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INTRODUCTION

The NIH Guidelines for funding human embryonic stem cell (“hESC”) research are invalid because they violate the Dickey-Wicker Amendment, Pub. L. No. 111-117, § 509(a)(2), 123 Stat. 3034, 3280–81 (2009), and because they were promulgated in violation of the Administrative Procedure Act (“APA”). Plaintiffs are entitled to summary judgment on both grounds—and nothing in the D.C. Circuit’s divided opinion vacating the preliminary injunction leads to a different result. *See Sherley v. Sebelius*, No. 10-5287, ___ F.3d ___, 2011 WL 1599685 (D.C. Cir. Apr. 29, 2011). Indeed, the D.C. Circuit considered only one of Plaintiffs’ claims—namely, the argument that the Guidelines unlawfully fund “research in which a human embryo or embryos are destroyed.” It expressly declined to address two other claims, *id.* at *9, each of which independently compels summary judgment for Plaintiffs.¹

First, each time grant-awarding officials and federally funded scientists support or engage in hESC research, they “knowingly subject” human embryos “to risk of injury or death,” in violation of Dickey-Wicker. The federally sponsored hESC research that the Guidelines support inevitably creates a substantial risk—indeed, a virtual certainty—that more human embryos will be destroyed in order to derive more hESCs for research purposes.

Second, even if the Guidelines could be squared with Dickey-Wicker (which they cannot), they nevertheless must be vacated because they were promulgated in violation of the APA. Defendants concededly turned a blind eye to tens of thousands of comments challenging the ethical and scientific merits of hESC research. Defendants’ *only* excuse for their ostrich-like approach is their mistaken view that Executive Order 13,505 limited the scope of the rulemaking

¹ Although Plaintiffs’ motion for a preliminary injunction has been reinstated (with respect to claims this Court did not address) in light of the D.C. Circuit’s ruling, the parties’ summary-judgment motions are now fully briefed, and the case is ripe for final decision on the merits.

to the question of *how* hESC research should be funded, not *whether* such research should be funded. But nothing in the Executive Order prevented Defendants from deeming hESC research ineligible for federal support—and it is startling that Defendants even argue to the contrary, since the Order authorizes funding only for “responsible” and “scientifically worthy” stem cell research, and Defendants themselves echoed those criteria in the Draft Guidelines. *See* 74 Fed. Reg. 18,578, 18,578 (Apr. 23, 2009); Exec. Order 13,505, 74 Fed. Reg. 10,667, 10,667 (Mar. 11, 2009). Put simply, it was Defendants—not the Order—that took the key question off the table by short-circuiting the public-comment process and refusing to consider contrary views.

Finally, although the D.C. Circuit majority did not find a likelihood of success on the argument that the Guidelines fund research in which embryos are destroyed, this Court is not precluded from granting Plaintiffs summary judgment based on that claim, and the plain text of the statute requires invalidation of the Guidelines on that ground as well.

BACKGROUND

The D.C. Circuit expressly limited its merits analysis to Plaintiffs’ claim that the Guidelines violate Dickey-Wicker’s ban on funding “research in which a human embryo or embryos are destroyed.” *Sherley*, 2011 WL 1599685, at *9. Although the court acknowledged that Plaintiffs had “raised a ‘serious legal question’ on the merits,” *id.*, it accorded *Chevron* deference to Defendants’ cramped view of the word “research” and held that Plaintiffs were not likely to succeed on this claim, *id.* at *2, *6–8. The court declined to address Plaintiffs’ claim that the Guidelines violate Dickey-Wicker’s prohibition on funding “research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death,” because that argument had not yet been addressed by this Court. *Id.* at *9. For the same reason, the D.C. Circuit did not rule on Plaintiffs’ claim that NIH violated the APA by promulgating the Guidelines “through an inadequate notice-and-comment process.” *Id.*

ARGUMENT

I. The Guidelines Violate Dickey-Wicker Because They Fund “Research In Which” A Human Embryo Is Knowingly Subjected To Risk Of Injury Or Death.

