No. 12-454

In the Supreme Court of the United States

JAMES L. SHERLEY, ET AL., PETITIONERS

v.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the National Institutes of Health, in expanding its preexisting funding of embryonic-stem-cell research pursuant to an Executive Order of the President, permissibly declined to respond to comments seeking to revisit the question whether any such funding should occur at all.

2. Whether the court of appeals permissibly determined that its legal conclusion in a prior preliminary-injunction appeal—which was reached on a well-developed factual record, without unusual time constraints, and with the benefit of full briefing of the relevant legal issue by the parties—should be treated as law of the case.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-30a) is reported at 689 F.3d 776. The prior opinion of the court of appeals vacating the preliminary injunction (Pet. App. 31a-66a) is reported at 644 F.3d 388. The opinion of the district court (Pet. App. 67a-111a) is reported at 776 F. Supp. 2d 1.

JURISDICTION

The judgment of the court of appeals was entered on August 24, 2012. The petition for a writ of certiorari was filed on October 10, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Since the 1950s, medical researchers have recognized the unique scientific value of stem cells, which

"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." Pet. App. 33a; see *id.* at 69a. For most of the twentieth century, only one kind of stem cells—adult stem cells, which "are found in certain tissues in fully developed humans"—was available for scientific study. *Id.* at 69a (citation omitted). Although research on such cells has contributed to many important medical advances, adult stem cells remain "difficult to identify, isolate, maintain, and grow in the laboratory," National Acad. of Scis., *Understanding Stem Cells: An Overview of the Science and Issues from the National Academies* 8 (2006), http://dels.nas.edu/ resources/static-assets/materials-based-on-reports/booklets/Understanding_Stem_Cells._pdf. Adult stem cells are also "limited to producing only certain types of specialized cells," rather than a broad range of potential types of cells. Pet. App. 69a (citation omitted).

In 1998, medical researchers discovered a method for conducting research with another kind of stem cells: embryonic stem cells. Pet. App. 4a-5a. Embryonic stem cells, unlike adult stem cells, are "pluripotent, meaning they can develop into nearly any of the 200 types of human cell." *Id.* at 33a. For that reason, many researchers consider embryonic stem cells to be "far more valuable" than adult stem cells. *Id.* at 5a. Isolating embryonic stem cells to create a new stem-cell "line" requires a process that destroys the embryo. *Id.* at 33a. "Most embryonic stem cells are derived from embryos that develop from eggs that have been fertilized *in vitro*—in an *in vitro* fertilization clinic—and then donated for research purposes with the informed consent of the donors." National Insts. of Health, *Stem Cell Basics:*

What Are Embroyonic Stem Cells? (last modified Sept. 13, 2010), http://stemcells.nih.gov/info/basics/basics3.asp.

In addition to their pluripotency, embryonic stem cells have the advantage of being relatively easy to maintain and replicate. Pet. App. 33a; *Understanding Stem Cells* 8. Individual cells can be removed from a line for use in particular research projects (in which the cells can be converted to whatever type the researcher needs) without disrupting the line's growth or durability. Pet. App. 33a. Most stem-cell lines are maintained by research institutions or universities, which make the cells available to scientists, sometimes for a modest fee. *Id.* at 33a-34a.

Scientists have also recently started experimenting with a third category of stem cells, induced pluripotent stem cells, "which are adult stem cells reprogrammed to a stage of development at which they are pluripotent." Pet. App. 33a. Scientists are still investigating whether induced pluripotent stem cells differ from embryonic stem cells in clinically significant ways. National Insts. of Health, *Stem Cell Basics: What Are Induced Pluripotent Stem Cells?* (last modified Mar. 30, 2009), http://stemcells.nih.gov/info/basics/basics10.asp.

2. The National Institutes of Health (NIH), a component of the U.S. Department of Health and Human Services (HHS), "is the largest source of funding for medical research in the world." NIH, *About NIH* (last reviewed Aug. 7, 2012), http://www.nih.gov/about. Since 1996, Congress has included in its annual appropriation for HHS a condition known as the Dickey-Wicker Amendment, which 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 section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2012 (2012 Appropriations Act), Pub. L. No. 112-74, Div. F, § 508(a), 125 Stat. 1112; see Pet. App. 34a. At the time the Dickey-Wicker Amendment was originally enacted, human embryonic stem cells had not yet been isolated for use in medical research. Pet. App. 34a. Accordingly, 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." *Ibid.*

In 1999, after research on embryonic stem cells became feasible, the General Counsel of HHS issued a memorandum concluding that "[t]he statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition." C.A. App. 163; see Pet. App. 35a. Following a notice-and-comment period, NIH issued embryonic-stem-cell-research funding guidelines "to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner." NIH, HHS, *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*, 65 Fed. Reg. 51,976 (Aug. 25, 2000); see Pet. App. 35a.

