Exhibit

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--- F.3d ----, 2011 WL 1599685 (C.A.D.C.)
(Cite as: 2011 WL 1599685 (C.A.D.C.))

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Only the Westlaw citation is currently available.

United States Court of Appeals,
District of Columbia Circuit.
Dr. James L. SHERLEY, et al., Appellees
v.
Kathleen SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services, et al., Appellants.

No. 10–5287.
Argued Dec. 6, 2010.
Decided April 29, 2011.

Background: Two scientists brought suit to enjoin the National Institutes of Health from funding research using human embryonic stem cells (ESCs) pursuant to NIH's guidelines. The United States District Court for the District of Columbia, 686 F.Supp.2d 1, granted government's motion to dismiss. The Court of Appeals, 610 F.3d 69, reversed in part. On remand, the District Court, 704 F.Supp.2d 63, granted scientists' motion for a preliminary injunction. Government appealed.

Holdings: The Court of Appeals, Ginsburg, Circuit Judge, held that:
(1) NIH's interpretation of Dickey–Wicker Amendment was entitled to *Chevron* deference, and
(2) balance of equities tilted against granting preliminary injunction.

Vacated.

Karen LeCraft Henderson, Circuit Judge, filed a dissenting opinion.

West Headnotes

[1] Injunction 212 132

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)1 In General
212k132 k. Nature and Scope of Provisional Remedy. Most Cited Cases

Injunction 212 147

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)4 Proceedings
212k147 k. Evidence and Affidavits. Most Cited Cases

A preliminary injunction is an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.

[2] Injunction 212 138.1

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)2 Grounds and Objections
212k138.1 k. In General. Most Cited Cases

A plaintiff seeking a preliminary injunction must establish (1) that he is likely to succeed on the merits, (2) that he is likely to suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in his favor, and (4) that an injunction is in the public interest.

[3] Federal Courts 170B 776

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)1 In General
170Bk776 k. Trial De Novo. Most Cited Cases

Federal Courts 170B 815

170B Federal Courts
170BVIII Courts of Appeals

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170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk814 Injunction
170Bk815 k. Preliminary Injunction; Temporary Restraining Order. Most Cited Cases

A court of appeals reviews a district court's balancing of the four preliminary injunction factors for abuse of discretion; insofar as the inquiry depends upon a question of law, review is, of course, de novo.

[4] Abortion and Birth Control 4 126

4 Abortion and Birth Control
4k126 k. Funding and Insurance. Most Cited Cases

Statutes 361 219(6.1)

361 Statutes
361VI Construction and Operation
361VI(A) General Rules of Construction
361k213 Extrinsic Aids to Construction
361k219 Executive Construction
361k219(6) Particular Federal Statutes
361k219(6.1) k. In General. Most Cited Cases

Text of Dickey–Wicker Amendment, which barred federal funding specifically 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 the Public Health Service Act and a particular regulation of the Department of Health and Human Services, was ambiguous as to whether it barred funding for any project using embryonic stem cells (ESC), such that deference to administering agency's interpretation was warranted under *Chevron* as long as it reflected a permissible construction. Public Health Service Act, § 498(b), 42 U.S.C.A. 289g(b); 45 C.F.R. 46.204(b).

[5] Statutes 361 198

361 Statutes
361VI Construction and Operation
361VI(A) General Rules of Construction
361k187 Meaning of Language
361k198 k. Tense of Words. Most Cited Cases

Statutes 361 278.5

361 Statutes
361VI Construction and Operation
361VI(D) Retroactivity
361k278.4 Prospective Construction
361k278.5 k. In General. Most Cited Cases

The use of the present tense in a statute strongly suggests it does not extend to past actions. 1 U.S.C.A. § 1.

[6] Abortion and Birth Control 4 126

4 Abortion and Birth Control
4k126 k. Funding and Insurance. Most Cited Cases

National Institutes of Health's (NIH) determination that ambiguous text of Dickey–Wicker Amendment, which prohibited funding for "research in which a human embryo or embryos are destroyed," did not bar its funding a project using an embryonic stem cell (ESC) that was previously derived because a stem cell was not an "embryo" and could not develop into a human being, was reasonable, and thus entitled to *Chevron* deference, in light of the language of the statute and Congress's continued reenactment of the amendment unchanged year after year. Public Health Service Act, § 498(b), 42 U.S.C.A. 289g(b); 45 C.F.R. 46.204(b).

[7] Injunction 212 135

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)1 In General
212k135 k. Discretion of Court. Most Cited Cases

Although ordinarily a court of appeals may affirm the judgment of the district court on the basis of a different legal theory, the decision whether to grant a preliminary injunction is a matter of discretion, not a question of right; it is for the district court to determine, in the first instance, whether the plaintiffs' showing on a particular claim warrants preliminary

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injunctive relief.

[8] Abortion and Birth Control 4 126

4 Abortion and Birth Control
4k126 k. Funding and Insurance. Most Cited Cases

Injunction 212 138.66

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)3 Subjects of Relief
212k138.45 Public Officers, Boards and Municipalities; Schools and Colleges
212k138.66 k. Disposition of Public Money; Welfare and Social Security Benefits. Most Cited Cases

Balance of equities tilted against granting preliminary injunction enjoining the National Institutes of Health (NIH) from funding research using human embryonic stem cells (ESCs) pursuant to the NIH's guidelines; injunction would preclude the NIH from funding new ESC projects and would bar further disbursements to ESC researchers who had already begun multi-year projects in reliance upon a grant from the NIH, leaving their researchers' investments in project planning a loss, their expenditures for equipment a waste, and their staffs out of a job.

Appeal from the United States District Court for the District of Columbia (No. 1:09–cv–01575).Beth S. Brinkmann, Deputy Assistant Attorney General, U.S. Department of Justice, argued the cause for appellants. With her on the briefs were Ronald C. Machen Jr., U.S. Attorney, and Mark B. Stern, Stephanie R. Marcus, and Abby C. Wright, Attorneys. Joel McElvain, Senior Counsel, and R. Craig Lawrence, Assistant U.S. Attorney, entered appearances.

Jon E. Pettibone, Neal Goldfarb, and Andrew T. Karron were on the brief for amici curiae State of Wisconsin, et al. in support of appellants.

Robert P. Charrow and Laura Metcoff Klaus were on the brief for amicus curiae Regents of the University of California in support of appellants.

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

Dorinda C. Bordlee was on the brief for amicus curiae Maureen L. Condic in support of appellee.

Before: GINSBURG, HENDERSON, and GRIFFITH, Circuit Judges.

Opinion for the Court filed by Circuit Judge GINSBURG.

Dissenting opinion filed by Circuit Judge HENDERSON.

GINSBURG, Circuit Judge:

***1** Two scientists brought this suit to enjoin the National Institutes of Health from funding research using human embryonic stem cells (ESCs) pursuant to the NIH's 2009 Guidelines. The district court granted their motion for a preliminary injunction, concluding they were likely to succeed in showing the Guidelines violated the Dickey–Wicker Amendment, an appropriations rider that bars federal funding for research in which a human embryo is destroyed. We conclude the plaintiffs are unlikely to prevail because Dickey–Wicker is ambiguous and the NIH seems reasonably to have concluded that, although Dickey–Wicker bars funding for the destructive act of deriving an ESC from an embryo, it does not prohibit funding a research project in which an ESC will be used. We therefore vacate the preliminary injunction.

