United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 23, 2012 Decided August 24, 2012

No. 11-5241

JAMES L. SHERLEY, DR. AND THERESA DEISHER, DR.,
APPELLANTS

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:09-cv-01575)

Ryan J. Watson argued the cause for appellants. With him on the briefs were *Thomas G. Hungar*, *Thomas M. Johnson Jr.*, *Samuel B. Casey*, *Steven H. Aden*, and *Blaine H. Evanson*.

Adam J. White was on the brief for *amici curiae* Robert George, et al. in support of appellants.

Beth S. Brinkmann, Deputy Assistant Attorney General, U.S. Department of Justice, argued the cause for appellees. With her on the briefs were *Tony West*, Assistant Attorney General, *Ronald C. Machen Jr.*, U.S. Attorney, and *Mark B. Stern*, *Stephanie R. Marcus*, *Abby C. Wright*, and *Helen L.*

Gilbert, Attorneys. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Neal Goldfarb and *Andrew T. Karron* were on the brief for *amici curiae* Coalition for the Advancement of Medical Research, et al. in support of appellees.

Before: SENTELLE, *Chief Judge*, HENDERSON and BROWN, *Circuit Judges*.

Opinion for the Court filed by *Chief Judge* SENTELLE.

Concurring opinion filed by *Circuit Judge* HENDERSON.

Concurring opinion filed by *Circuit Judge* BROWN.

SENTELLE, *Chief Judge*: Appellants are researchers in the field of adult stem cells who oppose the use of federal funding for the development of embryonic stem-cell research. In district court they filed a complaint seeking declaratory and injunctive relief against appellee Secretary of Health and Human Services' implementation of regulations allowing federal funding of such research. They appeal from a district court order entering summary judgment in favor of the defendant. Because we conclude that the district court committed no error, we affirm the order and judgment under review.

I. The Current Litigation

In August of 2009, appellants and others filed the complaint commencing this action against the Secretary of Health and Human Services and the Director of the National Institutes of Health (NIH), seeking declaratory relief that NIH Guidelines authorizing the funding of research involving human embryonic stem cells was unlawful under 5 U.S.C. § 706(2)(A). In addition

to this and other declaratory relief, the complaint sought to have the court enjoin the defendants and their agencies from implementing, applying, or taking any action pursuant to the guidelines, or otherwise funding any research involving human embryonic stem cells. The district court ruled that none of the several plaintiffs had standing to bring the action and therefore dismissed it. *See Sherley v. Sebelius*, 686 F. Supp. 2d 1 (D.D.C. 2009). We reversed as to the two appellants now before the court, researchers in the field of adult stem cells, concluding that they have standing as competitors to bring these claims. *Sherley v. Sebelius*, 610 F.3d 69, 72-74 (D.C. Cir. 2010). We remanded the case to the district court for further proceedings. *Id.* at 75. On remand, the district court determined that Congress had, in an Appropriations Act rider called the Dickey-Wicker Amendment, clearly "provide[d] that *no* federal funds shall be used for '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 other regulatory and statutory regimes. *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70 (D.D.C. 2010) (quoting Pub. L. No. 111-8, § 508(a)(2)). The district court further concluded that the guidelines under litigation violated that statutory prohibition, that the plaintiffs demonstrated a strong likelihood of success on the merits, that the plaintiffs would suffer irreparable harm in the absence of preliminary injunction, that the balance of hardships weighed in favor of preliminary injunction, and that public interest weighed in favor of the issuance of a preliminary injunction. The court therefore entered the preliminary injunction sought by plaintiffs. Defendants appealed.

On appeal, we determined that NIH had reasonably interpreted the Dickey-Wicker Amendment and vacated the preliminary injunction entered by the district court. *Sherley v. Sebelius*, 644 F.3d 388, 390 (D.C. Cir. 2011). After the second

remand, the district court entered the summary judgment in favor of defendant now under review.

II. Background

The relevant facts are set forth in our opinion reviewing the preliminary injunction, *see Sherley*, 644 F.3d at 389-92, and in the two opinions of the district court, so we shall review them but briefly. Beginning in 1996, Congress has regularly included in appropriation bills a rider called the Dickey-Wicker Amendment, *see, e.g.*, Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, § 508. The Dickey-Wicker Amendment prohibits NIH from funding "(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 C.F.R. 46.204(b) and [42 U.S.C. § 289g(b)]." *Id.*

At the time of the adoption of the first Dickey-Wicker rider, scientists had not yet isolated embryonic stem cells (ESC), and the original enactment was apparently directed at another type of research performed on human embryos in the field of in vitro fertilization. *Sherley*, 644 F.3d at 390. By 1998, researchers had generated a stable line of ESCs available for further research. Although more mature stem cells were and remain available, many researchers consider the ESCs far more valuable because they are pluripotent—that is, they can be developed into any of nearly 200 different types of human cells for use in a broad range of medical research.