After President Bush took office in 2001, he continued the policy of permitting NIH to fund embryonic-

stem-cell research, but limited funding to projects that used "the approximately 60 then-extant cell lines derived from 'embryos that had already been destroyed.'" Pet. App. 35a (brackets omitted) (quoting *Address to the Nation on Stem Cell Research from Crawford, Texas*, 37 Weekly Comp. Pres. Doc. 1149, 1151 (Aug. 9, 2001)). When Congress reenacted the Dickey-Wicker Amendment later that year, the relevant congressional committees indicated their view that the Amendment's language permitted the funding of embryonic-stem-cell research in accordance with President Bush's policy. See H.R. Rep. No. 229, 107th Cong., 1st Sess. 180 (2001) ("The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language 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 policy outlined by the President."); S. Rep. No. 84, 107th Cong., 1st Sess. 18-19 (2001) ("The Committee * * * directs [NIH] to award grants for human embryonic stem cell research as quickly as possible, in strict compliance with ethical guidelines."); see also H.R. Rep. No. 231, 110th Cong., 1st Sess. 288 (2007); H.R. Rep. No. 636, 108th Cong., 2d Sess. 199 (2004).

After President Obama took office in 2009, he issued an Executive Order that "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.'" Pet. App. 35a (quoting Exec. Order No. 13,505, § 2, 3 C.F.R. 229 (2010) (Executive Order) (reprinted at Pet. App. 116a-118a)). President Obama directed NIH to re-

view its existing guidelines on human stem cell research and to "issue new NIH guidance on such research that is consistent with this order." *Id.* at 117a (Executive Order § 3).

Later that year, following a notice-and-comment period, NIH issued new stem-cell-research-funding guidelines, which remain in effect today. *National Institutes of Health Guidelines for Human Stem Cell Research*, 74 Fed. Reg. 32,170 (July 7, 2009) (Guidelines) (reprinted at Pet. App. 131a-153a). The Guidelines observed that "funding of the derivation of stem cells from human embryos is prohibited by" the Dickey-Wicker Amendment. Pet. App. 153a. But they explained that "[s]ince 1999, [HHS] has consistently interpreted [the Dickey-Wicker Amendment] as not applicable to research using [embryonic stem cells], because [such cells] are not embryos as defined" in the statute. *Id.* at 143a; see *ibid.* ("This longstanding interpretation has been left unchanged by Congress, which has annually reenacted the [Dickey-Wicker] Amendment with full knowledge that HHS has been funding [embryonic-stem-cell] research since 2001."). For a project involving embryonic-stem-cell research to receive funding, the Guidelines require that any stem-cell line it uses be derived from an embryo that was (1) created for in vitro fertilization but is no longer needed for that purpose, and (2) freely donated by individuals who were informed of the other options for the embryo's disposition. *Id.* at 148a-149a. NIH maintains a registry of stem-cell lines that meet these criteria and are therefore eligible to be used in federally funded research. See Office of Extramural Research, NIH, *NIH Human Embryonic Stem Cell Registry* (last updated, July 13, 2011), http://grants.nih.gov/stem_cells/registry/current.htm.

When Congress reenacted the Dickey-Wicker Amendment following the issuance of NIH's 2009 Guidelines, the House Committee stated in its report that the Amendment "should not be construed to limit Federal support for research involving human embryonic stem cells carried out in accordance with policy outlined by the President." H.R. Rep. No. 220, 111th Cong., 1st Sess. 273 (2009); see also S. Rep. No. 66, 111th Cong., 1st Sess. 121-122 (2009); H.R. Conf. Rep. No. 366, 111th Cong., 1st Sess. 982 (2009). Congress has since continued to reenact the Dickey-Wicker Amendment without change. Full-Year Continuing Appropriations Act, 2011, Pub. L. No. 112-10, Div. B, §§ 1101(a), 1104, 125 Stat. 102-103; Appropriations Act § 508, 125 Stat. 1112.