I. Background

As we explained at an earlier stage of this case, stem cells have the potential of yielding treatments for a wide range of afflictions because scientists can cause them to function as any one of a number of specific types of cell. 610 F.3d 69, 70 (2010) (*Sherley I*). We there considered two different classes of human stem cells: adult stem cells, which are somewhat specialized, and ESCs, which are pluripotent, meaning they can develop into nearly any of the 200 types of human cell. In addition to these two established categories, we note the recent development of induced pluripotent stem cells, which are adult stem cells reprogrammed to a stage of development at which they are pluripotent. There is some debate as to which type of stem cell holds more promise of yielding therapeutic applications.

Adult stem cells can be found in the various tissues and organs of the human body. ESCs, by contrast, can be found only in a human embryo; isolating an ESC requires removing the "inner cell mass" of the embryo, a process that destroys the embryo. The stem cells among the 30 or so cells in the inner cell mass are then placed in a culture, where they will divide continuously without differentiating, thus forming a "stem cell line" of identical cells. An individual ESC may be removed from the line without disrupting either the multiplication process or the durability of the line. The removed cell may then be used in a research project—either by the investigator who extracted it or by another—in which the ESC will be caused to develop into the type of cell pertinent to that research. Most stem cell lines are maintained by one or another of several research universities, which make them available for scientific use, usually for a small fee.

The plaintiffs in this case, Drs. James Sherley and Theresa Deisher, are scientists who use only adult stem cells in their research. They contend the NIH has, by funding research projects using ESCs, violated the Dickey–Wicker Amendment, which the Congress has included in the annual appropriation for the Department of Health and Human Services each year since 1996. Dickey–Wicker prohibits the NIH from funding:

> ***2** (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 section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

Pub.L. No. 111–117, § 509(a)(2), 123 Stat. 3034, 3280–81.

In 1996, when the Congress first passed Dickey–Wicker, scientists had taken steps to isolate ESCs but had not yet been able to stabilize them for research in the laboratory. The historical record suggests the Congress passed the Amendment chiefly to preclude President Clinton from acting upon an NIH report recommending federal funding for research using embryos that had been created for the purpose of in vitro fertilization. *See* O. Carter Snead, *Science, Public Bioethics, and the Problem of Integration*, 43 U.C. DAVIS L.REV. 1529, 1546 (2010). Dickey–Wicker became directly relevant to ESCs only in 1998, when researchers at the University of Wisconsin succeeded in generating a stable line of ESCs, which they made available to investigators who might apply for NIH funding.

For that reason, on January 15, 1999, the General Counsel of the Department of Health and Human Services issued a memorandum addressing whether Dickey–Wicker permits federal funding of research using ESCs that had been derived before the funded project began; she concluded such funding is permissible because ESCs are not "embryos." After notice and comment, the NIH issued funding guidelines consistent with this opinion, *see* 65 Fed.Reg. 51,976 (2000), but the NIH did not fund any ESC research project while President Clinton was in office.

Early in 2001, President Bush directed the NIH not to fund any project pursuant to President Clinton's policy; later that year he decided funding for ESC research would be limited to projects using the approximately 60 then-extant cell lines derived from "embryos that ha[d] already been destroyed." *See* 37 WEEKLY COMP. PRES. DOC.. 1149, 1151 (Aug. 9, 2001); *see also* Exec. Order No. 13,435, 72 Fed.Reg. 34,591 (2007); *Doe v. Obama*, 631 F.3d 157, 159 (4th Cir.2011). Meanwhile, the Congress continued to reenact Dickey–Wicker each year of the Bush Administration.

Upon assuming office in 2009, President Obama lifted the temporal restriction imposed by President Bush and permitted the NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." Exec. Order 13,505, 74 Fed.Reg. 10,667, 10,667 (2009). The NIH, after notice-and-comment rulemaking, then issued the 2009 Guidelines, 74 Fed.Reg. 32,170–32,175 (July 7, 2009), which are currently in effect. In the Guidelines, the NIH noted "funding of the derivation of stem cells from human embryos is prohibited by ... the Dickey–Wicker Amendment." *Id.* at 32,175/2. The Guidelines further addressed Dickey–Wicker as follows:

> ***3** Since 1999, the Department of Health and Human Services (HHS) has consistently interpreted

> [Dickey–Wicker] as not applicable to research using [ESCs], because [ESCs] are not embryos as defined by Section 509. This longstanding interpretation has been left unchanged by Congress, which has annually reenacted the Dickey [sic] Amendment with full knowledge that HHS has been funding [ESC] research since 2001. These guidelines therefore 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 32,173/2.

In place of President Bush's temporal limitation, the 2009 Guidelines instituted specific ethical restrictions upon ESC research funded by the NIH: Such research may be conducted only upon stem cell lines derived from embryos that "were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose," and that "were donated by individuals who sought reproductive treatment ... who gave voluntary written consent for the human embryos to be used for research purposes," and who were not paid therefor. *Id.* at 32,174/2–3. Moreover, the research may use stem cell lines derived from an embryo donated after the effective date of the Guidelines only if the in vitro clinic had fully informed the donor of all possible options for disposing of the embryo and had taken other specified procedural steps to separate reproductive treatment from donation. *Id.*

After the 2009 Guidelines were issued, the Congress once again reenacted Dickey–Wicker as part of the appropriations bill for fiscal year 2010. The Congress has not enacted an appropriations bill for FY 2011, adopting instead a series of continuing resolutions that have carried Dickey–Wicker forward to the present. Neither party to this case has suggested the Congress might modify Dickey–Wicker for the remainder of FY 2011.

Drs. Sherley and Deisher and a number of others filed this suit in August 2009 and moved the district court for a preliminary injunction. Instead, the district court granted the Government's motion to dismiss the suit for want of standing. The plaintiffs appealed and we reversed in part, holding the doctors alone had standing because they competed with ESC researchers for NIH funding. *Sherley I*, 610 F.3d at 72–74.

On remand, the district court granted the doctors' motion and issued a preliminary injunction providing "that defendants and their officers, employees, and agents are enjoined from implementing, applying, or taking any action whatsoever pursuant to the [2009 Guidelines], or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." Upon the Government's motion, this court stayed the preliminary injunction pending appeal thereof. In the meantime, proceedings have continued in the district court, where the parties have cross-moved for summary judgment. The only question before us now, therefore, is the propriety of the preliminary injunction.

II. Analysis

***4** [1][2] A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 129 S.Ct. 365, 376, 172 L.Ed.2d 249 (2008). "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* at 374.

