



**TABLE OF CONTENTS**

	<b><u>Page(s)</u></b>
Preliminary Statement .....	1
Background .....	1
Discussion .....	4

**TABLE OF AUTHORITIES**

<b><u>Cases</u></b>	<b><u>Page(s)</u></b>
<i>Barnhart v. Walton</i> , 535 U.S. 212 (2002) .....	3, 10
<i>Carr v. United States</i> , 130 S. Ct. 2229 (2010) .....	6
<i>Chevron U.S.A., Inc. v. Natural Res. Def. Council</i> , 467 U.S. 837 (1984) .....	1, 2
<i>Sherley v. Sebelius</i> , — F.3d —, 2011 WL 1599685 (D.C. Cir. Apr. 29, 2011) .....	<i>passim</i>
<i>United States v. Alston-Graves</i> , 435 F.3d 331 (D.C. Cir. 2006) .....	9
 <b><u>Statutes and Regulations</u></b>	
Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81 (2009) .....	1, 4
Pub. L. No. 112-10, Div. B, §§ 1101, 1104, 125 Stat. 38, 102-03 (2011) .....	2
74 Fed. Reg. 32,170 (July 7, 2009) .....	2, 3, 6, 7
 <b><u>Miscellaneous</u></b>	
S. Rep. No. 111-66 (Aug. 4, 2009) .....	10

## PRELIMINARY STATEMENT

On appeal from a prior order in this case, the D.C. Circuit has held that NIH has reasonably interpreted the Dickey-Wicker Amendment to permit the funding of human embryonic stem cell (“hESC”) research. *Sherley v. Sebelius*, — F.3d —, 2011 WL 1599685 (D.C. Cir. Apr. 29, 2011). This Court has permitted the parties to submit supplemental briefs addressing their summary judgment motions “in light of the D.C. Circuit’s opinion.” Dkt. 78 at 1. Because the reasoning of the court of appeals’ opinion conclusively resolves plaintiffs’ claim under Dickey-Wicker, summary judgment should be awarded in favor of defendants.

## BACKGROUND

When it granted plaintiffs’ motion for a preliminary injunction, this Court reasoned that they were likely to succeed in their claim that NIH had violated Dickey-Wicker by issuing the 2009 Guidelines governing the funding of hESC research projects. The court of appeals disagreed, and reversed. It held that NIH’s interpretation of Dickey-Wicker was entitled to deference “under the familiar two-step framework” of *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). *Sherley*, slip op. at 10.

Under the first step of the *Chevron* test, the court looked to whether Congress had “directly spoken to the precise question at issue” in the text of Dickey-Wicker, and held that Congress had not done so. The statute provides that NIH may not use appropriated 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 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81 (2009). The court of appeals held

that the Amendment does not unambiguously bar funding for hESC research, even though hESCs are derived from embryos, “because Dickey-Wicker is written in the present tense, addressing research ‘in which’ embryos ‘are’ destroyed, not research ‘for which’ embryos ‘were destroyed.’” Slip op. at 11.<sup>1</sup> The court held that this language could be read to require NIH to “determine whether what is proposed to be funded meets with [Dickey-Wicker’s] requirements.” *Id.* Under this reading, “a grant application to support research that includes the derivation of stem cells would have to be rejected,” *id.*, but NIH would not be required to treat the research for which the funds are sought to include “acts or processes, such as deriving [hESCs], that predated the federally funded research,” *id.* at 11 n.\*. The court of appeals accordingly rejected plaintiffs’ claim that the derivation of an hESC line necessarily is part of later “research” that uses that hESC line. “The definition of research is flexible enough to describe either a discrete project or an extended process, but this flexibility only reinforces our conclusion that the text is ambiguous.” *Id.* at 12.