3. Petitioners are medical researchers who work with adult stem cells. Pet. App. 2a. Along with several other plaintiffs, they sued the Secretary of HHS and the Director of NIH shortly after promulgation of the 2009 Guidelines, seeking to preclude NIH from funding embryonic-stem-cell research. *Id.* at 2a-3a.

The district court originally dismissed the complaint for lack of standing. Pet. App. 78a; see 686 F. Supp. 2d 1. The court of appeals reversed with respect to petitioners. 610 F.3d 69. It concluded that petitioners have "competitor standing" to challenge the Guidelines, because the Guidelines permit the funding of a wider range of projects, thereby (in the court's view) requiring petitioners to make a greater effort to obtain grants for their own projects and reducing their odds of receiving funding. *Id.* at 72-74.

The district court subsequently issued a preliminary injunction barring implementation of the Guidelines, concluding on the merits that the Dickey-Wicker Amendment unambiguously bars NIH from funding any

embryonic-stem-cell research. 704 F. Supp. 2d 63, 70-72. The court of appeals stayed the injunction pending resolution of an appeal by the government. Pet. App. 37a-38a.

After full briefing and argument, the court of appeals reversed. Pet. App. 31a-66a. The court applied the deference framework set forth in *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837 (1984), and concluded that "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." Pet. App. 46a; see *id.* at 40a-50a. The court rejected petitioners' argument that the Dickey-Wicker Amendment unambiguously precludes funding of *all* projects involving embryonic stem cells, noting the Amendment's use of the present tense (forbidding "research 'in which' embryos 'are' destroyed, not research 'for which' embryos 'were destroyed'") and reasoning that investigation utilizing a stem-cell line could be considered different "research" from the creation of that line. *Id.* at 41a-42a. The court additionally explained that "although the Guidelines do not define the term 'research,' they do make clear the agency's understanding that 'research involving [embryonic stem cells]' does not necessarily include the antecedent process of deriving the cells." *Id.* at 43a. The court also observed that "Congress has reenacted Dickey-Wicker unchanged year after year 'with full knowledge that HHS has been funding [embryonic stem cell] research since 2001.'" *Id.* at 46a (quoting Guidelines, 74 Fed. Reg. at 32,173).

Judge Henderson dissented. Pet. App. 53a-66a. In her view, the Dickey-Wicker Amendment unambiguous-

ly prohibits the funding of research using human embryonic stem cells. *Ibid.*

4. On remand, the district court granted the government's motion for summary judgment. Pet. App. 67a-111a. The court of appeals affirmed. *Id.* at 1a-30a.

The court of appeals first concluded that petitioner's primary argument—that the Guidelines violate the Dickey-Wicker Amendment's "ban on federal funding of 'research in which a human embryo or embryos are destroyed'"—was foreclosed by the law-of-the-case doctrine, because the court had already decided that issue in the preliminary-injunction appeal. Pet. App. 7a-13a. The court acknowledged that a preliminary-injunction appeal—which may involve an underdeveloped record or rushed briefing, and which may not actually decide merits questions—does not always establish the law of the case. *Id.* at 9a-11a. But it reasoned, after consulting the decisions of other circuits and a leading treatise (18B Charles A. Wright et al. *Federal Practice and Procedure* § 4478.5, at 792 (2d ed. 2002) (Wright)), that the law-of-the-case doctrine does apply "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 decision-making process that included full briefing and argument without unusual time constraints." Pet. App. 11a; see *id.* at 11a-13a.

As relevant here, the court of appeals also rejected petitioners' argument that the Guidelines were invalid because NIH had promulgated them without responding to comments that had categorically objected to the funding of any embryonic-stem-cell research at all. Pet. App. 14a-17a. The court of appeals acknowledged that the notice-and-comment provision of the Administrative

Procedure Act (APA), 5 U.S.C. 553, generally requires agencies to respond "to significant points raised by the public." Pet. App. 14a (citation omitted). But it determined that NIH "had reasonably limited the scope of its Guidelines to implement [President Obama's] Executive Order" and that the disregarded comments "simply did not address any factor relevant to implementing the Executive Order." *Id.* at 16a. Whereas the Executive Order "makes it quite plain that its dominant purpose was to 'remove' President Bush's 2001 'limitations' on funding human [embryonic-stem-cell] research and to 'expand' NIH support for human stem-cell research, 'including human embryonic stem cell research,'" the "comments at issue advocate[d] ending all [embryonic-stem-cell] research funding—even for research that has been eligible for funding for a decade under the 2001 restrictions." *Id.* at 15a-16a (quoting Executive Order §§ 1-2, Pet. App. 116a-117a); see *id.* at 16a-17a.