The Dickey-Wicker Amendment prohibits NIH from funding “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) and Section 498(b) of the Public Health Service Act.” Pub. L. No. 111-117, § 509(a)(2), 123 Stat. at 3280–81. Under 45 C.F.R. § 46.204(b), such risk may be no more than “minimal.” Moreover, a person need not *intend* a consequence in order to act “knowingly”; instead, “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.” *United States v. Alston-Graves*, 435 F.3d 331, 337 (D.C. Cir. 2006) (internal quotation marks omitted). In addition, the Supreme Court recently held that a person acts “knowingly” when he acts with “willful blindness.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068–69 (2011).

By authorizing federal funding for hESC research, the Guidelines flout this requirement. They inevitably create a more-than-minimal risk that human embryos will be destroyed in order to derive more hESCs for federally funded research purposes. *See* Pls.’ Mem. 19–20 [Dkt. #55]; Pls.’ Reply 12–17 [Dkt. #70]. The Guidelines, and the research that they encourage and fund, obviously subject embryos to risk of injury or death because they use, and create demand for, hESCs that can be obtained only by destroying embryos. Part II.A of the Guidelines even details the procedures for acquiring additional embryos to be destroyed for research purposes “on or after the effective date of the[] Guidelines,” explicitly confirming Defendants’ knowledge of the destructive consequences of the Guidelines. 74 Fed. Reg. 32,170, 32,172 (July 7, 2009). What is more, Defendants admit that, as of September 2010, NIH had *already* approved for use under the

Guidelines at least two stem cell lines derived from embryos that were donated and destroyed after promulgation of the Guidelines. *See* Defs.’ Mem. & Opp. 26 [Dkt. #57–58].

The D.C. Circuit’s recent opinion casts no doubt on Plaintiffs’ “risk of injury or death” claim. *First*, the majority reasoned that the present tense of the verb “are” suggests that the statute “does not extend to past actions,” and that Plaintiffs are therefore unlikely to succeed in showing that all research depending upon *prior* derivation of hESCs is prohibited. 2011 WL 1599685, at *5. Even if the majority’s reading were correct, it would have no bearing on Plaintiffs’ “risk of injury or death” claim, which is based not on a risk caused by conduct in the past, but on a risk created in the *present*: The ongoing availability of federal funding for hESC research, and each federally funded project that requires hESCs, increases the demand for hESCs, thereby creating a substantial risk that more will be derived.

Second, the D.C. Circuit considered the term “research,” concluding that it could “describe either a discrete project or an extended process,” 2011 WL 1599685, at *6. But that conclusion does not undermine Plaintiffs’ claim based on Dickey-Wicker’s “risk of injury or death” prong. Pls.’ Mem. 19. The D.C. Circuit accorded *Chevron* deference to NIH’s alleged view of “research,” 2011 WL 1599685, at *6–8, but *Chevron* deference is plainly inapplicable to Plaintiffs’ “risk of injury or death” argument, which was never addressed by NIH and does not hinge on whether “research” describes a “discrete project” or “an extended process.” Even if “research” refers (counterintuitively) only to a “discrete project,” the ongoing funding of hESC research projects inevitably subjects embryos to risk of harm, as it means that more hESCs will be needed, and more embryos must be destroyed, to meet future demand.

Defendants’ response—that the statute is concerned only with embryos that are actually “involved” in the research that subjects them to an increased risk of harm, Defs.’ Mem. & Opp. 26; Defs.’ Reply 11 n.8 [Dkt. #73]—requires a blatant rewriting of the statutory text. Defendants’

argument depends upon adding the term “involved” as a condition for the ban in the statute. But the statute does not, as Defendants would like, specify that the embryo placed at risk must be the same embryo “involved” in the federally funded project. Rather, the statute bans federally funded research that knowingly subjects *any* embryos to risk of injury or death.

