

[ORAL ARGUMENT NOT YET SCHEDULED]
No. 10-5287

IN THE
United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

JAMES L. SHERLEY, DR., *et al.*,

Appellees,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES, *et al.*,

Appellants.

ON APPEAL FROM THE UNITED STATES
DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

**BRIEF OF *AMICUS CURIAE* THE REGENTS OF THE
UNIVERSITY OF CALIFORNIA IN SUPPORT OF APPELLANTS**

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GLOSSARY

<u>Term</u>	<u>Definition</u>
APA	Administrative Procedure Act
ASC	adult stem cells
Beckwith Decl.	Declaration of Steven V.W. Beckwith, PhD. In Support of the Regents' Motion for Leave to Intervene on Appeal (September 20, 2010)
BBRI	Boston Biomedical Research Institute
Deisher Decl.	Declaration of Dr. Theresa Deisher (August 16, 2009), JA at 168
hESC	human embryonic stem cells
iPSC	induced pluripotent stem cells
JA	Joint Appendix
Kriegstein Decl.	Declaration of Arnold R. Kriegstein, M.D., PhD. In Support of the Regents' Motion for Leave to Intervene on Appeal (September 20, 2010)
MSTP	Medical Scientist Training Program
NIH	National Institutes of Health
PHS	Public Health Service
Policies and Guidelines	Clinton Administration: Memorandum to Harold Varmus, M.D., Director, NIH from Harriet S. Rabb, General Counsel of HHS, Federal Funding for Research Involving Human Pluripotent Stem Cells (Jan. 15, 1999) at JA 161

NIH Guidelines 65 Fed. Reg. 51,976 (Aug. 25, 2000)

Bush Administration:

Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells, 66 Fed. Reg. 57,107 (Nov. 14, 2001)

Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001)

Executive Order No. 13,435, Expanding Approved Stem Cell Lines in Ethically Responsible Ways, 72 Fed. Reg. 34,591 (June 20, 2007)

NIH Plan for Implementation of Executive Order 13435: Expanding Approved Stem Cell Lines in Ethically Responsible Ways, 72 Fed. Reg. 34, 589 (June 22, 2007).

Obama Administration:

Executive Order No. 13,505, 74 Fed. Reg. 10,667 (March 9, 2007) at JA 276

NIH Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009) (“2009 NIH Guidelines”) at JA 280

SBIR	Small Business Innovation Research grant
Sherley Decl.	Declaration of Dr. James Sherley (August 13, 2009), JA at 166
UC	Regents of the University of California or University of California System

INTEREST OF *AMICUS CURIAE*

On August 23, 2010, the district court granted a preliminary injunction that blocked funding by the National Institutes of Health (“NIH”) for research using human embryonic stem cells (“hESC”). The case pitted the interests of two plaintiffs who sought to improve their chances of receiving NIH support against the interests of institutions and their scientists that had already been awarded NIH grants and patients who believe that research using hESC holds the key to cures for diseases that have eluded scientists for decades. The lower court decided that the two plaintiffs’ interests outweighed those of the scientist and patient communities. The judge reached this conclusion without hearing from any grantees, their scientists or patients. Following the government’s appeal to this Court, the Regents of the University of California, on behalf of the University of California System (“UC”), filed a motion to intervene to make its views known. UC is the largest recipient of both research and cooperative agreement funding from NIH, including funding for research using hESC. UC researchers have made great strides in using hESC to develop potential treatments for brain injuries and diseases, spinal cord injuries, diabetes and other autoimmune disorders. The funding from NIH makes it possible for UC to train promising physician-researchers, and employ scientists, technicians and staff. The district court’s injunction jeopardizes research and training grants, and threatens to curtail promising avenues of scientific inquiry. Although this Court denied UC’s motion to intervene, it *sua sponte* granted UC status as an *amicus curiae*.

SUMMARY OF ARGUMENT

At the preliminary injunction stage, plaintiffs must introduce evidence of competitive standing; they have made one allegation mirrored in two declarations that they will be competitively injured. A single sentence absent any evidence cannot support an injunction that would foreclose approximately \$130 million in research funding per annum and abrogate more than 100 grant contracts with parties not before this Court.