Isolating ESCs for research requires that the cells be removed from a human embryo, cultured, and stabilized into a "stem cell line." This process of "derivation" destroys the embryo. The cells from this line may then be used for years by

researchers, who differentiate the cells into whatever kinds of cells they need for a particular research project. Thus, the initial derivation process requires the destruction of a human embryo. The particular research projects using the earlier derived stem cells, however, does not involve the destruction of any further embryos.

It is this distinction between funding research projects directly involving the destruction of a human embryo and projects using embryonic stem cells derived from an earlier destruction that underlies the controversy giving rise to the present litigation. In 2001, President George W. Bush, for ethical reasons, declared that federal funds would be used in research on embryonic stem cells only if such cells were drawn from one of the sixty or so stem cell lines already existing at the time of President Bush's declaration. Address to the Nation on Stem Cell Research from Crawford, Texas, 37 WEEKLY COMP. PRES. DOC. 1149, 1151 (Aug. 9, 2001). President Bush later formalized this policy in an Executive Order. Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007).

So matters stood until 2009, when President Obama issued an Executive Order revoking Executive Order No. 13,433. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009). The Order stated that NIH "may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." *Id.*

As required by the Executive Order and after notice and comment, NIH issued new "Guidelines for Human Stem Cell Research," 74 Fed. Reg. 32,170 (July 7, 2009) (Guidelines). The Guidelines "recognize the distinction, accepted by Congress, 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 [ESCs] that does not involve an embryo nor result in an embryo's destruction, for which Federal funding is permitted." *Id.* at 32,173. Under the Guidelines, an ESC research project may receive NIH funding as long as it utilizes cells from lines (1) created by *in vitro* fertilization for reproductive purposes, (2) no longer needed for that purpose, and (3) voluntarily donated by the individuals who owned them—even if that line was derived after 2001. *Id.* at 32,174.

During the notice and comment proceedings, the current appellants filed comments opposing the use of federal funds for any embryonic stem-cell research. NIH did not respond to their comments. After the adoption of the guidelines, appellants brought the present action.

III. Analysis

We note at the outset that our review of the district court's grant of summary judgment in favor of the government is *de novo*. *See, e.g.*, *Calhoun v. Johnson*, 632 F.3d 1259, 1261 (D.C. Cir. 2011). Therefore, our duty is to undertake the same examination as did the district court. On summary judgment review in general, that requires the court to grant summary judgment in favor of the moving party if that party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. In this court, as in the district court, the APA governs the scope of administrative reviews such as the one before us. That Act requires a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Thus, we, as did the district court, must allow summary judgment for appellees, unless appellants have produced in the record at least enough

support for their position to establish "a genuine dispute" as to some material fact from which we could discern that the adoption or implementation of the guidelines by the appellees was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." There is no serious dispute of fact in this case. Appellants advance three arguments for invalidating the NIH guidelines, each of which relies upon a proposition of law.

1. Dickey-Wicker

Appellants' first and principal argument is that the NIH guidelines violate the Dickey-Wicker ban on federal funding of "research in which a human embryo or embryos are destroyed." On this issue, the law of the case is established against them.

The purpose of the law-of-the-case doctrine is to ensure that "the *same* issue presented a second time in the *same case* in the *same court* should lead to the *same result*." *LaShawn A. v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996). The courts are appropriately "'loathe' to reconsider issues already decided," except in the case of "extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice.'" *Id.* (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (quoting *Arizona v. California*, 460 U.S. 605, 618 n.8 (1983))). Appellants' argument before us in the preliminary-injunction review was the same as now. Specifically, they asserted then and assert now that the Dickey-Wicker ban "unambiguously" extends to any research project that uses ESCs. *Sherley*, 644 F.3d at 395. Their argument, now and before, is that if a funded research project involves the use of an ESC, then an embryo necessarily has been destroyed, and the ban of Dickey-Wicker has been violated. *See generally id.* at 393-94. Briefly put, appellants contend that all ESC research is "research" in which

a human embryo or embryos are destroyed and, therefore, NIH's guidelines violate Dickey-Wicker by authorizing federal funding of such research. This is precisely the same argument we rejected in our review of the preliminary injunction order.

Applying *Chevron* analysis, *see Chevron U.S.A., Inc., v. NRDC*, 467 U.S. 837, 842-43 (1984), we held that NIH had reasonably interpreted Dickey-Wicker's ban on funding "research in which . . . embryos are destroyed" to allow federal funding of ESC research. *Sherley*, 644 F.3d at 393-96. We explained that "research" as used in Dickey-Wicker was a "flexible" (*i.e.*, ambiguous) term. *Id.* at 394. It could be understood as the plaintiffs construed the term—an "extended process" that would include the initial derivation of stem cells. Or "research" could take on NIH's narrow interpretation as a "discrete project" separate from derivation. *Id.* Given that ambiguity, we deferred under *Chevron* to NIH's permissible construction of Dickey-Wicker: "research" as used in Dickey-Wicker may reasonably be understood to mean a "discrete endeavor" that excludes the initial derivation of ESCs. *Id.* at 396 n.*. Under that interpretation, Dickey-Wicker permits federal funding of research projects that utilize already-derived ESCs—which are not themselves embryos—because no "human embryo or embryos *are* destroyed" in such projects. *Id.* at 393-96 (emphasis added). Plaintiffs' argument on this theory for relief is no different than it was in our prior review. Therefore, unless they have established some "extraordinary circumstance," *LaShawn A.*, 87 F.3d at 1393, the law of the case is established and we will not revisit the issue.