Under the second step of the *Chevron* test, the court of appeals held that NIH had reasonably interpreted the use of the term “research” in Dickey-Wicker, and so sustained that interpretation. When it published the Guidelines at issue in this case, NIH reasoned that “hESCs are not embryos as defined” by the Amendment, and that the statute “recognize[d] the distinction . . . between the derivation of stem cells from an embryo that results in the embryo’s destruction, for which Federal funding is prohibited, and research involving hESCs that does not involve an embryo nor result in an embryo’s destruction, for which Federal funding is permitted.” 74 Fed. Reg. 32,170, 32,173 (July 7, 2009). The court of appeals held that NIH had reasonably read the statute to distinguish between the derivation of hESCs and later research involving hESCs:

---

<sup>1</sup> Appropriations for the current fiscal year remain subject to the terms of the Dickey-Wicker Amendment. Pub. L. No. 112-10, Div. B, §§ 1101, 1104, 125 Stat. 38, 102-03 (2011).

[NIH's interpretation] is surely as sensible as the plaintiffs' alternative, in which the derivation of a cell line is deemed part of every one of the scores if not hundreds of subsequent research projects – although pursued by different scientists, perhaps many years later – to use one of the derived cells. To define derivation as “research,” in other words, makes at least as much sense as to treat the one-off act of derivation as though it had been performed anew each time a researcher, however remote in time or place, uses a stem cell from the resulting line.

Slip op. at 15.

The court also held that NIH had reasonably interpreted the term “research” in light of its surrounding terms in Dickey-Wicker:

Broadening our focus slightly, however, we can see the words surrounding “research” in the statute support the NIH's reading. Because the Congress wrote with particularity and in the present tense – the statute says “in which” and “are” rather than “for which” and “were” – it is entirely reasonable for the NIH to understand Dickey-Wicker as permitting funding for research using cell lines derived without federal funding, even as it bars funding for the derivation of additional lines.

Slip op. at 15-16.

Finally, the court of appeals held that Congress had ratified NIH's interpretation. It noted that Congress had reenacted the statute annually without change ““with full knowledge that HHS has been funding [ESC] research since 2001.”” Slip op. at 16, quoting 74 Fed. Reg. at 32,173. Congress's reenactment of the statute provided ““further evidence . . . [it] intended the Agency's interpretation, or at least understood the interpretation as statutorily permissible.”” *Id.*, quoting *Barnhart v. Walton*, 535 U.S. 212, 220 (2002) (court of appeals' alterations). On this score, the parties had disputed whether NIH had a “longstanding” interpretation of Dickey-Wicker to which Congress had deferred. The court of appeals held that this dispute was immaterial: “[T]his is not a situation in which we are asked to infer the Congress's assent from its inaction over a long period. Regardless how much time has passed, reenactment is evidence the Congress approves the agency's application of the statute.” Slip op. at 16-17 n.\*.

The court of appeals noted that plaintiffs had also argued that the funding of hESC research violates Dickey-Wicker because that funding “creates demand for human embryonic stem cells,” and that demand would require the destruction of more embryos. Slip op. at 18. The court expressed its doubt that this argument was distinct from plaintiffs’ primary statutory interpretation argument, but declined to resolve the issue, since this Court had not based its preliminary injunction on that theory. *Id.* For the same reason, the court of appeals declined to consider plaintiffs’ argument that NIH had violated the Administrative Procedure Act. *Id.* at 19.

### **DISCUSSION**

The court of appeals has conclusively resolved the primary claim that plaintiffs have advanced in this case. The court held that Dickey-Wicker is ambiguous, and that NIH had reasonably read the statute to permit the funding of hESC research but to forbid funding for the derivation of hESCs. Plaintiffs, presumably, will now switch gears and advance an alternative theory that Dickey-Wicker forbids any actions that “incentivize” the destruction of embryos.

Their argument runs as follows: “Misled by NIH’s imprimatur on hESC research and by inaccurate media portrayals of promised dramatic cures, some parents will inevitably view donation for research as a worthy cause even though they would be unwilling simply to discard living embryos, and the Guidelines unquestionably place such embryos at risk.” Pls.’ Reply in Supp. of Mot. for Summ. J. at 14-15, Dkt. 70. Because the Guidelines endorse a message that hESC research is worthwhile, plaintiffs reason, any research funded under the Guidelines is “research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death” greater than that allowed in the referenced statute and regulation addressing research involving fetuses in utero. Pub. L. No. 111-117, Div. D, § 509(a)(2).