Defendants’ claim that the Guidelines do not subject additional embryos to “risk of injury or death” because new stem cell lines could be derived from embryos destroyed before the Guidelines took effect, Defs.’ Reply 12, likewise distorts Dickey-Wicker. That additional hESCs might be derived from previously destroyed embryos does not eliminate the risk that other embryos have been—and will continue to be—destroyed as a result of the Guidelines. At most, the fact that some pre-Guidelines hESCs might be used arguably helps mitigate the risk to embryos. But that is insufficient, because any risk that is more than “minimal” is too much. Moreover, many existing hESC lines derived from previously destroyed embryos are subject to narrow use restrictions or are derived because they contain unique genetic properties that are of research interest, Decl. of Dr. James L. Sherley in Support of Pls.’ Suppl. Br. ¶¶ 3–12, necessitating further embryo destruction to create hESC lines for other purposes. For example, researchers created line SIVFO17, which is in the process of being added to the NIH registry, to research a specific genetic condition—and the organization associated with this line plans to derive more disease-specific hESC lines from embryos with genetic diseases. *Id.* ¶ 9.

The same is true of Defendants’ contention that the Guidelines do not create an illegal risk because the destruction of embryos depends upon the decisions of donors. Defs.’ Reply 11–12. By making federal funding available for the use of hESC lines once they are derived, the Guidelines unquestionably increase the risk that donors will offer additional embryos to be destroyed. It defies common sense to believe that donors, promised dramatic cures from such human embryonic stem cell lines and assured (erroneously) by the NIH that such research is

ethical and beneficial, are not more likely to donate embryos for destruction under the Guidelines. *See* Br. of Amicus Curiae State of Wisconsin et al. at 16–18 (eliminating funding “inevitably would affect pending and planned research”); Br. of Amicus Curiae Regents of the Univ. of Cal. at 18–19 (same). That the risk might be greater if donors’ independent decisions were removed from the equation does not prove that the risk embryos *do* face is merely minimal.

II. Defendants Promulgated The Guidelines In Violation Of The APA.

Even if the Guidelines could be squared with Dickey-Wicker (which they cannot), they must be vacated because they were promulgated in violation of the APA. The APA undisputedly required Defendants to consider and respond to all relevant comments that, ““if adopted, would require a change in an agency’s proposed rule,”” Defs.’ Mem. & Opp. 33 (quoting *Home Box Office, Inc. v. FCC*, 367 F.2d 9, 35 n.58 (D.C. Cir. 1977)); to consider the relevant data and the important issues, *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); to articulate a sufficient explanation, *id.*; and to approach the rulemaking with an open mind, *see Fed. Express Corp. v. Mineta*, 373 F.3d 112, 120 (D.C. Cir. 2004).

Defendants did just the opposite. They *admittedly* disregarded (by deeming irrelevant) roughly 30,000 comments—60% of all comments received—that questioned the merits of hESC research based on its many ethical and scientific shortcomings. Defs.’ Mem. & Opp. 37; Defs.’ Reply 22; Defs.’ Resp. to Pls.’ Stmt. of Material Facts (“Defs.’ Resp.”) ¶¶ 37–39 [Dkt. #59]. And public statements by NIH’s then-Acting Director prove that NIH had prejudged the question whether to expand the number of stem cell lines eligible for funding. Defs.’ Resp. ¶¶ 25, 38.