We pause to consider how we are to treat these four factors. Before *Winter*, this court and others had allowed that a strong showing on one factor could make up for a weaker showing on another. *See Davenport v. Int'l Bhd. of Teamsters*, 166 F.3d 356, 360–61 (D.C.Cir.1999); *see also Winter*, 129 S.Ct. at 392 (Ginsburg, J., dissenting) ("courts have evaluated claims for equitable relief on a 'sliding scale,' sometimes awarding relief based on a lower likelihood of harm when the likelihood of success is very high"). In *Davis v. Pension Benefit Guaranty Corp.*, 571 F.3d 1288, 1292 (2009), we noted that *Winter* "could be read to create a more demanding burden" than the sliding-scale analysis requires although, as we there observed, Justice Ginsburg does not think so, *see Winter*, 129 S.Ct. at 392. In *Davis*, however, we did not have to resolve the issue because we would have reached the same conclusion under either approach. 571 F.3d at 1292.

In their concurring opinion in *Davis*, two judges expressed the view that "under the Supreme Court's precedents, a movant cannot obtain a preliminary injunction without showing *both* a likelihood of success *and* a likelihood of irreparable harm, among other things." *Id.* at 1296. They noted that the *Winter* Court seemed to treat the four factors as independent requirements and specifically to reject the Ninth Circuit's statement that a strong likelihood of success on the merits lessens the movant's burden to showing merely a "possibility" rather than a "likelihood" of irreparable harm. *Id.* (citing *Winter*, 129 S.Ct. at 374–76); *see also* *Nken v. Holder*, ——U.S. ——, 129 S.Ct. 1749, 1763, 173 L.Ed.2d 550 (2009) (Kennedy, J., concurring) ("When considering success on the merits and irreparable harm, courts cannot dispense with the required showing of one simply because there is a strong likelihood of the other").

Like our colleagues, we read *Winter* at least to suggest if not to hold "that a likelihood of success is an independent, free-standing requirement for a preliminary injunction," *Davis*, 571 F.3d at 1296 (concurring opinion). Although the Fourth Circuit has read the same case to similar effect, *see* *Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 347 (2009), other circuits do not understand it to preclude continuing adherence to the sliding-scale approach, *see* *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1130–35 (9th Cir.2011); *Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35–38 (2d Cir.2010); *Hoosier Energy Rural Elec. Coop. v. John Hancock Life Ins. Co.*, 582 F.3d 721, 725 (7th Cir.2009). We need not wade into this circuit split today because, as in *Davis*, as detailed below, in this case a preliminary injunction is not appropriate even under the less demanding sliding-scale analysis.

***5** [3] We review the district court's balancing of the four factors for abuse of discretion. *Davis*, 571 F.3d at 1291. Insofar as the inquiry depends upon a question of law, our review is, of course, de novo. *Id.*; *Ark. Dairy Coop. Ass'n v. USDA*, 573 F.3d 815, 821 (D.C.Cir.2009). In this case, our de novo review is central to the plaintiffs' likelihood of success on the merits, *see* *City of Las Vegas v. Lujan*, 891 F.2d 927, 931–32 (D.C.Cir.1989), which success depends upon an issue of statutory interpretation.

A. Likelihood of Success on the Merits

In entering the preliminary injunction, the district court concluded the plaintiff doctors are likely to succeed in demonstrating the 2009 Guidelines are inconsistent with the limits upon funding in the Dickey–Wicker Amendment. 704 F.Supp.2d 63, 70–72 (2010). We approach this issue under the familiar two-step framework of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984): If the Congress has "directly spoken to the precise question at issue," then we must "give effect to the unambiguously expressed intent of Congress"; if instead the "statute is silent or ambiguous with respect to the specific issue," then we defer to the administering agency's interpretation as long as it reflects "a permissible construction of the statute."

1. *Chevron* step one

[4] We begin our review, of course, by looking to the text of Dickey–Wicker, which bars federal funding specifically 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 the Public Health Service Act and a particular regulation of the Department of Health and Human Services. The district court held, and the plaintiffs argue on appeal, this provision unambiguously bars funding for any project using an ESC. They reason that, because an embryo had to be destroyed in order to yield an ESC, any later research project that uses an ESC is necessarily "research" in which the embryo is destroyed. For its part, the Government argues the "text is in no way an unambiguous ban on research using embryonic stem cells" because Dickey–Wicker is written in the present tense, addressing research "in which" embryos "are" destroyed, not research "for which" embryos "were destroyed."

[5] The use of the present tense in a statute strongly suggests it does not extend to past actions. The Dictionary Act provides "unless the context indicates otherwise ... words used in the present tense include the future as well as the present." 1 U.S.C. § 1. As the Supreme Court has observed, that provision implies "the present tense generally does not include the past." *Carr v. United States*, —— U.S. ——, 130 S.Ct. 2229, 2236, 176 L.Ed.2d 1152 (2010). The context here does not, as our dissenting colleague would have it, indicate a different understanding. To

the contrary, as amicus the University of California urges in its brief, and as the Government emphasized at oral argument, NIH funding decisions are forward-looking, requiring the NIH to "determine whether what is proposed to be funded meets with its requirements." Therefore, a grant application to support research that includes the derivation of stem cells would have to be rejected.[FN*]

***6** The plaintiffs respond by reiterating their primary argument: Because "research" using an ESC includes derivation of the ESC, the derivation does not predate but is an integral part of the "research." The conclusion does not follow from the premise; at best it shows Dickey–Wicker is open to more than one possible reading.[FN*] The plaintiffs also argue we must read the term "research" broadly because the Congress, had it intended a narrower reading, would have used a term identifying a particular action, as it did in subsection (1) of Dickey–Wicker, which specifically bars the "creation" of an embryo for "research purposes." We see no basis for that inference. 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.

2. *Chevron* step two

[6] We turn, therefore, to *Chevron* step two, under which we must uphold the NIH's interpretation of Dickey–Wicker if it is but "reasonable." *See Chevron*, 467 U.S. at 844, 104 S.Ct. 2778. Recall the relevant text is the prohibition against funding for "research in which a human embryo or embryos are destroyed." The NIH determined Dickey–Wicker does not bar its funding a project using an ESC that was previously derived because a stem cell is not an "embryo" and cannot develop into a human being. The plaintiffs do not dispute this much of the agency's reasoning.

The plaintiffs argue instead the NIH is not entitled to deference because it never offered an interpretation of the term "research." Their premise is not entirely correct: In the 2009 Guidelines the NIH expressly distinguished between the derivation of ESCs and "research involving [ESCs] that does not involve an embryo nor result in an embryo's destruction." 74 Fed.Reg. 32,173/2. Thus, although the Guidelines do not define the term "research," they do make clear the agency's understanding that "research involving [ESCs]" does not necessarily include the antecedent process of deriving the cells.