Appellants have offered an exception to the law-of-the-case doctrine which they argue should permit us to revisit the issue. As they point out, we have held that "the decision of a trial or appellate court whether to grant or deny a preliminary injunction does not constitute law of the case for the purpose of further

proceedings and does not limit or preclude the parties from litigating the merits." *Berrigan v. Sigler*, 499 F.2d 514, 518 (D.C. Cir. 1974); *see also Belbacha v. Bush*, 520 F.3d 452, 458 (D.C. Cir. 2008). Therefore, appellants reason, we are not bound by our prior determination in the review of the grant of preliminary injunction. However, on the facts of this case, the exception to the law-of-the-case doctrine is inapplicable.

The generally recognized precedent for the preliminary injunction exception to the law-of-the-case doctrine arises from the nature of a preliminary injunction. That equitable remedy is a stopgap measure, generally limited as to time, and intended to maintain a status quo or "to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). In trial court, this would mean that a determination had been made without discovery or the other full range of exploratory and preparatory pretrial procedures and without a full trial on the merits. In appellate review, the court of appeals must often consider such preliminary relief without the benefit of a fully developed record and often on briefing and argument abbreviated or eliminated by time considerations. *See, e.g.*, *Cohen v. Brown Univ.*, 101 F.3d 155, 169 (1st Cir. 1996). Thus arose the exception to the law-of-the-case doctrine. An appellate court in a later phase of the litigation with a fully developed record, full briefing and argument, and fully developed consideration of the issue need not bind itself to the time-pressured decision it earlier made on a less adequate record.

Furthermore, independent of the preliminary-injunction exception, a decision in the preliminary-injunction context may fail to garner law-of-the-case effect simply because it fails to satisfy an element of the law-of-the-case rule itself: the requirement that a court must "affirmatively decide[ ]" an issue, explicitly or by necessary implication, to establish law of the

case. *Crocker v. Piedmont Aviation, Inc.*, 49 F.3d 735, 739 (D.C. Cir. 1995). The standard for granting a preliminary injunction essentially asks—in part—whether a plaintiff is "likely to succeed on the merits" of his claim. *See, e.g.*, *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). To the extent an appellate court predicts, without making a definitive legal conclusion, that the plaintiffs *probably* or *likely* will or will not succeed on the merits, it cannot be said that the court "affirmatively decided" the issue such that it would bind an appellate court at a later stage of the litigation.

The question raised by this appeal is whether we should apply the preliminary-injunction exception to the law-of-the-case preclusion where the reasons for its application are absent. That is, where the earlier ruling, though on preliminary-injunction review, was established in a definitive, fully considered legal decision based on a fully developed factual record and a decisionmaking process that included full briefing and argument without unusual time constraints, why should we not follow the usual law-of-the-case jurisprudence? While we have not previously provided a definitive answer to that question, several other circuits and commentators have.

For example, in *Naser Jewelers, Inc. v. City of Concord*, 538 F.3d 17 (1st Cir. 2008), the First Circuit considered an appeal from summary judgment upholding a city ordinance against a First Amendment challenge. The circuit had previously affirmed the denial of preliminary injunction in the same case. In holding that the law-of-the-case doctrine applied, even though the first decision was in the denial of a preliminary injunction and the second appeal was from the entry of summary judgment, that circuit noted that "the doctrine applies when [the] court has previously ruled on a motion for preliminary injunction and 'the record before the prior panel was sufficiently developed and the facts necessary to shape the prior legal matrix

were sufficiently clear.'" *Id.* at 20 (quoting *Cohen v. Brown Univ.*, 101 F.3d 155, 169 (1st Cir. 1996) (other citations, quotation marks, and alterations omitted)).

In *This That and The Other Gift and Tobacco, Inc. v. Cobb County*, 439 F.3d 1275, 1284-85 (11th Cir. 2006), the Eleventh Circuit reached a similar decision, citing its own precedent to the effect that prior clear legal conclusions reached at the preliminary injunction stage would be afforded law-of-the-case status. In *Entergy, Arkansas, Inc. v. Nebraska*, 241 F.3d 979, 987 (8th Cir. 2001), the Eighth Circuit afforded law-of-the-case status to an Eleventh Amendment issue "carefully considered" in deciding the course of the preliminary injunction appeal. And in *Royal Insurance Co. of America v. Quinn-L Capital Corp.*, 3 F.3d 877, 880-81 (5th Cir. 1993), the Fifth Circuit ruled to the same effect. One of the leading commentators on federal jurisprudence has stated, "A fully considered appellate ruling on an issue of law made on a preliminary injunction appeal, however, does become the law of the case for further proceedings in the trial court on remand and in any subsequent appeal." 18B Charles A. Wright et al., Fed. Prac. & Proc. Juris. § 4478.5 (2d ed.).