Defendants’ only answer to these fatal defects—that the issue whether to fund hESC research at all was outside the rulemaking’s scope—rests entirely on the false premise that Executive Order 13,505 had already resolved that issue. Defs.’ Mem. & Opp. 34–40; Defs.’ Reply 19–24. The Executive Order did no such thing. The Order merely “remove[d]” existing

“limitations” on funding for stem cell research imposed by prior “Presidential actions.” 74 Fed. Reg. at 10,667. Importantly, it further stated that NIH “*may* support and conduct” stem cell research, including hESC research, that is both “responsible” and “scientifically worthy,” *id.* (emphasis added), thus making it NIH’s responsibility to determine which research satisfied those criteria. The Draft Guidelines themselves echo the same criteria, explaining that the Guidelines’ purpose was to ensure that NIH-funded stem cell research is “ethically responsible” and “scientifically worthy.” 74 Fed. Reg. at 18,578. It is ironic that Defendants use an Executive Order that authorized NIH to fund only scientifically worthy and ethically responsible research to excuse their utter disregard for comments that went to those precise issues.

In any event, the Order certainly did not tie NIH’s hands by commanding it to fund hESC research. Indeed, Defendants concede this very point. Defs.’ Mem. & Opp. 36 (“defendants have *not* [argued] that the [Order] directly mandated that funds be awarded for hESC research”). Because the Order admittedly did not mandate that NIH must fund hESC research, it necessarily follows that NIH did, in fact, have to resolve the question whether to fund any hESC research.

Nothing in the Order suggests that Defendants were precluded from making hESC research ineligible for federal funding. Lifting the limitations imposed by prior “Presidential actions” did not commit the agency to any particular course; it gave NIH more leeway, not less. Nor, contrary to Defendants’ claim, did the Order’s stated goal of “expand[ing] NIH support for the exploration of human stem cell research” *in general*, 74 Fed. Reg. at 10,667, compel NIH to expand or continue funding human *embryonic* stem cell research *in particular*. Defendants’ makeweight contention that the Order did not explicitly “invite[]” NIH to deny funding for certain types of research, Defs.’ Mem. & Opp. 36, also proves nothing; the Order’s command that the agency review and revise its existing guidance and procedures was invitation enough.

Defendants' rejoinder that a categorical ban on funding hESC research would have been inconsistent with NIH's statutory peer-review process for assessing funding applications, which the Executive Order purportedly "restored," Defs.' Mem. & Opp. 35–37; Defs.' Reply 19–21, is equally unfounded. Nothing in the Executive Order limited NIH to resolving all questions of which projects to fund exclusively through that *ad hoc* evaluation process (a process the Order does not even mention). Nor did the existence of a case-by-case selection process preclude NIH from placing other bright-line limitations on the research projects it will fund. Defendants fail to explain why categorical limitations and case-by-case selection cannot coexist. Indeed, like the Bush Administration policies they replaced, the Guidelines *themselves* impose categorical restrictions on which projects may receive support—for example, foreclosing federal funding for cloning or breeding animals, and prohibiting payments for donated embryos, 74 Fed. Reg. at 32,175—whether or not an expert peer-review panel would agree.

Defendants, in short, cannot hide behind Executive Order 13,505. The Order removed prior presidential restrictions and commanded—or, at the very least, permitted—NIH to determine which types of "responsible" and "scientifically worthy" stem cell research should receive federal funding. And, apart from the Order, Defendants point to nothing that prevented them from concluding that *no* hESC research meets those criteria. Consequently, Defendants had no warrant to write off as "irrelevant" all comments categorically opposing funding for hESC research because of its numerous ethical and scientific shortcomings. Defs.' Resp. ¶ 39. Dismissing such comments as "unresponsive," *id.* ¶ 38, is no better than an agency's calling only for comments in support of its proposals. The issue whether to fund any hESC research was closed to public debate only because Defendants themselves took it off the table. For that reason, the Guidelines must be vacated.

III. The Guidelines Violate Dickey-Wicker Because They Fund “Research In Which A Human Embryo Or Embryos Are Destroyed.”

Plaintiffs also are entitled to summary judgment because the Guidelines violate Dickey-Wicker’s ban on “research in which a human embryo or embryos are destroyed.” § 509(a)(2), 123 Stat. at 3280. Nothing in the D.C. Circuit’s divided ruling vacating the preliminary injunction changes this Court’s correct conclusion that Defendants’ interpretation is inconsistent with the statute’s text, structure, and common sense. *See* Pls.’ Mem. 13–19; Pls.’ Reply 7–12.