The plaintiffs, invoking our opinion in *Public Citizen, Inc. v. HHS*, 332 F.3d 654, 661 (2003), argue the agency's effort in this respect is insufficiently specific to warrant our deference. In the cited case we did not defer to HHS because the agency had not actually addressed the disputed portion of the statute; indeed, it had "[done] little more than repeat the statutory language" and had failed to offer any explanation for its position that a Peer Review Organization could "inform" a Medicare beneficiary of its disposition of his complaint about a treating physician with a form letter lacking most of the pertinent information. *Id.* There was, in short, "no reasoning that we [could] evaluate for its reasonableness." *Id.* Here, in contrast, the NIH has explained how funding an ESC project is consistent with the Dickey–Wicker Amendment. The plaintiffs' objection that the NIH has not explicitly defined a word in the statute—an important word, to be sure—is mere cavil; it disregards the agency's use of the term, which implicitly but unequivocally gives "research" a narrow scope, thus ensuring no federal funding will go to a research project in which an embryo is destroyed. *See Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 420, 112 S.Ct. 1394, 118 L.Ed.2d 52 (1992) (that agency's "interpretation of the word 'required' " was implicit "does not mean that we may not defer to that interpretation").

***7** To this point the plaintiffs apparently respond that the NIH has, by treating derivation as part of "research," shown its understanding of Dickey–Wicker is unreasonable. Their argument is that, because the standard definition of "research" requires some kind of scientific inquiry, and deriving ESCs, standing alone, involves no such inquiry, the act of derivation can be deemed "research" only if it is part of a larger project. The plaintiffs refer us to 45 C.F.R. § 46.102(d), *supra* at —— n. *; *see also, e.g.*, MERRIAM–WEBSTER DICTIONARY ONLINE,, http://merriam-webster.com/dictionary/research (last visited Mar. 20, 2011) ("careful or diligent search"; "studious inquiry or examination; *especially:* investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws"); OXFORD ENGLISH DICTIONARY ONLINE, http://www.oed.com/viewdictionaryentry/Entry/163432

(last visited Mar. 22, 2011) ("Systematic investigation or inquiry aimed at contributing to knowledge of a theory, topic, etc., by careful consideration, observation, or study of a subject"). The plaintiffs' premise is valid in part: Because the Guidelines state Dickey–Wicker bans funding for the derivation of ESCs and Dickey–Wicker bans only "research," it is clear the NIH treats the act of derivation as "research." The Government expressly confirmed this much at oral argument when counsel flatly stated "derivation is research." Less clear is whether the act of derivation, by itself, comes within a standard definition of research, that is, whether it involves any investigation or inquiry. On that score, the Government pointed out at oral argument that "stem cells are not pre-labeled cells that you can simply extract," and argued "the scientific process" of derivation, in which cells are "extracted and put into mediums where [they] can grow" before being examined and chemically treated, "itself involves experimentation."

Rather than rely upon that account of derivation qualifying as research, let us assume for the sake of the plaintiffs' argument derivation involves no scientific inquiry; it does not follow that the NIH may define derivation as "research" only if or insofar as the derivation is tethered to some later project using the derived cells. Although an understanding of "research" that includes the derivation of stem cells is not the ordinary reading of that term, it 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.[FN*] The fact is the statute is not worded precisely enough to resolve the present definitional contest conclusively for one side or the other.

***8** 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.

Further, adding the temporal dimension to our perspective, we see, as the NIH noted in promulgating the 2009 Guidelines, the Congress has reenacted Dickey–Wicker unchanged year after year "with full knowledge that HHS has been funding [ESC] research since 2001," 74 Fed.Reg. 32,173/2, when President Bush first permitted federal funding for ESC projects, provided they used previously derived ESC lines. As the plaintiffs conceded at oral argument, because this policy permitted the NIH to fund projects using ESCs, it would have been prohibited under their proposed reading of Dickey–Wicker. So, too, with the policy the Clinton Administration announced in 1999 and, of course, with the 2009 Guidelines promulgated by the Obama Administration. The plaintiffs have no snappy response to the agency's point that the Congress's having reenacted Dickey–Wicker each and every year provides "further evidence ... [it] intended the Agency's interpretation, or at least understood the interpretation as statutorily permissible." *Barnhart v. Walton*, 535 U.S. 212, 220, 122 S.Ct. 1265, 152 L.Ed.2d 330 (2002); *accord Lindahl v. OPM*, 470 U.S. 768, 782 n. 15, 105 S.Ct. 1620, 84 L.Ed.2d 674 (1985) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change" (internal quotation marks omitted)).[FN*]

3. Subsidiary Arguments

A few matters remain. First, we note, because the plaintiffs bring solely a facial challenge to the Guidelines, we have no occasion to consider their suggestion that the NIH might grant the researcher who derived an ESC line federal funds for research using it, which would link the act of derivation more closely to subsequent research and test the distinction between them drawn by the NIH. However that case—were it ever to materialize—might play out is irrelevant here.[FN*] To prevail in their challenge to the Guidelines on their face the plaintiffs "must establish that no set of circumstances exists under which the [Guidelines] would be valid," *Reno v. Flores*, 507 U.S. 292, 301, 113 S.Ct. 1439, 123 L.Ed.2d 1 (1993) (internal quotation marks omitted); it is not enough for the plaintiffs to show the Guidelines could be applied unlawfully, *see Air Transp. Ass'n of Am. v. DOT*, 613 F.3d 206, 213 (D.C.Cir.2010); *see also Am. Hosp. Ass'n v. NLRB*,

499 U.S. 606, 619, 111 S.Ct. 1539, 113 L.Ed.2d 675 (1991) ("that petitioner can point to a hypothetical case in which the rule might lead to an arbitrary result does not render the rule 'arbitrary or capricious' ").[FN**]

***9** [7] The plaintiffs also argue the Guidelines transgress the prohibition in Dickey–Wicker against "research in which a human embryo or embryos are ... knowingly subjected to risk of injury or death." To the extent this argument is distinct from the plaintiffs' principal argument that all ESC research is research in which an embryo is destroyed, it relies upon the proposition that ESC research "creat[es] demand for[ ] human embryonic stem cells," which "*necessitate[s]* the destruction of embryos." The district court did not address this theory in entering the preliminary injunction. Although ordinarily we "may affirm the judgment of the district court on the basis of a different legal theory," *Harbor Ins. Co. v. Stokes*, 45 F.3d 499, 501 (D.C.Cir.1995) (summary judgment), the decision whether to grant a preliminary injunction is a matter of discretion, not a question of right, *see Winter*, 129 S.Ct. at 376–77. Not surprisingly, therefore, the plaintiffs have not identified, nor have we found, any precedent for upholding a preliminary injunction based upon a legal theory not embraced by the district court. In this as in every such case, it is for the district court to determine, in the first instance, whether the plaintiffs' showing on a particular claim warrants preliminary injunctive relief. For the same reason we do not pass upon the plaintiffs' argument they are likely to succeed on their claim under the Administrative Procedure Act that the NIH promulgated the Guidelines "through an inadequate notice-and-comment process."

Because those of the plaintiffs' legal arguments that are properly before us do not stand up well to analysis, it follows they have not shown they are more likely than not to succeed on the merits of their case. Indeed, were we to adopt the strict reading given *Winter* by our concurring colleagues in *Davis*, our inquiry would end here. Under the sliding-scale approach, however, we must go on to determine whether the other three factors so much favor the plaintiffs that they need only have raised a "serious legal question" on the merits. *See Wash. Metropolitan Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843–44 (D.C.Cir.1977) ("a court, when confronted with a case in which the other three factors strongly favor interim relief may exercise its discretion to grant a stay if the movant has made a substantial case on the merits"). That much the plaintiffs have done. We turn therefore to another of the four factors, whether "the balance of equities tips in [the plaintiffs'] favor," *Winter*, 555 U.S. at ——, 129 S.Ct. at 374. Because it does not, we need not consider either of the other two factors.