Appellants insist application of the preliminary injunction exception is mandated by circuit precedent. For this proposition, they rely on *Berrigan* and *Belbacha*. They note that in *Berrigan*, we stated, "The decision of a trial or appellate court whether to grant or deny a preliminary injunction does not constitute the law of the case for the purposes of further proceedings and does not limit or preclude the parties from litigating the merits, unless there has been an order of consolidation pursuant to Rule 65(a)(2), not the case here." 499 F.2d at 518. In *Belbacha*, we stated, "An order denying preliminary relief, however, 'does not constitute the law of the case,' although it can be 'persuasive.'" 520 F.3d at 458 (quoting

Berrigan). No doubt these cases state the generally applicable rule for preliminary-injunction decisions. However, the case before us is factually distinguishable. The time constraints and limited record available to the court in those cases are not present here. We therefore follow the other circuits in concluding that the exception is not present either. Appellants' first argument fails.

2. Subjected to Risk

Appellants make a second argument that is intertwined with their first. They note that Dickey-Wicker also bans "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death." § 508(a)(2). Even if the NIH guidelines do not violate the Dickey-Wicker ban on funding "research in which a human embryo or embryos are destroyed" (because law of the case accorded *Chevron* deference to NIH's interpretation), appellants maintain that the guidelines still run afoul of the "subjected to risk" language. They theorize that conducting a federally funded ESC research project increases the demand for more ESC lines, which in turn incentivizes the destruction of more embryos to create those lines, thus subjecting those embryos to risk. NIH responds that no embryos are subjected to risk of injury or death in any ESC research project using already derived ESCs and not otherwise involving the use of embryos.

Although appellants can credibly argue that this precise question of statutory interpretation is not within the law of the case, our result is nonetheless controlled by that doctrine. Law of the case has established that *Chevron* deference applies. It is established that "research" as used in Dickey-Wicker is an ambiguous term, and that NIH's interpretation of the term "research" as a discrete project rather than an extended process is reasonable. Under that definition of "research," the

destruction of embryos that occurs in the ESC derivation process is not a part of individual ESC research projects using already derived ESCs. Therefore, ESC research is no more "research in which . . . embryos are . . . subjected to risk" than it was "research in which . . . embryos are . . . destroyed." Appellants' theory shifts focus from the embryo destroyed in the past to embryos for which an ESC research project "incentivizes" future destruction. But none of those embryos are "destroyed" or "subjected to risk" *in* an ESC research project. The language of Dickey-Wicker does not ban funding for, *e.g.*, "research which provides an incentive to harm, destroy, or place at risk human embryos." As we have held before, the NIH interpretation of the statute's actual language is reasonable.

3. Failure to Reply to Comments

The plaintiffs finally contend that NIH violated the APA by issuing the Guidelines without addressing comments categorically objecting to ESC research, which the plaintiffs consider relevant to NIH's decision to expand the availability of ESC research funding. While this contention remains unfettered by decisions made in *Sherley II*, it fares no better than the Dickey-Wicker arguments.

APA Section 553 requires agencies to provide the public with notice of a proposed rulemaking, an opportunity to comment, and, "[a]fter consideration of the relevant matter presented," a "concise general statement" of the rule's basis and purpose. 5 U.S.C. § 553. We have said before that "the opportunity to comment is meaningless unless the agency responds to significant points raised by the public." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977). That said, an agency's failure to address a particular comment or category of comments is not an APA violation *per se*. *See, e.g.*, *Thompson v. Clark*, 741 F.2d 401, 408 (D.C. Cir. 1984) ("[APA

§ 553] has never been interpreted to require the agency to respond to every comment, or to analyze every issue or alternative raised by the comments, no matter how insubstantial."). We review an agency's response to comments under the same arbitrary-and-capricious standard to which we hold the rest of its actions. *See Home Box Office*, 567 F.2d at 35 n.58. Put simply, "The failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors." *Covad Commc'ns v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006) (quoting *Thompson*, 741 F.2d at 409).

The comments identified by appellants cited scientific and ethical problems with ESC research and categorically objected to funding any ESC research at all. They advocated funding other types of stem-cell research instead. Crucially, however, this recommended course of action is diametrically opposed to the direction of Executive Order 13,505, which NIH sought to "implement" by issuing the Guidelines, *see* 74 Fed. Reg. at 32,170. That Order makes it quite plain that its dominant purpose was to "remove" President Bush's 2001 "limitations" on funding human ESC research and to "expand" NIH support for human stem-cell research, "including human embryonic stem cell research." *See* 74 Fed. Reg. at 10,667, §§ 1-2 (titled "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells"). Yet the comments at issue advocate ending all ESC research funding—even for research that has been eligible for funding for a decade under the 2001 restrictions. Following these commenters' lead would directly oppose the clear import of the Executive Order, which sought to remove limitations on ESC research and to expand NIH support for stem-cell research.