Although the court of appeals did not directly dispose of this argument, it stated its doubt as

to whether “this argument is distinct from the plaintiffs’ principal argument.” *Sherley*, slip op. at 18. Its intuition was correct. Plaintiffs’ “incentivization” theory fails for the same reason that their original theory did. Whether or not plaintiffs are correct to speculate that the Guidelines or “media portrayals” will encourage patients of IVF clinics to donate embryos, that donation is still not “*research in which*” an embryo is knowingly subjected to a risk of injury or death.

The court of appeals has recognized that the term “research,” as used in Dickey-Wicker, is “flexible enough to describe . . . a research project.” Slip op. at 12; *see also id.* at 15 n.\* (“[O]ur point is that ‘research,’ although susceptible to a broad definition, is also reasonably understood as a more discrete endeavor.”). And in upholding NIH’s reasonable interpretation of that ambiguous language, the court of appeals noted that Congress had chosen the phrase “in which,” rather than the phrase “for which”—a choice that Congress had made with “particularity.” Slip op. at 16. Thus, the court of appeals recognized that the term “research” may properly be read to connote a discrete research project, and that the phrase “in which” must be read in conjunction with the term “research” in order to understand the scope of the statute.

These holdings dispose of plaintiffs’ “incentivization” claim. The language on which plaintiffs rely – referring to embryos that are “knowingly subjected to risk of injury or death” – applies only to “research in which” that harm will occur. Under the court of appeals’ reading of the statute, as under NIH’s reading, funding is only barred for research projects in which an embryo is knowingly subjected to a risk of harm in the context of the embryo’s use in that particular project. After all, much as Congress chose the phrase “in which” rather than “for which,” *see* slip op. at 16, it also could have chosen the phrase “*from which*” had it meant the prohibition to extend beyond the discrete research project in question to reach any possible future incentive for destruction.

Consistent with this understanding of Dickey-Wicker, if research *actually involving* an

embryo poses risk to that embryo, such as preimplantation genetic diagnosis, then NIH does not fund the activity. *See* 74 Fed. Reg. at 32,173. Nothing in the language of the statute, however, demands that NIH look beyond the scope of the particular hESC research project in question to guess whether – ten, 25, or 100 years after that research project has concluded – someone might donate an embryo or engage in research involving embryos as a consequence of advances in scientific understanding achieved as a result of that research project.<sup>2</sup> Yet that is exactly what plaintiffs’ “incentivization” theory would demand.

The statute thus does not refer at all to embryos other than those involved in a particular research project. But even if that were not the case, plaintiffs’ fallback “incentivization” theory still could not be reconciled with the statute’s use of the term “knowingly.” Dickey-Wicker does not prohibit any chain of events that conceivably could lead to a risk of injury for an embryo; it instead prohibits funding for research in which embryos are “knowingly” subjected to a risk of injury. Plaintiffs surmise that researchers funded under the Guidelines must “know” that their research, coupled with NIH’s “imprimatur” and optimistic “media portrayals,” will cause more patients of IVF clinics to donate embryos for use in hESC research. In other words, under plaintiffs’ theory, a scientist must be engaging in “research in which” he “knowingly” subjects embryos to harm, simply

---

<sup>2</sup> The court of appeals also relied on the present tense canon to uphold NIH’s reasonable interpretation of Dickey-Wicker. The court noted that “unless the context indicates otherwise . . . words used in the present tense include the future as well as the present.” Slip op. at 11 (citing *Carr v. United States*, 130 S. Ct. 2229, 2236 (2010)). The court of appeals reasoned that this prospective focus made sense, as “NIH funding decisions are forward looking, requiring the NIH to determine whether what is proposed to be funded meets with its requirements.” *Id.* Plaintiffs may try to stretch this reference to “forward looking” decisions into an endorsement of their “incentivization” theory. But there is no dispute that Dickey-Wicker applies in the future in the same way that it does in the present; an application that proposes to use NIH funds to destroy an embryo would be denied five years from now the same way it would be denied today. Now and in the future, however, the prohibition is on funding “research in which” that harm occurs.

because he cannot disprove that his research might cause a future IVF patient to donate embryos to be used for research.

