part of the "research" process. *See* Pls.Br. 16-24. Defendants also ignore the argument, bolstered by a Supreme Court case decided after *Sherley II*, that a present-tense verb may refer to a previous point in time when "absurd results" would follow from interpreting the present-tense verb as a reference to only current activity. *See McNeill v. United States*, 131 S. Ct. 2218, 2221-24 (2011).

Moreover, Defendants offer no plausible response to Plaintiffs' showing that Dickey-Wicker's adoption of the standard of risk from the Human Subject

Protection Regulations incorporated the attendant definition of "research." *See* Defs.Br. 42-43. Dickey-Wicker expressly forbids research posing a risk to embryos "greater than that allowed for *research* on fetuses in utero under 45 C.F.R. 46.204(b)." Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, div. F, § 508(a)(2), 125 Stat. 786 (2011) (emphasis added). By incorporating § 46.204(b)'s standard of risk for "research on fetuses in utero," the statute necessarily incorporates the definition of "research" used in those regulatory provisions. *See Sherley v. Sebelius*, 644 F.3d 388, 402 & n.1 (D.C. Cir. 2011) (Henderson, J., dissenting). Those regulations define "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d). Consistent with that interpretation of the term by Defendants, "research" is a holistic process that encompasses preliminary phases such as "development" and subsequent phases like "testing" and "evaluation."

The Guidelines themselves belie Defendants' attempt to distinguish stem-cell derivation from "research." The section of the Guidelines stating that derivation may not be funded by the federal government, for example, is entitled "Other *Research* Not Eligible for NIH Funding." J.A.49 (emphasis added). Additionally, as Defendants acknowledge, the Guidelines regulate *which human embryos* may be acquired for derivation and destruction, and require researchers to

verify the source of their stem-cell lines as a condition of receiving federal research funds. *See* Defs.Br. 34-35 (citing J.A.48). As the *Sherley II* panel recognized, "it is clear the NIH treats the act of derivation as 'research.'" J.A.521.

Finally, Defendants offer no answer to Plaintiffs' argument that Dickey-Wicker's structure suggests Congress intended to broadly prohibit any research involving the destruction of human embryos. *Cf.* Pls.Br. 18-19.[6] Nor do Defendants offer any meaningful response, let alone authority, to rebut Plaintiffs' point that NIH cannot claim deference because it is not the only agency charged with administering the statute. *See* Pls.Br. 42; Defs.Br. 37 n.4.

C. The Guidelines Violate Dickey-Wicker Because Defendants And Human Embryonic Stem-Cell Researchers Knowingly Subject Embryos To Risk Of Injury Or Death.

Plaintiffs' opening brief established that human embryonic stem-cell research also violates the third prong of Dickey-Wicker, which prohibits funding of "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. 46.204(b)." § 508(a)(2). The Guidelines violate this third prong because Defendants know that human embryonic stem-cell research creates

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[6] Defendants also fail to respond to Plaintiffs' and *amici*'s showing that the legislative history of Dickey-Wicker indicates that Congress intended to prevent federal funding for human embryonic stem-cell research. *See* Pls.Br. 37; Brief for *Amici Curiae* Robert George and Other Scholars 13-28.

demand for additional embryonic stem-cell lines, which necessitates the destruction of more embryos, thereby subjecting those embryos to risk of injury or death.

Under the regulations incorporated into Dickey-Wicker, if research subjects embryos to even a "minimal" risk of injury, that research cannot be federally funded. Pls.Br. 26. The undisputed record evidence shows that NIH anticipated the need for additional embryonic stem-cell lines once federal funding became available, by creating a registry of stem-cell lines and "articulat[ing] requirements" to govern all "future embryo donations [for research] in the United States." J.A.46; *see* J.A.482; J.A.286. Defendants' indisputable knowledge that their federally funded research was subjecting embryos to risk is all that is required to violate the statute.

Defendants do not contest that "to satisfy prong three of Dickey-Wicker, it is enough that Defendants or researchers *understand* that their actions will result in an increased risk of harm to embryos." Pls.Br. 25 (emphasis added). Nor do they dispute that the risk to embryos must not be more than "minimal"—that is, "'not greater . . . than [risk] ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.'" Pls.Br. 26 (quoting 45 C.F.R. § 46.102(i)). And Defendants do not even address the evidence Plaintiffs cited showing that Defendants knew they were encouraging the

destruction of additional embryos by promulgating the Guidelines, and that researchers view the availability of federal funding as an incentive to derive additional stem-cell lines with new characteristics. *See* J.A.544-45; J.A.546-47.

Rather, Defendants' entire response to Plaintiffs' risk-of-injury analysis—an issue this Court explicitly reserved in *Sherley II* and has never decided—consists of a terse discussion that fails to cite a single case other than the decision below. *See* Defs.Br. 43-45. Defendants principally rely on the district court's statement that the statutory phrase "in which" "restrict[s] the types of research for which funding is prohibited to research that knowingly subjects a human embryo or embryos to risk of injury or death *within* the research." Defs.Br. 44 (quoting J.A.680-81). But Defendants ignore Plaintiffs' demonstration that "the phrase 'knowingly subjected to risk' does not impose a physical-presence requirement," in light of the ordinary meaning of "knowingly subjected." Pls.Br. 31.