NIH may not simply disregard an Executive Order. To the contrary, as an agency under the direction of the executive

branch, it must implement the President's policy directives to the extent permitted by law. *See Bldg. & Const. Trades Dept. v. Allbaugh*, 295 F.3d 28, 32-33 (D.C. Cir. 2002) (citing THE FEDERALIST NO. 72, at 463 (Alexander Hamilton) (Benjamin F. Wright ed., 1961)). Bound as it is to carry out the President's directives, NIH thus reasonably limited the scope of its Guidelines to implement the Executive Order. And because the Executive Order's entire thrust was aimed at *expanding* support of stem-cell research, it was not arbitrary or capricious for NIH to disregard comments that instead called for termination of all ESC research (including research that the executive branch has permitted since 2001). Such comments simply did not address any factor relevant to implementing the Executive Order.

While the district court also rejected the plaintiffs' APA claim, it did so by relying in part on its holding that NIH's interpretation of the Executive Order deserved deference under *Udall v. Tallman*, 380 U.S. 1, 16-17 (1965). The plaintiffs claim that such deference is unwarranted for a variety of reasons. We have no reason to resolve this argument here. We need not rely on deference to NIH's interpretation of Executive Order 13,505 to conclude that NIH's choice to disregard the comments at issue was not arbitrary or capricious. NIH stated that the scope of its Guidelines was to "implement Executive Order 13505," 74 Fed. Reg. at 32,174, and that Order plainly starts from the premise that NIH should continue to fund at least some ESC research. NIH's decision to dismiss comments seeking to reopen that premise for debate therefore did not demonstrate a failure to consider relevant factors.

Conclusion

For the above reasons, we affirm the district court's grant of summary judgment in favor of the government.

So ordered.

KAREN LECRAFT HENDERSON, *Circuit Judge*, concurring:

My colleagues correctly note that *Sherley v. Sebelius*, 644 F.3d 388 (D.C. Cir. 2011) (*Sherley I*), applied *Chevron* to uphold the National Institute of Health (NIH) Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009) (Guidelines). *See* Maj. Op. at 8. Although the law of the case prevents us from reconsidering that holding, I write separately for the record to point out that *Chevron* review is inapplicable to the Guidelines.

"Not every agency interpretation of a statute is appropriately analyzed under *Chevron*." *Ala. Educ. Ass'n v. Chao*, 455 F.3d 386, 392-93 (D.C. Cir. 2006). *Chevron* applies only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.' " *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001)). In short, we accord *Chevron* deference only when reviewing an agency's "construction of a statutory scheme *it is entrusted to administer*." *Id.* at 227-28 (quoting *Chevron*, 467 U.S. at 844) (emphasis added). "[W]hen an agency interprets a statute other than that which it has been entrusted to administer, its interpretation is not entitled to [*Chevron*] deference." *Dep't of Treasury v. FLRA*, 837 F.2d 1163, 1167 (D.C. Cir. 1988). NIH's construction of the Dickey-Wicker Amendment falls outside the *Chevron* ambit because NIH was not charged with administering the Amendment, as is obvious from both its language and its substance.

First, the Amendment's language makes clear its administration is not within the exclusive province of NIH or its parent agency, the Department of Health and Human Services. It has been enacted annually as a rider to an omnibus appropriations act, in a division governing "Departments of *Labor*, Health and Human Services, *and Education, and Related Agencies Appropriations*." Consolidated Appropriations Act of 2012, Pub. L. No. 112-74, div. F., § 508(a), 125 Stat. 786, 1112

(2011) (emphasis added); *see also, e.g.*, Consolidated Appropriations Act of 2011, Pub. L. No. 111-117, div. D, § 509(a), 123 Stat. 3034, 3280-81 (2010) (same division title); Omnibus Appropriations Act of 2010, Pub. L. No. 111-8, § 509(a), div. F, 123 Stat. 524, 803 (2009) (same). Because each annual rider by its terms applies generally to multiple agencies, *Chevron* deference is not due any one agency's interpretation of its language. *See Proffitt v. FDIC*, 200 F.3d 855, 860 (D.C. Cir. 2000) ("When a statute is administered by more than one agency, a particular agency's interpretation is not entitled to Chevron deference."). In the past, we have "declined to defer to an agency's interpretation of a statute when more than one agency is granted authority to interpret the same statute," reasoning that "[i]n such cases, it cannot be said that Congress implicitly delegated to one agency authority to reconcile ambiguities or to fill gaps, because more than one agency will independently interpret the statute." *Salleh v. Christopher*, 85 F.3d 689, 692 (D.C. Cir. 1996) (citing, *e.g.*, *Rapaport v. U.S. Dep't of Treasury*, 59 F.3d 212, 216-17 (D.C. Cir. 1995), *cert. denied*, 516 U.S. 1073 (1996); *Benavides v. U.S. Bureau of Prisons*, 995 F.2d 269, 272 n.2 (D.C. Cir. 1993); *Prof'l Reactor Operator Soc'y v. U.S. Nuclear Regulatory Comm'n*, 939 F.2d 1047, 1051 (D.C. Cir. 1991)). *Sherley I* therefore erred in applying *Chevron* to NIH's interpretation.