Plaintiffs' theory not only defies common sense, it ignores the safeguards that NIH incorporated in the Guidelines with respect to embryo donation. If an institution proposes research that would use hESCs that have been derived from embryos donated in the United States after the date that the Guidelines were published, it must provide assurances that the hESCs have been derived from embryos "[t]hat were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose," and "[t]hat were donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32,174. The Guidelines impose specific requirements designed to ensure that embryos are donated only with the donors' voluntary, informed consent, including the requirement that "[a]ll options" that were available at a particular facility pertaining to the embryos had been explained to the donors. *Id.*

Given these safeguards – even if the statute were read, implausibly, to require a review of the risk of injury not only to an embryo involved in a particular research project, but to any embryos in the future – plaintiffs' theory would still require them to demonstrate that researchers "know" all of the following when they proceed with NIH funds for hESC research:

- (1) NIH, in providing funding for a research project involving hESCs, creates an "imprimatur" in favor of hESC research;
- (2) that imprimatur will be coupled with "media portrayals" that portray hESC research in a positive light, and those media portrayals would not otherwise have occurred if NIH had not published Guidelines for the funding of hESC research;
- (3) patients of IVF clinics, who have created embryos for reproductive purposes but who no longer need those embryos for those purposes, will be "incentivized" by these media portrayals to give written permission to donate unused embryos for research purposes;

(4) this “incentivization” will outweigh the contrary “incentivization” that would arise from the Guidelines’ requirement that the patient be informed of all of the options, such as donation of embryos for adoption, that are available at the reproductive facility;

(5) the IVF patients would not otherwise have chosen to donate their embryos for hESC research in the absence of federal funding, given that the option to donate embryos to support privately-funded hESC research would remain even if federal funding were not available;

(6) the IVF patients would not choose to dispose of their embryos through other methods that could cause harm to those embryos; and

(7) the decision of a particular IVF patient could be traced to an “incentivization” created by a particular NIH-funded research project, and that the researcher knowingly subjects that future patient’s embryos to that risk.

Plaintiffs do not provide any evidence that any of these assumptions are true. Indeed, this Court, quite understandably, has already refused to engage in plaintiffs’ invitation to string together a chain of inferences in this manner:

The choice, however, is not simply whether to donate embryos for research or for adoption. The donors must choose between continuing to store the embryos, discarding them, donating them for research, or giving them to an adoption agency involved in embryonic adoption. This choice is *solely* within the discretion of individuals in possession of embryos that are no longer needed for reproductive purposes. By allowing funding for hESC research, the guidelines do not interfere with the discretion of potential donors.

Memorandum Opinion at 5-6, Dkt. No. 36 (emphasis added).<sup>3</sup>

To the contrary of plaintiffs’ speculative chain of inferences, almost all of the stem cell lines on the NIH registry were created from embryos donated prior to the Guidelines, when federal funding for research on new lines was not available. *See* Landis Decl. ¶ 14, Dkt. 58, Ex. A. Even in the absence of federal funding for hESC research, hESCs have been, and would continue to be, derived from human embryos. Plaintiffs’ assertion that the Guidelines somehow create a known risk

---

<sup>3</sup> This Court so reasoned in rejecting Nightlight Christian Adoptions’ claim of standing, a holding that plaintiffs did not question on appeal.

to embryos is meritless when the Guidelines do nothing to change the private sources of funding for the process of derivation. It is, accordingly, implausible to assume that a researcher “knowingly” subjects embryos to risk simply because he uses NIH funds instead of private funds for hESC research. *See United States v. Alston-Graves*, 435 F.3d 331, 337 (D.C. Cir. 2006) (“the word ‘knowingly’ ... means that the defendant realized what she was doing and was aware of the nature of her conduct and did not act through ignorance, mistake or accident”). Given the range of options that is available to potential donors, and that would be available to them with or without federal funding for hESC research, it is not plausible to read Dickey-Wicker to prohibit funding for hESC research on plaintiffs’ “incentivization” theory.