Judge Henderson filed a concurring opinion, expressing the view that "*Chevron* review is inapplicable to the Guidelines," but agreeing that the law-of-the-case doctrine foreclosed reconsideration of that issue. Pet. App. 18a-22a. Judge Brown filed a separate concurring opinion, agreeing with Judge Henderson that *Chevron* deference was inapplicable, but concluding that the government should prevail even without *Chevron* deference, because Congress had repeatedly reenacted the Dickey-Wicker Amendment without change in the face of Presidential policies consistently permitting at least some funding of embryonic-stem-cell research. *Id.* at 23a-28a. Judge Brown also concurred in the holding that the Guidelines were lawfully promulgated, reasoning that "NIH cannot be said to have acted arbitrarily and capriciously by refusing to re-open a debate that, as a practi-

cal matter, has been foreclosed for more than a decade." *Id.* at 28a-30a.

ARGUMENT

Petitioners renew their contention (Pet. 13-26) that NIH's 2009 Guidelines were procedurally invalid, and further contend (Pet. 27-35) that the court of appeals erred in applying the law-of-the-case doctrine. The court of appeals' decision is correct and does not conflict with any decision of this Court or any other court of appeals. No further review is warranted.

1. a. Petitioners' procedural argument misconstrues the decision below. Contrary to petitioners' assertion (Pet. 13), the court of appeals did not hold "that the President may exempt agencies from their duty to obey undisputedly valid procedural requirements imposed by Congress." Rather, the court of appeals simply reasoned that (1) an agency need only respond to comments that bear on factors relevant to the action it is considering; (2) the action at issue here was the implementation of an Executive Order; (3) the Executive Order directed the agency to consider broadening, not narrowing, the scope of its funding for embryonic-stem-cell research; and (4) comments advocating the elimination of all such funding, including funding that had been permitted for a decade, were not relevant to that course of action. Pet. App. 14a-17a; see, *e.g.*, *id.* at 16a-17a ("NIH stated that the scope of its Guidelines was to 'implement Executive Order 13505,' and that Order plainly starts from the premise that NIH should continue to fund at least some [embryonic-stem-cell] research. NIH's decision to dismiss comments seeking to reopen that premise for debate therefore did not demonstrate a failure to consider relevant factors.").

Petitioners do not dispute that an agency's proposed action may be limited in scope. See, *e.g.*, 5 U.S.C. 553(b)(3) (notice of proposed rulemaking "shall include * * * either the terms or substance of the proposed rule or a description of the subjects and issues involved"). Nor do they dispute that an agency may permissibly decline to respond to comments that address questions outside the range of its proposal. See, *e.g.*, *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir.) (agency need only respond to comments "relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule"), cert. denied, 434 U.S. 829 (1977). That is all NIH did here: it proposed a limited action (namely, the expansion of preexisting funding for embryonic-stem-cell research) and then declined to respond to comments that went beyond the scope of that limited proposal (namely, by suggesting that the agency should fund no embryonic-stem-cell research at all). Pet. App. 14a-17a; see NIH, *Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice*, 74 Fed. Reg. 18,578, 18,578 (Apr. 23, 2009) (reprinted at Pet. App. 119a-130a) ("The purpose of these draft Guidelines is to implement Executive Order 13505, issued on March 9, 2009, as it pertains to extramural NIH-funded research, to establish policy and procedures under which NIH will fund research in this area, and to help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law."). As Judge Brown observed, 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." Pet. App. 30a (Brown, J., concurring).

Petitioners suggest (Pet. 16) that because the scope of NIH's proposal was delimited by Executive Order, the Executive Order had the impermissible effect of "ordering agency officials openly to disobey the APA and dispense with notice and comment." The conclusion does not follow from the premise. The powers of the President include the authority to set the substantive policymaking agenda for Executive agencies. See *Building & Constr. Trades Dep't* v. *Allbaugh*, 295 F.3d 28, 32 (D.C. Cir. 2002) ("[Executive Branch] officers are duty-bound to give effect to the policies embodied in the President's direction, to the extent allowed by the law."), cert. denied, 537 U.S. 1171 (2003); *Sierra Club* v. *Costle*, 657 F.2d 298, 406 (D.C. Cir. 1981) ("The authority of the President to control and supervise executive policymaking is derived from the Constitution."). Directing NIH to propose an expansion, but not a contraction, of its funding for embryonic-stem-cell research constitutes a valid exercise of Presidential policymaking, not a circumvention of the procedural requirements of the APA.