Second, the Amendment, as a rider to a federal appropriations statute, is "not within [any agency's] area of expertise" and therefore a particular agency's interpretation thereof "receives no deference." *U.S. Dep't of Navy v. FLRA*, 665 F.3d 1339, 1348 (D.C. Cir. 2012); *see, e.g.*, *Ass'n of Civilian Technicians, Tony Kempenich Mem'l Ch. 21 v. FLRA*, 269 F.3d 1119, 1121 (D.C. Cir. 2001) (court does not defer to FLRA's "interpretation of the Department of Defense Appropriations Act, a statute not committed to the Authority's administration" but "reviews such purely legal questions de novo"). Indeed the rider's language reveals no express

delegation of authority—implicit or explicit—to any agency to administer its provisions—which is unsurprising given that the rider itself confers no substantive authority on any agency to do anything; it simply—and plainly—prohibits the Departments of Labor, Health and Human Services and Education, as well as "[r]elated [a]gencies," from using the appropriated funds for the specifically enumerated purposes.

Because the Dickey-Wicker Amendment does not delegate administrative authority to the Department of Health and Human Services or to NIH, I believe that *Sherley I* incorrectly applied the *Chevron* framework. *See* 644 F.3d at 392 (D.C. Cir. 2011) ("We approach this issue under the familiar two-step framework of *Chevron* . . . ."). The court should instead have interpreted the statute de novo, according no deference to NIH's interpretation.[*] *See Ass'n of Civilian Technicians*, 269 F.3d at 1121; *Proffitt*, 200 F.3d at 860; *see also Dep't of Treasury*, 837 F.3d at 1167 ("Because the FLRA's refusal to award back pay did not rest on an interpretation of its organic statute, but rather on its reading of the Back Pay Act—a general statute—the FLRA's interpretation is entitled to respect before this court, but we are not bound by its construction of the statute even if reasonable."). Had we done so, I believe we would have invalidated the Guidelines as contrary to the Amendment's plain and unambiguous text. *See Sherley I*, 644 F.3d at 400-02 (Henderson, J., dissenting) (*Sherley I Dissent*).

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[*]Even so-called *Skidmore* deference is not available because it also applies only to an agency interpretation of a statute the agency administers. *See United States v. Mead Corp.*, 533 U.S. at 228 (under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), "[t]he fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position") (footnotes omitted).

The Amendment prohibits federal funding of ''research in which a human embryo or embryos are destroyed." Pub. L. No. 112-74 § 508(a)(1). Contrary to the holding in *Sherley I*, this ban plainly *prohibits* federal funding that the Guidelines expressly *permit*—namely, the funding of human embryonic stem cell (hESC) research that is conducted after the destruction of the embryo. *See* 74 Fed. Reg. at 32,174. This conclusion is compelled by the dictionary definition of "research" as a "systematic inquiry or investigation," which necessarily includes not only "the first sequence of hESC research [involving] the derivation of stem cells from the human embryo" but also "the succeeding sequences of hESC research." *Sherley I Dissent*, 644 F.3d at 401. The *Sherley I* majority, however, ignored the Amendment's plain meaning, manufacturing ambiguity where there was none. *Sherley I Dissent*, 644 F.3d at 399, 402-05. Nevertheless, *Sherley I*'s *Chevron* step-two analysis is the law of the case and we are bound thereby. *See* Maj. Op. at 7-12.

BROWN, *Circuit Judge*, concurring: Despite many points of agreement with my colleagues, I write separately because we converge from different paths and there are aspects of this case that—NIH's insouciance notwithstanding—should trouble the heart. Even Dr. James Thompson, the researcher credited with being the first to successfully derive human embryonic stem cells, has admitted: "If human embryonic stem cell research does not make you at least a bit uncomfortable, you have not thought about it enough." Gina Kolata, *Man Who Helped Start Stem Cell War May End It*, N.Y. TIMES, Nov. 22, 2007.

I. *Chevron* Deference

If this was ever a simple case it long ago ceased to be one. The judiciary, the executive branch, the scientific community, and numerous legal commentators have put forth disparate interpretations of the Congressional prohibition on the use of federal funds for stem cell research.[1] Legislators, too, express