B. Balance of the Equities

[8] The district court reasoned the "balance of hardships weighs in favor of an injunction" because, for ESC researchers, "the injunction would simply preserve the *status quo* and would not interfere with their ability to obtain private funding." 704 F.Supp.2d at 72. On the other hand, the court thought it certain that increased competition would "threaten [the plaintiffs'] very livelihood." *Id.* at 72–73.

***10** As we see it, however, a preliminary injunction would in fact upend the status quo. True, the plaintiffs compete with ESC researchers for funding—indeed, that is why they have standing to bring this case, *see Sherley I*, 610 F.3d at 71–74—but they have been competing with ESC researchers since 2001. The 2009 Guidelines inflict some incremental handicap upon the plaintiffs' ability to compete for NIH money—they point to the additional time and money they must expend and have had to expend since 2001 to meet the additional competition from researchers proposing to use ESCs—but it is necessarily uncertain whether invalidating the Guidelines would result in the plaintiffs getting any more grant money from the NIH. Accordingly, we cannot say that, if the plaintiffs are to litigate this case without the benefit of interim relief, then the 2009 Guidelines will place a significant additional burden upon their ability to secure funding for their research.

The hardship a preliminary injunction would impose upon ESC researchers, by contrast, would be certain and substantial. The injunction entered by the district court would preclude the NIH from funding new ESC projects it has or would have deemed meritorious, thereby inevitably denying other scientists funds they would have received. Even more problematic, the injunction would bar further disbursements to ESC researchers who have already begun multi-year projects in reliance upon a grant from the NIH; their investments in project planning would be a loss, their expenditures for equipment a waste, and their staffs out of a job. The record shows private funding is not generally available for stem cell research but even

if, as the district court thought, private donors or investors would provide a reasonable alternative source of funds for ESC researchers, 704 F.Supp.2d at 72, it remains unclear why such donors or investors would not similarly support the plaintiffs' research using adult stem cells and why the plaintiffs' "very livelihood" instead depends upon obtaining grants from the NIH.

All this is to say the balance of equities tilts against granting a preliminary injunction. That, combined with our conclusion the plaintiffs have not shown they are likely to succeed on the merits, leads us to hold the district court abused its discretion in awarding preliminary injunctive relief.

III. Conclusion

Because the plaintiffs have not shown they are likely to succeed on the merits, we conclude they are not entitled to preliminary injunctive relief. We reach this conclusion under the sliding scale approach to the preliminary injunction factors; *a fortiori* we would reach the same conclusion if likelihood of success on the merits is an independent requirement. Therefore, the preliminary injunction entered by the district court must be and is

Vacated.

KAREN LeCRAFT HENDERSON, Circuit Judge, dissenting:

The majority opinion has taken a straightforward case of statutory construction and produced a result that would make Rube Goldberg tip his hat. Breaking the simple noun "research" into "temporal" bits, Maj. Op. at ——, ——, ——, narrowing the verb phrase "are destroyed" to an unintended scope, *id.* at ——, dismissing the definition section of implementing regulations promulgated by the Department of Health and Human Services (HHS) (in case the plain meaning of "research" were not plain enough), *id.* at —— n. *, my colleagues perform linguistic jujitsu. I must therefore respectfully dissent.

***11** The Government appeals from the district court's entry of a preliminary injunction prohibiting it "from implementing, applying, or taking any action whatsoever pursuant to" the NIH Guidelines for Human Stem Cell Research (Guidelines), 32 Fed.Reg. 32,170 (July 7, 2009), "or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." Order, *Sherley v. Sebelius*, 704 F.Supp.2d 63 (D.D.C.2010) (No. 09–1575). "On a motion for a preliminary injunction, the district court must balance four factors: (1) the movant's showing of a substantial likelihood of success on the merits, (2) irreparable harm to the movant, (3) substantial harm to the nonmovant, and (4) public interest." *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291 (D.C.Cir.2009). We review the district court's weighing of the preliminary injunction factors for abuse of discretion and its findings of fact under the clearly erroneous standard. *Id.* To the extent its decision turns on a question of law, our review is de novo. *Id.* I believe that the plaintiffs, researchers who use adult stem cells only, are likely to succeed on the merits of their challenge to the Guidelines and that the district court did not abuse its discretion in weighing the preliminary injunction factors in favor of granting the injunction. Accordingly, I would affirm.

I. Likelihood of Success on the Merits

The majority opinion sets out the background information describing the "derivation" of human embryonic stem cells (hESCs) from a human embryo—which action destroys the embryo—and the subsequent use of the hESCs in the hope of remedying many serious, and often fatal, diseases and debilitating physical conditions. I take no exception to that portion of the majority opinion except to the extent that it recites the "historical record suggests the Congress passed the [Dickey–Wicker] Amendment chiefly" to address matters other than hESC research. Maj. Op. at ——. The Government's brief suggests otherwise. After explaining that the Congress enacted the Amendment "in reaction to a 1994 NIH panel report," Appellants' Br. 21, it recites that the 1994 report advocated federal funding of research "designed to improve the process of *in vitro* fertilization, to determine whether embryos carried genetic abnormalities, *and to isolate embryonic stem cells.*" *Id.* (second emphasis added). There is no reason to assume, therefore, the Congress did not consider hESC research when it first enacted the Dickey–Wicker Amendment (Amendment) in 1996.

The Amendment, reenacted annually as a rider to appropriations legislation, prohibits the expenditure of federal funds both for "the creation of a human embryo or embryos for research purposes" and for "research in which a human embryo or embryos are destroyed." Consolidated Appropriations Act of 2010,

Pub.L. No. 111–117, § 509(a), 123 Stat. 3034, 3280–81 (Dec. 16, 2009). It is the latter ban that the plaintiffs claim is violated by the 2009 Guidelines. Determining whether hESC research is "research in which a human embryo or embryos are destroyed" requires determining the meaning of "research." The plaintiffs contend that all hESC research constitutes research in which human embryos are destroyed and that the Amendment accordingly prohibits federal funding thereof. The Government counters that the derivation of hESCs and the subsequent use of those cells, although both research, are not part of the same—and prohibited—research. We construe the Amendment under the familiar two-step approach set forth in *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). *Chevron* step one asks if the "Congress has directly spoken to the precise question at issue." *Id.* at 842, 104 S.Ct. 2778. "We start with the plain meaning of the text, looking to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Blackman v. District of Columbia*, 456 F.3d 167, 176 (D.C.Cir.2006) (internal quotation marks omitted). I believe we need go no further than *Chevron* step one here because the plain meaning of the Amendment is easily grasped. *See id.* ("If the [statute] has a plain and unambiguous meaning, our inquiry ends so long as the resulting statutory scheme is coherent and consistent." (internal quotation marks omitted)). Accordingly, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842–43, 104 S.Ct. 2778.