The term "knowingly," Plaintiffs explained, merely requires an awareness that a particular consequence is likely to follow from one's actions. Pls.Br. 25 (citing case law interpreting word "knowingly"). "Subjected," in turn, means "to make liable," "predispose," "cause to undergo or submit to," or "expose." *Id.* at 31. Thus, the embryo "knowingly subject[ed]" to risk need not be the same one that was destroyed to create the stem cell used during a particular experiment. Rather, it is enough that the government and researchers are aware that federally

funded human embryonic stem-cell research incentivizes the destruction of more embryos to create more stem-cell lines to obtain further federal funding for additional research. Indeed, Defendants offer no response to Plaintiffs' showing that scientists have indicated interest in conducting federally funded research on additional lines with different genetic properties. Pls.Br. 28-29. All that is required to violate Dickey-Wicker is the awareness of the risk to embryos created by this market, not the actual realization of injury or death during any particular human embryonic stem-cell experiment.

Defendants' counsel (with no support in the Guidelines) also implausibly challenge the factual premise that the Guidelines do not provide an incentive to destroy additional embryos. Defs.Br. 45. But the Guidelines on their face state that their goal is "ensuring that the greatest number of ethically derived hESCs are eligible for Federal funding." J.A.46 (emphasis added). Defendants would have the Court believe that the Guidelines have *no* effect on whether additional human embryonic stem-cell lines will be derived in the first place. Defs.Br. 45. This violates the plain language of their own Guidelines, as well as common sense and basic economic principles. *E.g.*, James Gwartney et al., *Economics: Private and Public Choice* 101-03 (2009) (subsidies increase quantity demanded, absent fully inelastic demand). It also violates the principle that the government cannot defend regulation on the basis that it will not have its natural and intended effect—here, to

provide an incentive and regulatory framework for the donation of embryos and derivation of "the greatest number" of stem-cell lines. *See Bus. Roundtable*, 647 F.3d at 1156 (vacating SEC rule because agency's justification "is tantamount to saying the saving grace of the rule is that it will not entail costs if it is not used").

Defendants maintain that the Guidelines do not create an incentive to derive additional human embryonic stem-cell lines because "NIH funded research may use stem cell lines derived from human embryos only if the stem cell lines 'were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose'" and the donors "'gave voluntary written consent for human embryos to be used for research purposes.'" Defs.Br. 45 (quoting J.A.48). "There is no reason to conclude," Defendants argue, "that embryos donated for stem cell derivation would otherwise be implanted." Defs.Br. 45. Defendants are mistaken on multiple levels.

As an initial matter, it is not the case that, as Defendants erroneously state, "stem cell lines" are "created using in vitro fertilization" and donated by individuals via informed consent. Rather, *embryos* are created and donated in that manner. Providing federal dollars to promote the derivation of stem-cell lines may not influence the initial decision of couples to use in vitro fertilization, but it certainly will influence the decision of some couples to donate embryos to scientists for research purposes and for the scientists to seek out potential donors

and invest in derivation of additional stem-cell lines. Indeed, as chronicled in Plaintiffs' opening brief, University of Michigan researchers explicitly stated their intent to develop additional lines and "to submit the lines to [NIH] for inclusion in the national registry of human embryonic stem cell lines that are eligible for federal research funding." J.A.545-46 (internal quotation marks omitted). This has now come to pass: In February 2012, NIH approved a new human embryonic stem-cell line derived by University of Michigan researchers in October 2010, more than a year after promulgation of the Guidelines. Press Release, University of Michigan, *U-M Human Embryonic Stem Cell Line Placed on National Registry* (Feb. 14, 2012), *at* http://www.uofmhealth.org/news/human-embryonic-stem-cell-line-placed-on-national-registry (also noting that the University has submitted two additional lines to NIH and expects "soon" to submit eight additional lines); NIH Human Embryonic Stem Cell Registry: Detailed Information for Line #147, *at* http://grants.nih.gov/stem_cells/registry/current.htm?id=490 (last visited Mar. 10, 2012).[7]

[7] Defendants assert that Plaintiffs' "theory of causation is attenuated in the extreme" because human embryonic stem cells would be derived from embryos even in the absence of federal funding. Notably, Defendants cite *no* evidence for that assertion. Nor do they cite *any* evidence supporting their view that stem-cell lines derived after promulgation of the Guidelines were not even "minimally" caused by the Guidelines, despite Plaintiffs' citation to an explicit statement by University of Michigan researchers to that effect. Defendants'

What is more, Defendants' insistence that donated embryos might not "otherwise be implanted" is speculative and irrelevant. It is speculative because embryos can be stored for years, even decades, before being implanted and carried to term by their biological or adoptive mothers. It is irrelevant because Dickey-Wicker is violated regardless of whether embryos would otherwise be implanted or carried to term. The relevant question is whether the embryos *themselves*—not a hypothetical future fetus or newborn—are subjected to more than "minimal" risk by the Guidelines. Since the Guidelines pose more than "minimal" risk to the embryos by incentivizing their destruction, the Guidelines contravene Dickey-Wicker, and must be struck down.

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amici observe that most of the lines on the NIH Registry were created before President Obama's Executive Order. But at least three were created after it (Defs.' Mot. Summ. J. 26; Press Release, University of Michigan, *supra*), despite the relatively short amount of time that has elapsed since the Guidelines were promulgated.

CONCLUSION

For these reasons and those set forth in Plaintiffs' opening brief, this Court should reverse the judgment below and remand with directions to enter summary judgment for Plaintiffs.

Respectfully submitted,

Dated: March 12, 2012

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CERTFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,876 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and D.C. Circuit Rule 32(a)(1).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman type.

Dated: March 12, 2012

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of March, 2012, I electronically filed the foregoing Appellants' Reply Brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system.

Service was accomplished on the following persons on this 12th day of March, 2012, by the appellate CM/ECF system:

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