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[1] *See, e.g.*, *Sherley v. Sebelius*, 704 F. Supp. 2d 63 (D.D.C. 2009); Jenny Shum, *Moral Disharmony: Human Embryonic Stem Cell Patent Laws, WARF, and Public Policy*, 33 B.C. INT'L & COMP. L. REV. 153, 163 (2010) ("Essentially, the amendment rendered any scientific research on hESCs ineligible for federal funding."); Ronald Green, *Political Interventions in U.S. Human Embryo Research: An Ethical Assessment*, 38 J.L. MED. & ETHICS 220, 224 (2010) ("Dickey-Wicker not only prohibits research that risks or destroys an embryo—applying to embryos whether in vitro or in utero the same protections applied to fetuses and even more stringent protections than those afforded children—but it defines the embryo as any organism produced by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes"); Maite S. Kollmann, *Taking the Moral High Road: Why Embryonic Stem Cell Research Should Be Strictly*

conflicting views.[2] Disagreement is inevitable when what lies at the core of the dispute is a profound question about the boundaries of science—one that is irreducibly controversial because the slippery slope is precipitous in both directions. Ours, though, is not the legislative burden of bringing considered resolution to this contested question. We ponder a much narrower, much more prosaic query that serves only as a rough proxy for the metaphysics: does the Dickey-Wicker Amendment's prohibition on federal funding of "research in which a human embryo or embryos are destroyed" or "knowingly subjected to the risk of death or injury," Pub. L. No.112-74, sec. 508(a)(1–2), preclude federal funding for *all* human embryonic stem cell research? And how much deference, if any, should be accorded to the agency's view that stem cell research can be decoupled from the derivation of the stem cell line?

Regulated, 2 FAULKNER L. REV. 145, 155 (2010) ("[NIH] General Counsel Rabb concluded that the Dickey-Wicker Amendment, which prohibited the use of funds allocated to the HHS for human embryo research, would not be applicable to research using hESCs 'because such cells are not a human embryo within the statutory definition.'").

[2] In the Senate hearing convened to respond to the district court's initial injunction in this case, Senator Wicker maintained that "if human embryonic stem cell research is to be done at all, it should be paid for with nontaxpayer funds." *The Promise of Human Embryonic Stem Cell Research: Hearing before S. Subcomm. on Appropriations*, Statement of Sen. Roger Wicker, 111th Cong. 3–4 (2010). In the same hearing, Senator Feinstein excoriated the District court's "alarming" decision as "an unprecedented and highly restrictive interpretation of the Dickey-Wicker amendment." *The Promise of Human Embryonic Stem Cell Research: Hearing before S. Subcomm. on Appropriations*, Statement of Sen. Dianne Feinstein, 111th Cong. 33 (2010).

Every substantive decision in this case's checkered past has proceeded under the assumption that *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), controls the statutory interpretation. I thus welcome—and heartily concur with—the portion of Judge Henderson's concurring opinion dealing with this threshold determination. Like her, I conclude *Chevron* does not apply and the court should have accorded no deference to NIH's interpretation. *See AKM LLC dba Volks Constructors v. Sec. of Labor*, 675 F.3d 752, 764–69 (D.C. 2012) (Brown, J., concurring). But in this case, deference is not dispositive. Judge Henderson finds the Amendment's ban "plainly prohibits federal funding that the Guidelines expressly permit—namely, the funding of human embryonic stem cell (hESC) research that is conducted after destruction of the embryo." Concurrence at 4 (Henderson, J.). I am not so sanguine. Judge Henderson's reading is certainly plausible and undoubtedly consistent with the initial conclusion of the trial court that the language "reflects the unambiguous intent of Congress to enact a broad prohibition of funding research in which a human embryo is destroyed." *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70–71 (D.D.C. 2010). But it still does not tell us how to define "research" in light of the many layers of executive orders, agency interpretation, and legislative acquiescence with which we must now deal.

Congressional efforts to grapple with the ethical challenges arising from the extraordinary advances in biomedicine and biotechnology date back at least to the passage of the National Research Act in 1974. *See* Pub. L. No. 93-348, 88 Stat. 342. Since then, there has been no shortage of committees, boards, and panels all dedicated to the study and consideration of the moral, legal, and ethical dimensions of using human subjects, or human cellular or

genetic materials, in scientific experiments.[3] More recently, Congress passed the NIH Revitalization Act of 1993, Pub. L. 103-43, under which NIH established the Human Embryo Research Panel ("HERP"). While the bill's focus was human reproductive biology, HERP concluded that "[r]esearch involving the development of embryonic stem cells [done] with embryos resulting from IVF treatment for infertility or clinical research that have been donated" was "acceptable" and could receive federal funding. Human Embryo Research Panel, Volume I of the Report of the Human Embryo Research Panel, 75–76 (September 1994).[4]

Congress passed the Dickey-Wicker Amendment in 1996 partially in response to some of HERP's bolder recommendations, perhaps agreeing with the Washington Post that the Panel had gone "a step too far." *See* Green, *supra*, at 224. The Amendment was not directed at the precise research at issue here,[5] but whatever the Amendment's original purpose, President Clinton's decision in 1999 to announce a policy of federal funding for embryonic stem cell research—and Congress's decision to pass the Amendment unchanged

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[3] The Ethics Advisory Board ("EAB"), for example, came into being in the late 1970s around the time scientists produced the first test-tube baby. The EAB focused on federal support for *in vitro* fertilization ("IVF") and embryo transfer. *See* Ethics Advisory Board, Report and Conclusions: HEW Support of Research Involving Human *In Vitro* Fertilization and Embryo Transfer 1–7 (May 4, 1979), *available at* http://bioethics.georgetown.edu/pcbe/reports/past_commissions/HEW_IVF_report.pdf. For a list of other prominent past commissions, see O. Carter Snead, *Science, Public Bioethics, and the Problem of Integration*, 43 U.C. DAVIS L. REV. 1529, 1539 n. 32 (2010).