***12** The district court correctly looked to the dictionary definition of "research" as "diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications, etc." *Sherley v. Sebelius*, 704 F.Supp.2d at 70 (citing Random House Dictionary); *see also* Maj. Op. at —— (quoting Oxford English Dictionary Online ("Systematic investigation or inquiry aimed at contributing to knowledge of a theory, topic, etc., by careful consideration, observation, or study of a subject")). Research, then, comprises a systematic inquiry or investigation. And "systematic" connotes sequenced action. XVII Oxford English Dictionary 498 (2d ed. 1989) ("systematic": "Arranged or conducted according to a system, plan, or organized method ...."); *see also CACI Int'l, Inc. v. St. Paul Fire & Marine Ins. Co.*, 566 F.3d 150, 158–59 (4th Cir.2009) (describing "systematic" behavior as "a series of acts" (internal quotation marks omitted)). The first sequence of hESC research is the derivation of stem cells from the human embryo. The derivation of stem cells destroys the embryo and therefore cannot be federally funded, as the Government concedes. *See* Maj. Op. at —— ——. I believe the succeeding sequences of hESC research are likewise banned by the Amendment because, under the plain meaning of "research," they continue the "systematic inquiry or investigation."

That the intent of the 1996 Congress, in enacting the Amendment, is to prohibit all hESC research—not just research attendant on the derivation of the cells—is clear by comparing the language used to ban federal funding for the creation of an embryo with the language the plaintiffs rely on. *See Erlenbaugh v. United States*, 409 U.S. 239, 244, 93 S.Ct. 477, 34 L.Ed.2d 446 (1972) (rule that statutes *in pari materia* should be construed together "is but a logical extension of the principle that individual sections of a single statute should be construed together"); *Motion Picture Ass'n of Am. v. FCC*, 309 F.3d 796, 801 (D.C.Cir.2002) ("Statutory provisions *in pari materia* normally are construed together to discern their meaning."). While the Amendment prohibits federal financing of the "creation of a human embryo ... for research purposes," it does *not* use parallel language in addressing the destruction of embryos. It bans federal funding of "research" rather than the "destruction of human embryos for research purposes." Research, then, is the express target of the ban the Congress imposed with respect to the destruction of a human embryo. This makes perfect sense because in 1996, according to the record, hESC research had barely begun. Deisher Decl. ¶ 7. The Congress, recognizing its scant knowledge about the feasibility/scope of hESC research, chose broad language with the plain intent to make the ban as complete as possible. Because the meaning of research is plain, and the intent of the Congress to ban the federal funding of hESC research is equally plain, I would stop at *Chevron* step one and enjoin the Guidelines as violative of the Amendment to the extent they allow federal funds to be used for hESC research.

***13** If there *were* any uncertainty about the extent of the Amendment's ban, it would be erased by reading the Amendment's language in full, as the district court—again, correctly—did. The ban on federal funding of hESC research provides that federal funds

may not be used for:

> [R]esearch 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 section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

Pub.L. No. 111–117, § 509(a)(2), 123 Stat. at 3280–81. The Amendment's incorporation of 45 C.F.R. § 46.204(b)—HHS's own regulation—relates to "[r]esearch involving pregnant women and fetuses," as section 46.204 is entitled. "Research," as used in section 46.204(b), means "a *systematic investigation, including research development,* testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d) (emphasis added); *see id.* § 46.202 ("definitions in § 46.102 [are] applicable to [§ 46.204]"). In expressly linking "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death" and "research on fetuses in utero under 45 C.F.R. 46.204(b)," the Congress unambiguously manifested its intent that "research" as used in the Amendment is to have the same meaning as "research" used in section 46.204(b).[FN1] Moreover, the "presumption that a given term is used to mean the same thing throughout a statute" is "at its most vigorous when a term is repeated within a given sentence," as "research" is in the Amendment. *Brown v. Gardner*, 513 U.S. 115, 118, 115 S.Ct. 552, 130 L.Ed.2d 462 (1994). Section 46.102(d) confirms that research involves sequenced action by defining it to include "development, testing and evaluation" sequences. "Research development" perfectly describes the first sequence of hESC research, that is, the derivation of the cells. The testing and evaluation sequences of hESC research cannot be performed without first conducting the research involved in deriving hESCs from the human embryo. The derivation of hESCs is, thus, the *sine qua non* developmental sequence on which all subsequent sequences of hESC research rest. Moreover, nothing in the record suggests that hESCs are derived for any purpose other than the testing and evaluation of those cells. That hESCs cannot be tested and evaluated unless and until they are derived from a human embryo, combined with the fact that derivation of hESCs is done solely as part of a "systematic investigation" of those cells, demonstrates that derivation is the necessary first sequence of hESC research. Because derivation of hESCs necessarily destroys a human embryo or embryos, and because derivation constitutes at least hESC research development under the Amendment, all hESC research is "research in which a human embryo or embryos are destroyed." Accordingly, the plaintiffs' challenge to the Amendment is likely to succeed because the Amendment prohibits the expenditure of federal funds to engage in hESC research in all of its sequences.

***14** In my view, the majority opinion strains mightily to find the ambiguity the Government presses.[FN2] Treating "research" as composed of free-standing pieces, it concludes that the only piece that is banned is the derivation of the hESCs. The authority for this novel reading of "research" is not the dictionary but the Amendment's use of the phrase "in which a human embryo or embryos *are* destroyed" rather than "for which a human embryo or embryos *were* destroyed." Maj. Op. at —— (emphases added).[FN3] The majority opinion correctly notes that the Dictionary Act, which provides that "unless the context indicates otherwise ... words used in the present tense include the future as well as the present," 1 U.S.C. § 1, implies "that the present tense generally does not include the past," *Carr v. United States*, —— U.S. ——, 130 S.Ct. 2229, 2236, 176 L.Ed.2d 1152 (2010). That is not true, however, where, as here, "the context indicates otherwise." 1 U.S.C. § 1. *See Lindh v. Murphy*, 521 U.S. 320, 331, 117 S.Ct. 2059, 138 L.Ed.2d 481 (1997) ("one has to strain to find ... ambiguity" in reading statutory provision that "is applicable if a State *establishes* ... a mechanism" to include State that *established* mechanism before statute's enactment (first emphasis added)); *Abercrombie v. Clarke*, 920 F.2d 1351, 1359 (7th Cir.1990) (finding "abundantly clear that Congress intended the present tense language [in provisions of Financial Institutions Reform, Recovery, and Enforcement Act of 1989 providing for civil monetary penalties] to apply to past acts"), *cert. denied*, 502 U.S. 809, 112 S.Ct. 52, 116 L.Ed.2d 29 (1991); *Bell v. Maryland*, 378 U.S. 226, 236, 84 S.Ct. 1814, 12 L.Ed.2d 822 (1964) ("very possibl[e]" that Maryland Court of Appeals would hold "the use of the present tense instead of the more usual future tense" in Maryland statute "to apply to past as well as future conduct"); *Coal. for Clean Air v. S. Cal. Edison Co.*, 971 F.2d 219, 225 (9th Cir.1992) ("The present tense is commonly used to refer to past, present, and future all at the same time. We believe that Congress used the present tense word ... because it