Petitioners additionally appear to contend (Pet. 22-24) that the Executive Order did, in fact, permit NIH to withdraw its support for embryonic-stem-cell research altogether. That fact-bound contention lacks merit and does not warrant this Court's review. The Executive Order begins by noting "broad agreement in the scientific community" that "[r]esearch involving human embryonic stem cells and non-embryonic stem cells * * * should be supported by Federal funds." Pet. App. 116a (Executive Order § 1). It states that "[f]or the past 8 years, the authority of [HHS and NIH] to fund and conduct human embryonic stem cell research has been limited by Presidential actions." *Ibid.* (Executive Order § 1). And it declares that "[t]he purpose of this order is

to remove those limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." *Id.* at 116a-117a (Executive Order § 1); see *id.* at 118a (Executive Order § 5) (expressly revoking President Bush's limitations on embryonic-stem-cell research). The text of the Executive Order thus expressly makes clear the President's policy favoring embryonic-stem-cell funding, and—by removing Presidentially-imposed limitations in order to expand such funding—does not contemplate that NIH would eliminate such funding completely.

b. Because petitioners misconstrue the decision below, the conflict that they posit (Pet. 17-21) with the Third Circuit's decision in *NRDC* v. *United States Envt'l Prot. Agency*, 683 F.2d 752 (1982), is illusory. In that case, the Third Circuit held that the Environmental Protection Agency (EPA) lacked "good cause" under 5 U.S.C. 553(b)(B) to excuse its failure to comply with the APA's notice-and-comment requirements. 683 F.3d at 764-767. The court rejected EPA's reliance on Executive Order 12,291, 3 C.F.R. 127 (1982), which required agencies to conduct a Regulatory Impact Analysis before taking certain actions, observing that the order did not purport to excuse compliance with the APA's procedural requirements and that "EPA in this case could have complied with both the APA and E.O. 12291." *NRDC*, 683 F.2d at 765. The Third Circuit's decision in no way suggests that an agency, when it does engage in notice-and-comment, must respond to comments urging a course of action that is both outside the scope of the proposed action and not contemplated by the Executive Order that animated the proposal.

Petitioners likewise err in positing (Pet. 22-23) a conflict with the asserted holdings of other circuits that "where an executive order's text is clear, it controls." As a threshold matter, because petitioners allege (Pet. 23) that the D.C. Circuit itself has in the past adopted the rule they now urge, petitioners allege, at most, an intra-circuit conflict that would not warrant this Court's intervention. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (per curiam). In any event, contrary to petitioners' suggestion, the court of appeals in this case did not rely solely on the perceived purpose of the Executive Order, inferred from ambiguous language. Rather, the court of appeals gave effect to the plain language of the Executive Order, which expressly states that "[t]he purpose of this order is to remove the[] limitations" on "the authority of [HHS and NIH] to fund and conduct human embryonic stem cell research." Pet. App. 116a (Executive Order § 1). The court of appeals expressly stated that it "need not rely on deference" to NIH's interpretation of the Executive Order, because the Order "plainly starts from the premise that NIH should continue to fund at least some [embryonic-stem-cell] research." *Id.* at 16a-17a.

2. a. Further review of the court of appeals' law-of-the-case conclusion is similarly unwarranted. The law-of-the-case doctrine "posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Pepper* v. *United States*, 131 S. Ct. 1229, 1250 (2011) (quoting *Arizona* v. *California*, 460 U.S. 605, 618 (1983)). The doctrine "does not apply," however, "if the court is 'convinced that its prior decision is clearly erroneous and would work a manifest injustice.'" *Id.* at

1250-1251 (quoting *Agostini* v. *Felton*, 521 U.S. 203, 236 (1997)) (brackets omitted).

The court of appeals in this case recognized that, under its own precedent, a prior appellate decision reviewing the grant or denial of a preliminary injunction often does not constitute law of the case in further proceedings on the merits. Pet. App. 9a-10a. Because an appellate court "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," the 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." *Id.* at 10a. The court of appeals also acknowledged that the law-of-the-case doctrine would not apply in circumstances where the preliminary-injunction appeal simply made a prediction about "whether a plaintiff is likely to succeed on the merits" of his claim, without "affirmatively decid[ing]" the merits themselves. *Ibid.* (internal quotation marks and citations omitted).