The D.C. Circuit’s assessment at a preliminary stage that Plaintiffs had not shown a likelihood of success on the merits is not binding in future phases of the case. *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (“conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits”) (citations omitted). A decision denying a preliminary injunction “rests on nothing more than a tentative appraisal of the probable result on the merits,” and thus it generally “do[es] not constitute law of the case.” *Wilcox v. United States*, 888 F.2d 1111, 1114 (6th Cir. 1989) (internal quotation marks omitted) (reversing district court’s award of summary judgment to defendants based solely on prior denial of preliminary injunction). Moreover, this is not merely an abstract legal principle: Substantial case law demonstrates that this Court is free to rule for Plaintiffs on the ground that hESC research is “research in which a human embryo or embryos are destroyed.”²

² *See Harris v. Fitchville Twp. Trs.*, 154 F. Supp. 2d 1182, 1186–87, 1189 (N.D. Ohio 2001) (awarding relief on claims that regulations were unconstitutional, despite prior conclusion that plaintiffs were unlikely to succeed on the merits); *Consumers Union v. New Regina Corp.*, 664 F. Supp. 753, 760, 764 (S.D.N.Y. 1987) (holding that vacatur of preliminary injunction based on plaintiff’s unlikelihood of success on the merits did not foreclose plaintiff’s claims; denying defendants’ summary judgment motion); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 106 F. Supp. 2d 696, 697 (D.N.J. 2000) (granting a permanent injunction, despite prior denial of a preliminary injunction due partly to unlikelihood of success on the merits).

Nor does the D.C. Circuit’s analysis show that Defendants’ interpretation is correct. Indeed, Judge Henderson agreed with this Court that the statute’s text unambiguously bars that interpretation. *Sherley*, 2011 WL 1599685, at *11–12 (Henderson, J., dissenting); *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70–71 (D.D.C. 2010). Although the majority disagreed, it held only that the statutory text is ambiguous and that the reading Defendants have advanced in this litigation is reasonable. 2011 WL 1599685, at *6. Additionally, the majority erred in applying *Chevron*, given that the Guidelines do not even contain Defendants’ contrived definition of “research.”³ And the majority’s only answer to this point—*i.e.*, that NIH’s use of “research” implies that it construed the term narrowly, *id.*—is undercut by the fact (ignored by the majority) that NIH itself previously took the *opposite* view. *See* Pls.’ Reply 23. Finally, in reading Dickey-Wicker’s present-tense reference to “research in which . . . embryos are destroyed” to exclude prior acts, the majority failed to address Plaintiffs’ argument (subsequently bolstered by a Supreme Court opinion) that such a reading produces the absurd result that NIH may fund the already-completed act of destroying embryos. *See McNeill v. United States*, ___ U.S. ___, No. 10-5258, 2011 WL 2175212, at *5 (June 6, 2011) (holding that present-tense verb encompassed past events due partly to “absurd results that would follow” by reading it to refer only to the present).

CONCLUSION

This Court should grant Plaintiffs’ motion, deny Defendants’ motion, and enter judgment (1) declaring that the Guidelines are vacated and invalid because they are contrary to law, were promulgated without observing the procedures required by law, and are arbitrary and capricious, and (2) permanently enjoining further implementation of the Guidelines.

Dated: June 24, 2011

Respectfully submitted,

³ *Chevron* is also inapplicable because NIH is not the only agency charged with administering Dickey-Wicker. *See, e.g., Collins v. NTSB*, 351 F.3d 1246, 1252–53 (D.C. Cir. 2003).

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of June, 2011, I caused a true and correct copy of the foregoing Plaintiffs' Supplemental Brief in Light of D.C. Circuit Decision to be served on Defendants' counsel and potential amici electronically by means of the Court's ECF system.

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