did *not* wish to limit [the statute's] reach to either past or future disapprovals."); *United States v. Reilly Tar & Chem. Corp.*, 546 F.Supp. 1100, 1108–09 (D.Minn.1982) (provision allowing United States to seek injunction against any person "contributing to" handling, storage, treatment, transportation or disposal of solid or hazardous waste could be applied, at motion to dismiss stage, to past owner of inactive site who was no longer "contributing to the condition"); *cf. Carr*, 130 S.Ct. at 2244–45 (Alito, J., dissenting) (responding to majority's reliance on statute's use of present tense to reject statute's reach to past tense by noting that "modern legislative drafting manuals," including those used by both the United States Senate and House, "teach that, except in unusual circumstances, all laws ... should be written in the present tense"); *Nickell v. Beau View of Biloxi, LLC*, No. 10–60204, 636 F.3d 752, 756–57 (5th Cir.2011) (notwithstanding general rule, context indicated otherwise where inclusion of future events would conflict with statute of limitations and other time-limited rights conferred by statute); *see also Guidiville Band of Pomo Indians v. NGV Gaming, Ltd.*, 531 F.3d 767, 776 (9th Cir.2008) ("[O]n its own terms the Dictionary Act ... looks first to 'context,' and only if the 'context' leaves the meaning open to interpretation does the default provision come into play."). There is no question that, here, context manifests that the present tense includes both the past as well as the future.[FN4] As already discussed, the derivation of hESCs constitutes *at least* research development, which, in *context*, means that it is "research in which a human embryo or embryos are [at any point] destroyed."

***15** But it is not only the majority opinion's view of verb tenses that is wrong. My colleagues rest their *Chevron* step two analysis on the transformation of "research" into "research project" in the Amendment's text. In other words, it reads "research" as if it were synonymous with "research project." Maj. Op. at ——— – ———, ——— – ———, ———. But "research" is the overall "systematic investigation or inquiry" in a field—here, hESCs—of which each project is simply a part. Webster's Third New International Dictionary 1813 (1993) ("project" means "a definitely formulated *piece* of research" (emphasis added)). Without the majority opinion's misreading of "research" as "research project," the entire notion of pieces of research evaporates—taking with it the "ambiguity" that sets *Chevron* step two in motion.[FN5]

Finally, it is of little moment that the Congress has reenacted the Amendment unchanged every year since 1996. While congressional reenactment ordinarily means the Congress intended to adopt an existing agency interpretation of the statute, *e.g.*, *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 846, 106 S.Ct. 3245, 92 L.Ed.2d 675 (1986), "[t]here is an obvious trump to the reenactment argument ... in the rule that '[w]here the law is plain, subsequent reenactment does not constitute an adoption of a previous administrative construction,' " *Brown v. Gardner*, 513 U.S. 115, 121, 115 S.Ct. 552, 130 L.Ed.2d 462 (1994) (quoting *Demarest v. Manspeaker*, 498 U.S. 184, 190, 111 S.Ct. 599, 112 L.Ed.2d 608 (1991)). Moreover, "congressional silence lacks persuasive significance, particularly where administrative regulations are inconsistent with the controlling statute," *id.* (internal quotation marks and citations omitted), and "[a] regulation's age is no antidote to clear inconsistency with a statute," *id.* at 122, 115 S.Ct. 552.[FN6] Because I believe the Government's reading of the Amendment contravenes the Amendment's plain meaning, I am unpersuaded that the Congress, by simply reenacting the Amendment, has sanctioned that reading.[FN7] Accordingly, the plaintiffs have demonstrated to me a strong likelihood that they will prevail on the merits.

II. Remaining Factors

In addition to likelihood of success on the merits, the plaintiffs must also show "(2) irreparable harm to [them], (3) [no] substantial harm to the [Government], and (4) [the] public interest [is not harmed]," *Davis*, 571 F.3d at 1291, in order to obtain injunctive relief.

To demonstrate irreparable harm in the absence of an injunction, the plaintiffs' injury "[must be] of such *imminence* that there is a clear and present need for equitable relief to prevent irreparable harm." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C.Cir.2006) (internal quotation marks omitted). We earlier held that these two plaintiffs do indeed suffer "an actual, here-and-now injury" from the Guidelines and that the probability they will "lose funding to projects involving [h]ESCs" is "substantial enough ... to deem the injury to them *imminent*." *Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C.Cir.2010) (emphasis added). As the district court noted, moreover, their injury is irreparable because we "cannot compensate [them] for their lost opportunity to receive funds." *Sherley*, 704 F.Supp.2d at 72. The majority

opinion now dismisses their injury as "necessarily uncertain." Maj. Op. at ——. At the same time, my colleagues see no uncertainty in the harm to the Government if the injunction is affirmed. *Id.* I agree that enjoining the Guidelines would disrupt any hESC research projects that have already received federal funding and therefore harm the Government. Finally, I believe the district court correctly determined that enjoining the Guidelines would further the public interest. *See* *Sherley*, 704 F.Supp.2d at 73 (" 'It is in the public interest for courts to carry out the will of Congress and for an agency to implement properly the statute it administers.' " (quoting *Mylan Pharms., Inc. v. Shalala*, 81 F.Supp.2d 30, 45 (D.D.C.2000))). As discussed *supra*, I believe the plaintiffs have made a strong showing of likelihood of success on the merits. Under the sliding scale approach that remains the law of our Circuit, *see* Maj. Op. at —— – ——, "[i]f the movant makes an unusually strong showing on one of the factors, then it does not necessarily have to make as strong a showing on another factor." *Davis*, 571 F.3d at 1291–92. Having concluded the plaintiffs have indeed made "an unusually strong showing" on the first factor, I cannot say the district court abused its discretion in balancing all of the factors in favor of granting preliminary injunctive relief.

***16** For the foregoing reasons, I respectfully dissent.

FN* The plaintiffs urge us to adopt the district court's view that Dickey–Wicker incorporates the definition of "research" in the Human Subject Protection regulations: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d). The Government argues otherwise, but we need not resolve this debate because, as the Government also argues, that a project involves "research development" or is " 'systematic' does not mean that it includes acts or processes," such as deriving ESCs, "that predated the federally funded research."

FN* The plaintiffs rely upon *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005), but that case is inapposite; it involved a statute that protected from an infringement claim the use of patented materials "reasonably related to the development and submission of information" to the FDA in a regulatory proceeding. Although the Court concluded the statute protected the use of patented materials at all phases of research, the ruling did not depend upon an interpretation of the term "research," and does not bear upon our understanding of "research" in Dickey–Wicker. *See* *id.* at 202, 125 S.Ct. 2372.

FN* Our dissenting colleague takes us to task for "read[ing] 'research' as if it were synonymous with 'research project,' " but we give it no such fixed meaning. Rather, our point is that "research," although susceptible to a broad definition, is also reasonably understood as a more discrete endeavor.

FN* The parties' disagreement over whether the NIH's interpretation should be deemed "longstanding" is beside the point; this 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. *Creekstone Farms Premium Beef L.L.C. v. USDA*, 539 F.3d 492, 500–501 & n. 10 (D.C.Cir.2008).