The court of appeals determined, however, that "on the facts of this case, the [preliminary-injunction] exception to the law-of-the case doctrine is inapplicable." Pet. App. 9a. The court explained that its earlier decision on the preliminary-injunction appeal had already "held that NIH had reasonably interpreted Dickey-Wicker's ban on funding 'research in which . . . embryos are destroyed' to allow federal funding of [embryonic-stem-cell] research." *Id.* at 8a (quoting *id.* at 40a-41a). And it concluded that this prior holding had been "established in a definitive, fully considered legal decision based on a fully developed factual record and a decision-making

process that included full briefing and argument without unusual time constraints." *Id.* at 11a. Petitioners offered the court of appeals no reason to reconsider that earlier holding; indeed, much of petitioners' briefing on the summary-judgment appeal was taken almost verbatim from their briefing in the preliminary-injunction appeal. Compare, *e.g.*, Pet'r Br. 16-24 (D.C. Cir. No. 11-5241), with Pet'r Br. 16-23 (D.C. Cir. No. 10-5287).

The court of appeals observed that its application of the law-of-the-case doctrine was consistent with the approach of other circuits. Pet. App. 11a-13a (citing *Naser Jewelers, Inc.* v. *City of Concord*, 538 F.3d 17, 20 (1st Cir. 2008); *This That & the Other Gift & Tobacco, Inc.* v. *Cobb Cnty.*, 439 F.3d 1275, 1284-1285 (11th Cir. 2006); *Entergy, Ark., Inc.* v. *Nebraska*, 241 F.3d 979, 987 (8th Cir.), cert. denied, 534 U.S. 889 (2001); *Royal Ins. Co. of Am.* v. *Quinn-L Capital Corp.*, 3 F.3d 877, 880-881 (5th Cir. 1993), cert. denied, 511 U.S. 1032 (1994)). The court drew additional support from the *Federal Practice and Procedure* treatise, which states that "[a] fully considered appellate ruling on an issue of law made on a preliminary injunction appeal * * * does become the law of the case for further proceedings in the trial court on remand and in any subsequent appeal." *Id.* at 12a (quoting Wright § 4478.5, at 794).

b. Petitioners contend (Pet. 27-30) that this Court's precedent "categorical[ly]" precludes a preliminary-injunction appeal from ever providing law of the case in a later merits appeal. But contrary to petitioners' contention, neither *Doran* v. *Salem Inn, Inc.*, 422 U.S. 922 (1975), nor *University of Texas* v. *Camenisch*, 451 U.S. 390 (1981), compels appellate courts invariably—and in-

efficiently—to reconsider de novo issues they have already fully and fairly decided.

The Court in *Doran* merely observed, in the course of reviewing a court of appeals' affirmance of a district court's preliminary-injunction order, that the district court "must have intended to refer only to the likelihood that respondents ultimately would prevail," not to "actually hold[] the [challenged] ordinance unconstitutional." 422 U.S. at 932. The decision in *Doran* did not address the law-of-the-case doctrine. Nor did it purport to constrict the various ways in which an appellate court reviewing a preliminary-injunction motion might conclude that a plaintiff is unlikely to succeed on the merits, one of which is to conclude that the plaintiff's merits argument is simply wrong as a matter of law. See *Thornburgh* v. *American Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 755-757 (1986) (recognizing that appellate courts can sometimes address the merits in an appeal of a preliminary injunction), overruled on other grounds by *Planned Parenthood* v. *Casey*, 505 U.S. 833 (1992).

In *Camenisch*, a deaf graduate student had sought a permanent injunction ordering his university to hire an interpreter for him. 451 U.S. at 391-392. The district court had granted a preliminary injunction, and the court of appeals had largely affirmed, but not before the student had graduated. *Id.* at 392-393. Because the issue of preliminary relief had become moot due to the graduation, this Court vacated the court of appeals' decision and remanded the case for a trial on the merits. *Id.* at 394. The Court rejected the contention that such a trial was unnecessary, reasoning that a live issue remained as to who (the student or the university) should pay for the interpreter hired pursuant to the prelimi-

nary injunction, and that the lower courts' rulings on the preliminary injunction had not finally decided the merits of plaintiff's suit. *Id.* at 393-398. In reaching that latter conclusion, the Court noted that preliminary injunctions are often granted in "haste" and "on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." *Id.* at 395. "A party thus is not required to prove his case in full at a preliminary injunction hearing, and the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at a trial on the merits." *Ibid.* (citation omitted).