[4] The panelists were foresighted as scientists had not yet derived human embryonic stem cells.

[5] *See* 142 CONG. REC. S429-01 (1996).

the following year—altered the interpretive calculus. *See* Joint Appendix at 523. In the same vein, Congress's decision to pass the Amendment unchanged for all eight years of the Bush Administration seems to confirm its acquiescence to *some* federal funding of research involving human embryonic stem cells.[6] Indeed, Congress supplemented this implicit approval of funding for embryonic stem cell research with contemporaneous Senate and House reports explicitly stating that the amendment "should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with the policy outlined by the President." NIH Br. at 14 (quoting H.R. Rep. No. 107-229, at 180 (Oct. 9, 2001)).

For this reason, I am of the view that *de novo* review would not change the outcome of the prior decision to affirm NIH's interpretation of the act. I thus join in the judgment of the majority opinion though I would reach the decision using the more familiar clear error standard of review under which we must vacate the logic of the prior holding and supply our own should we find that the prior decision was "clearly erroneous and would work a manifest injustice." *LaShawn v. Barry*, 87 F.3d 1389, 1395 (D.C. Cir. 1996) (referencing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988)). The facts in the record before us do not, however, rise to the level of these "extraordinary circumstances." *Id.* That we have only now, some four-years and multiple opinions later, questioned the propriety of *Chevron* strongly suggests that the decisions of the reasonable

[6] President Bush's policy was decidedly narrower than that of President Clinton, but it still authorized funding. Consequently, it must be said to violate the appellants' reading of the Dickey-Wicker Amendment.

jurists considering these matters were not "clearly erroneous."[7]

II. Failure to Reply to Comments

Although it is difficult to take issue with any part of the majority's catechism on the agency's refusal to respond to thousands of comments, the whole seems somewhat problematic. Obviously, the opportunity to comment is meaningless unless the agency responds substantively to significant points raised by the public. But the law of this Circuit is clear: an agency is only required to respond to comments if, for example, it can be established that the comment is "relevant to the agency's decision and which, if adopted, would require a change in [the] agency's proposed rule, *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n. 58 (D.C. Cir. 1977), or that a failure to respond would "demonstrate[] that the agency's decision was not based on a consideration of the relevant factors," *Covad Commc'ns Co. v. FCC*, 450 F.2d 186, 197 (D.C. Cir. 1993). In applying this test, however, the majority defines "relevance" as coextensive with the President's Executive Order and does so without imposing any clear limits on an agency's ability to ignore comments that contravene the executive's policy goals. I fear that without such boundaries there remains the distinct possibility that the executive power will expand at the expense of the APA's regulatory scheme and judicial review will be reduced to rubberstamping preordained results.

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[7] When the dust settles and the votes are tallied, a majority of this panel supports two seemingly conflicting positions: (1) that law of the case doctrine prevents us from reconsidering the earlier ruling that applied *Chevron* and (2) that *Chevron* does not apply. Thus, the majority opinion stands only for the proposition that the earlier result need not be overturned—not that the decision was correct in all respects.

Clearly, if the Dickey-Wicker Amendment's prohibition was unambiguous, NIH could not ignore an entire class of interpretive views because a broad reading of "research" would run counter to the executive's agenda. Similarly, I do not think the agency could attempt to implement an expansive program Congress had explicitly rejected by deeming challenges to its authority irrelevant. But this is not the case here. As an initial matter, the comments Appellants argue were wrongfully ignored focus *not* on the text of Dickey-Wicker or the question of legislative authorization, but on the Executive Order's (and the Guidelines') requirement that only "responsible" and "scientifically worthy" research should be eligible for funding. Appellant Br. at 45. This is fundamentally a policy question and we must respect the Executive's ability to reasonably define the contours of the proposed rulemaking. Nor is there a conflict between branches in NIH's decision to couch their rejection in more absolute terms, *i.e.*, declaring all comments "advocating a blanket ban on all funding for hESC research . . . not relevant.'" *See* Joint App'x at 479–80. The NIH cannot be said to have acted arbitrarily and capriciously by refusing to re-open a debate that, as a practical matter, has been foreclosed for more than a decade. Because I ultimately reach the same result, I thus concur with the majority's conclusion and leave the more technical questions of Executive Orders and deference for a later day.

The challenging—and constantly evolving—issues presented by bioethics are critical and complex. Striking the right balance is not easy and not, in the first instance, a task for judges. What must be defended is "the integrity of science, the legitimacy of government, and the continuing vitality" of concepts like human dignity.[8] Given the weighty interests at

[8] Snead, *supra* n. 3, at 1604.

stake in this encounter between science and ethics, relying on an increasingly Delphic, decade-old single paragraph rider on an appropriations bill hardly seems adequate.