Even in the unlikely event that some particular researcher “knows” that his project will lead to additional donations of embryos for research purposes, that would not assist plaintiffs in this facial challenge to the Guidelines. As the court of appeals noted, “[t]o prevail in their challenge to the Guidelines on their face,” *i.e.*, to the entirety of NIH’s hESC funding, “they must establish that no set of circumstances exists under which the Guidelines would be valid.” Slip op. at 17 (alteration omitted). The possibility that plaintiffs “can point to a hypothetical case,” *id.*, in which a researcher might “know” that his NIH-funded project will cause more embryos to be donated for research cannot support a facial attack on the Guidelines.

Thus, NIH reasonably interpreted Dickey-Wicker to permit the funding of research using hESC lines, but not to permit the funding of the destruction of an embryo. Plaintiffs’ theory that the Guidelines “incentivize” the donation of future embryos casts no doubt on whether NIH had reasonably interpreted the statute, both because future donors would not be engaging in “research in which” an embryo is subject to a risk of injury, and because it is not plausible to claim that NIH-funded researchers “knowingly” create the incentive for future donation. Even if there were any

doubt as to whether NIH had reasonably interpreted the statute, that doubt would be resolved by Congress's ratification of that interpretation. Congress re-enacted Dickey-Wicker without change in December 2009, five months after NIH published the Guidelines. Congress was not only aware of NIH's interpretation of the statute, it specifically endorsed that reading in the Committee Reports accompanying the re-enactment. *See, e.g.*, S. Rep. No. 111-66 at 121 (Aug. 4, 2009). As the court of appeals recognized, Congress's reenactment of Dickey-Wicker "provides 'further evidence . . . [it] intended the Agency's interpretation, or at least understood the interpretation as statutorily permissible.'" Slip op. at 16, quoting *Barnhart*, 535 U.S. at 220.

Plaintiffs had argued to the court of appeals, as they have argued here, that Congress could not have ratified NIH's interpretation, because the Bush Administration had followed a policy that "in no way encouraged the destruction of embryos," and because NIH's new policy was not sufficiently long-standing to create an inference of Congressional approval. Pls.' Reply Mem. at 20, Dkt. 70. The court of appeals rejected this argument: "Regardless how much time has passed, reenactment is evidence that Congress approves the agency's application of the statute." Slip op. at 16-17 n.\*. Congress endorsed NIH's interpretation of Dickey-Wicker in the Guidelines when it re-enacted the amendment without change in 2009. That endorsement is fatal to plaintiffs' fallback "incentivization" theory, which is merely a variant of their main theory that the court of appeals has already rejected.<sup>4</sup>

---

<sup>4</sup> Plaintiffs' APA claim also remains pending. That claim lacks merit, as defendants have previously explained. NIH evaluates the relative merits of particular research proposals through the ordinary operation of its statutorily-mandated peer review process. Nothing in the APA required NIH to short circuit that process to resolve scientific questions in a rulemaking instead. The court of appeals did not address the APA claim, and this supplemental brief is limited to the effect of the D.C. Circuit's opinion on this case. Defendants accordingly refer the Court to the discussion of this claim in their previously-filed briefs. *See* Defs.' Mem. in Supp. of Mot. for Summ. J. at 33-40, Dkt. 58; Defs.' Reply Mem. at 19-24, Dkt. 73.

Dated: June 24, 2011

Respectfully submitted,

TONY WEST  
Assistant Attorney General

IAN HEATH GERSHENGORN  
Deputy Assistant Attorney General

RONALD C. MACHEN JR.  
United States Attorney

/s/ Joel McElvain

JENNIFER RICKETTS

Director

SHEILA M. LIEBER, IL Bar No. 1567038

Deputy Director

ERIC R. WOMACK, IL Bar No. 6279517

JOEL McELVAIN, DC Bar No. 448431

TAMRA T. MOORE, DC Bar No. 488392

Attorneys

United States Department of Justice

Civil Division, Federal Programs Branch

20 Massachusetts Ave., NW

Washington, DC 20001

Tel: (202) 514-4020

Fax: (202) 616-8470

*Attorneys for Defendants*