Contrary to petitioners' contention, the just-quoted sentence (of which petitioners quote only the latter half) does not categorically preclude an appellate court from ever applying the law-of-the-case doctrine to a decision on a preliminary-injunction appeal. Rather, it simply recognized that a hasty ruling on a preliminary-injunction motion does not obviate the need for full consideration of the merits at a later stage. If the language were as broad as petitioners suggest, it is difficult to see how any court—including this Court—could ever reach precedential conclusions of law in the context of a preliminary injunction. Yet this Court sometimes does just that. See, *e.g.*, *Arizona* v. *United States*, 132 S. Ct. 2492, 2503, 2505, 2507 (2012) (concluding, in the context of a preliminary-injunction appeal, that certain provisions of Arizona law were preempted by federal law).

Camenisch neither presented nor decided the question presented here: whether a merits conclusion in an appellate preliminary-injunction decision becomes law of the case when the conclusion was reached with the benefit of a complete record and full briefing and argument. In *Camenisch*, the lower courts had "both properly

based their decisions not on the ultimate merits of [the] case but rather on the balance" of preliminary-injunction factors, and the court of appeals "certainly [had] not h[eld] that the standards for summary judgment had been met." 451 U.S. at 398. The procedural history, moreover, was "replete with circumstances indicating the necessity for a full trial on the merits," and bore "the marks of the haste characteristic of a request for a preliminary injunction," as the parties had "relied on a short stipulation of facts" and the university had apparently not settled on a consistent legal theory. *Id.* at 397-398. In contrast, the court of appeals in this case could conclude, and reasonably did conclude, that such concerns were absent, as the preliminary-injunction appeal decided a pure question of law on full briefing and without any undue haste. See, *e.g.*, Pet. App. 13a (distinguishing prior circuit precedent on the ground that "[t]he time constraints and limited record available to the court in those cases are not present here").

c. Petitioners acknowledge that the court of appeals' approach in this case is functionally identical to the approaches of at least four other circuits. See Pet. 31 (citing cases from the First, Fourth, Sixth, and Eleventh Circuits). They also do not contend that the result in this case would have been any different in the Fifth and Ninth Circuits, which, they say, "have held that a preliminary-injunction ruling is law of the case as to 'pure issues of law.'" Pet. 32 (citation omitted).

Petitioners err in suggesting (Pet. 30) that decisions of the Tenth and Federal Circuits categorically foreclose the possibility that a preliminary-injunction appeal could ever become law of the case. Neither of the decisions they cite addressed the question presented here, namely, the applicability of the law-of-the-case doctrine when

an "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 decision-making process that included full briefing and argument without unusual time constraints." Pet. App. 11a. In *Homans* v. *City of Albuquerque*, 366 F.3d 900, cert. denied, 543 U.S. 1002 (2004), the Tenth Circuit merely held that an injunction pending appeal granted by a two-judge motions panel, which "was limited to the conclusion that [the plaintiff] had shown a likelihood of success on the merits of his claim," was not law of the case. *Id.* at 904-905. The court observed that "a motions panel's decision is often tentative because it is based on an abbreviated record and made without the benefit of full briefing and oral argument"; noted that this particular motions panel had, in fact, expedited briefing and dispensed with oral argument; and rejected the notion that a full panel's consideration of an appeal could be foreclosed by the preliminary decision of a motions panel. *Id.* at 905 (citation omitted). Similarly, in *SEB S.A.* v. *Montgomery Ward & Co.*, 594 F.3d 1360 (2010), aff'd *sub nom. Global-Tech Appliances, Inc.* v. *S.E.B. S.A.*, 131 S. Ct. 2060 (2011), the Federal Circuit merely held that its prior affirmance, without opinion, of a district court's preliminary-injunction order did "not make the district court's claim construction in its 1999 opinion the law of the case." *Id.* at 1367-1368. It relied for that conclusion on the proposition that "claim construction for a preliminary injunction is not definitive without the more complete record that the district court deemed necessary to its own final decision." *Id.* at 1368 (internal quotation marks and citation omitted).