FN* The same is true of the plaintiffs' suggestion that a researcher might use federal funds to purchase ESCs; it is nothing more than another argument that the Guidelines could be applied unlawfully.

FN** As the dissent notes, a panel of this court once held this standard inapplicable to a facial statutory (as opposed to a facial constitutional) challenge to a regulation. *See* *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1407–08 (D.C.Cir.1998). That decision, however, was made in the mistaken belief that the "Supreme Court ha[d] never adopted a 'no set of circumstances' test to assess the validity of a regulation challenged as facially incompatible with governing statutory law." *Id.* at 1407. The Court had done just that several

years earlier in *Flores.* Although *Flores* is not literally, therefore, an "intervening" decision of the Supreme Court, *see* *Amfac Resorts, L.L.C. v. DOI*, 282 F.3d 818, 827 (D.C.Cir.2002), *vacated as not ripe sub nom.* *Nat'l Park Hospitality Ass'n v. DOI*, 538 U.S. 803, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003), we have followed it since *National Mining*, *see, e.g.*, *Air Transp. Ass'n*, 613 F.3d at 213; *Bldg. & Constr. Trades Dep't v. Allbaugh*, 295 F.3d 28, 33 (2002), and, bound as we are by a higher authority, do so again here.

FN1. That the Amendment references section 46.204(b) in comparing the risk of injury or death to a human embryo does not affect the Amendment's incorporation of section 46.102(d)'s definition of research. Determining the level of risk permitted for "research on fetuses in utero under [section] 46.204(b)" necessarily requires construing "research" and section 46.102(d) defines "research."

FN2. The Government may not have always taken this view of the Amendment. *See* Letter from Kate Berg, Deputy Scientific Director, NCHGR, to Wendy Fibison, Researcher at Georgetown University Medical Center (Oct. 10, 1996) (Joint Appendix 283) ("NIH position on embryo research" is federally funded researchers "[can]not engage in embryo related research" including certain types of "analysis from DNA derived from a human embryo"). *But see* Appellants' Reply Br. 7–8 (claiming Georgetown research, like derivation, "require[d] the removal of a cell from an embryo").

FN3. The Government's suggested change in inflection can fairly be described as Clintonesque ("It depends upon what the meaning of the word 'is' is." H.R.Rep. No. 105–830, at 40 (Dec. 16, 1998) (quoting Grand Jury Testimony of President W.J. Clinton, *Jones v. Clinton*, 36 F.Supp.2d 1118 (E.D.Ark.1999), at 57–58 (Aug. 17, 1998))).

FN4. Moreover, the Amendment combines the present tense "are" with the *past* participle "destroyed," that is, with "[a] verb form indicating past or completed action or time that is used as a verbal adjective." *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 39, 128 S.Ct. 2326, 171 L.Ed.2d 203 (2008) (alteration in original) (quoting American Heritage Dictionary 1287 (4th ed. 2000)). Other statutes similarly use the present tense, especially a combination of "is" with a past participle, to signify conduct that has already occurred. *See, e.g.*, 10 U.S.C. § 6253 (Secretary of Navy "may replace ... any medal of honor, Navy cross[etc.] awarded under this chapter that *is* stolen, lost, or destroyed or *becomes* unfit for use" (emphases added), that is, a medal which *has been* stolen, lost, or destroyed or become unfit for use before replacement).

FN5. Likewise, the sequenced action inherent in "research," *supra* pp. ——— – ———, does not equate to individual research "projects."

FN6. Moreover, the challenged Guidelines were not promulgated until 2009 so that congressional reenactment of the Amendment in the years *predating* 2009 signifies nothing in relation to the Guidelines.

FN7. The majority opinion dismisses the plaintiffs' challenge that the Guidelines permit a researcher to use federal funds to purchase hESCs and even permit a federally-funded researcher to derive the cells himself. Maj. Op. at ——— – ———. It concludes those possibilities do not affect the facial validity of the Guidelines because they do not demonstrate that "no set of circumstances exists under which the [Guidelines] would be valid." *United States v. Salerno*, 481 U.S. 739, 745, 107 S.Ct. 2095, 95 L.Ed.2d 697 (1987). Whether *Salerno*'s "no set of circumstances" approach is properly applied in the absence of a constitutional challenge is not altogether settled in our Circuit. We have held "that the *Salerno* standard does not apply" when assessing "the validity of a regulation challenged as facially incompatible with governing statutory law." *Nat'l Mining Ass'n v. U.S. Army Corps of*

Eng'rs, 145 F.3d 1399, 1407 (D.C.Cir.1998). In *National Mining* we "confirm[ed] that the normal *Chevron* test" applies and "is not transformed into an even more lenient 'no valid applications' test just because the attack is facial." *Id.*; *accord Becker v. FCC*, 95 F.3d 75, 78 (D.C.Cir.1996). Subsequently, however, we noted that *National Mining* "apparently overlooked *Reno v. Flores*, 507 U.S. 292, 113 S.Ct. 1439, 123 L.Ed.2d 1 (1993)." *Amfac Resorts, LLC v. Dep't of the Interior*, 282 F.3d 818, 826 (D.C.Cir.2002), *judgment vacated on other ground sub nom. Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003). In *Reno* the Supreme Court seemed to apply *Salerno*'s "no set of circumstances" test to an ultra vires challenge to a regulation. 507 U.S. at 300–01, 113 S.Ct. 1439. *But see id.* at 309–15, 113 S.Ct. 1439 (challenge to regulation does not succeed "if the regulation has a reasonable foundation, that is, if it rationally pursues a purpose that it is lawful for the [agency] to seek" (internal quotation marks and citation omitted)). As *Amfac* discusses, it is not clear whether the *Salerno* test applies to a purely statutory challenge or whether the standard set forth in *INS v. National Center for Immigrants' Rights, Inc.*, 502 U.S. 183, 188, 112 S.Ct. 551, 116 L.Ed.2d 546 (1991)—under which a regulation can be invalid even if it has some valid applicability—applies. *Amfac*, 282 F.3d at 827. *Amfac* acknowledges that it is of course bound by the decision of an earlier panel unless, *inter alia*, "an intervening Supreme Court decision alters the law of the circuit." 282 F.3d at 827. *Reno*, however, predates *National Mining*. *Amfac* does not resolve whether, "despite *Reno v. Flores*, *National Mining* ... must stand as circuit law unless and until the full court overrules it." 282 F.3d at 827. *Cf. Air Transp. Ass'n of Am. v. U.S. Dep't of Transp.*, 613 F.3d 206, 213 (D.C.Cir.2010) (applying *Reno* to facial challenge of regulation without discussing *Amfac* or *National Mining*); *Bldg. & Constr. Trades Dep't, AFL–CIO v. Allbaugh*, 295 F.3d 28, 33 (D.C.Cir.2002) (possibility agency could improperly apply executive order does not establish facial invalidity thereof). *See generally* Stuart Buck, Salerno *vs.* Chevron: *What to do About Statutory Challenges*, 55 Admin. L.Rev. 427 (2003).

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