The decision below is also consistent with what petitioners describe (Pet. 31-32) as the "more nuanced"

position of the Third and Eighth Circuits that "a preliminary-injunction ruling is law of the case when the relevant issue was decided on a full record, unless the original court denied taking a considered position on the ultimate merits of the issue." Petitioners argue (Pet. 32) that they would have prevailed under that approach because the preliminary-injunction opinion in this case did not actually decide the full merits question. At bottom, however, that argument is simply a disagreement with the court of appeals' interpretation of its own preliminary-injunction decision. Compare *ibid.*, with Pet. App. 8a-9a. That fact-bound dispute does not warrant this Court's review.

d. In any event, review of the court of appeals' law-of-the-case conclusion is unnecessary because petitioners' Dickey-Wicker argument would lack merit even if it were open to reconsideration. As the preliminary-injunction panel correctly concluded, NIH's consistent interpretation of the Amendment is entitled to deference, see Pet. App. 40a-50a, and Congress has repeatedly reenacted the Amendment with knowledge (and approval) of that interpretation, see *id.* at 46a-47a; pp. 5-7, *supra*; see also, *e.g.*, Pet. App. 27a (Brown, J., concurring) ("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."). If Congress disapproves of NIH's practice, it has had, and continues to have, ample opportunity to express such disapproval.

3. Finally, this case would be an unsuitable vehicle for reviewing either of the questions presented because petitioners lack standing to challenge NIH's 2009 Guidelines. The court of appeals concluded at the motion-to-

dismiss stage that petitioners' allegations were sufficient to support "competitor standing," under which "plaintiffs may establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate potential to compete with [their] own sales." 610 F.3d at 72-73 (internal quotation marks and citation omitted). That holding was erroneous, and, even if it were not, petitioners failed to demonstrate any injury-in-fact at the summary judgment stage of the proceedings.

To establish Article III standing, a plaintiff must demonstrate, *inter alia*, that he has "suffered an injury in fact * * * which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks, citations, and footnote omitted). Petitioners have not made that showing here. Funding for embryonic-stem-cell projects is not mutually exclusive of funding for adult-stem-cell projects; depending on the merits of each particular proposal, the amount of funding for both types of research could potentially increase. C.A. App. 176-177 (Decl. of Sarah Jean Rockey, Ph.D., ¶¶ 16, 18-20). NIH "does not set individual budgets by research category or methodology, and the awarding of a grant in response to an application is made on a case-by-case basis. Accordingly, it is impossible to accurately predict whether, how, or to what degree an application will compete with another for funding." *Id.* at 177 (Rockey Decl. ¶ 20).

Moreover, petitioners' affidavits filed at the summary-judgment stage make clear that they have not suffered any "personal and individual" harm, *Defenders of Wildlife*, 504 U.S. at 560 n.1, from having to compete with embryonic-stem-cell projects for NIH funding. As

of the time she filed her declaration, petitioner Deisher had not yet applied for a research grant from NIH. C.A. App. 297 (Decl. of Dr. Theresa Deisher ¶ 3). This Office has been informed by NIH that she has since applied for a grant (albeit for a project not involving adult stem cells), but standing "ordinarily depends on the facts *as they exist when the complaint is filed*." *Defenders of Wildlife*, 504 U.S. at 569 n.4 (citation omitted).

Petitioner Sherley's declaration states that he has "had four adult stem cell research grant applications go unscored since the Guidelines were implemented." C.A. App. 499 (Decl. of Dr. James Sherley ¶ 3). An "unscored" application, however, is one that did not even survive the first level of the peer-review process (which considers scientific and technical merit) to become eligible for NIH funding. *Id.* at 174-175 (Rockey Decl. ¶¶ 8-12). Sherley accordingly cannot demonstrate that his applications were competitive with applications for funding of embryonic-stem-cell projects. Sherley's declaration does state that he revised and resubmitted one of the unscored applications, *id.* at 499 (¶ 3), but the hypothesis that this application would survive peer review, let alone be denied a grant due to the funding of embryonic-stem-cell projects, is wholly conjectural. Finally, while this Office has been informed by NIH that Sherley has submitted additional adult-stem-cell-research grant applications since the time of his declaration (two of which did survive initial peer review), those more recent applications could not retroactively give him standing to file suit in 2009. *Defenders of Wildlife*, 504 U.S. at 569 n.4.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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