Plaintiffs are employees of research institutions who are seeking to vindicate the rights of their employers even though those employers are not parties to this litigation and one employer has indicated its opposition to the instant suit. Plaintiffs lack competitive standing because they are employees, not grantees, they are not legal parties to any NIH grant, do not own or administer any NIH grant, and have indicated no intention of seeking to become grantees, a label usually reserved for institutions not individuals. Grantees, to the extent they seek funding for a full range of stem cell research, *i.e.*, ASC, iPSC, hESC, do not compete for a single line of research and therefore, there is no competitive standing with respect to grantees. Plaintiffs have also failed to identify the “market” in which they compete. There are twenty-eight separate appropriations and funding units within NIH and plaintiffs do not compete in all, yet they are seeking to hold hostage funding for all.

Plaintiffs also lack standing because it is also unclear whether the district court can provide any relief. If the 2009 Guidelines are invalidated, nothing prevents NIH from funding hESC research. The Guidelines do not authorize funding of such research, but rather impose conditions on institutions seeking hESC funding. If the guidelines evaporate, the restrictions evaporate, but the statutory authorization remains. Conversely, if plaintiffs are challenging hESC

funding in general, they have waited too long. Such suit is barred by the six-year statute of limitations.

Even if plaintiffs had standing to request a preliminary injunction, the harm to the public and to grantees such as UC far outweigh the speculative harm offered by plaintiffs. Plaintiffs have not shown that they have lost any grants as a result of any government policy. In contrast, the impact of even a short-lived injunction was profound and affected research scientists, and threatened active research as well as teaching programs and jeopardized jobs. The district court considered none of this harm because plaintiffs failed to join the grantees. Since grants are contracts, plaintiffs were obligated to join all grantees as necessary parties under Fed. R. Civ. P. 19. Yet they have taken the opposite approach--seeking to keep the largest and most affected grantee out of this lawsuit. As a result, the injunction must be vacated under Rule 19.

ARGUMENT IN SUPPORT OF DEFENDANTS

I. Plaintiffs Are Not Likely to Succeed on the Merits

Plaintiffs have asked the courts to ordain science by judicial decree. At issue as a threshold matter is whether plaintiffs--two individual researchers--have standing to tilt the scientific tables by halting an entire field of federally funded medical research for the ostensible purpose of improving their odds of obtaining a federal grant.¹ The lower court erred in finding that plaintiffs were likely to succeed in this effort. This Court's review of a decision granting a preliminary

¹ Dr. Sherley's primary concern, expressed in his comment to the Proposed Guidelines, had little to do with competition and everything to do with his view of morality. Through counsel, he stated that he "is most centrally concerned that the proposed Guidelines fail to acknowledge that the scientific fact that human embryos are living human beings." Exhibit A-4 to Plaintiffs' Motion for Preliminary Injunction (Aug. 19, 2009) (Docket Entry No. 3).

injunction is well-established: the court reviews a district court's weighing of the preliminary injunction factors and its ultimate decision for abuse of discretion, but reviews the court's legal conclusions *de novo*. See *Davis v. Pension Benefit Guaranty Corp.*, 571 F.3d 1288, 1291-92 (D.C. Cir. 2009). Here, plaintiffs' case falters at the starting block because they have not established as a matter of law that they have standing to support the broad preliminary injunction granted by the district court.

A. Plaintiffs Have Not Established that They Have Standing to Bring This Action

1. Plaintiffs' Burden Now Is Much Higher Than It Was When Defending Against a Challenge Under Rule 12(b)(3)

A plaintiff's burden to establish standing varies with the status of the case. What might have been sufficient to withstand a motion to dismiss may not be sufficient to support a preliminary injunction. A plaintiff's burden to establish standing increases at each of the "successive stages of the litigation." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *Tooley v. Napolitano*, 556 F.3d 836, 838 (D.C. Cir.), *amended on other grounds*, 586 F.3d 1006 (2009) (plaintiffs' burden "to show each element [to support standing] grows increasingly stringent at each successive stage of the litigation."). For this reason, this Court's initial ruling on standing is not the "law of the case" at this juncture. See *Cale v. Johnson*, 861 F.2d 943, 947 (6th Cir. 1988) ("[I]t may prove proper to draw distinctions that rest on the stage that that proceeding has reached. Early pretrial rulings, for example, may often be subject to reconsideration as a case progresses toward trial...") (quoting 18 C. Wright, A. Miller & E. Cooper, FEDERAL PRACTICE AND PROCEDURE § 4478 pp. 790-95 (1981)). The district court had an obligation to reassess plaintiffs' standing before issuing a preliminary injunction. Its failure to do

so, in and of itself, is reversible error. In this case, standing is precluded as a matter of law.

2. Plaintiffs Have Not Demonstrated Any Competitive Injury

Plaintiffs' standing theory rests on their belief that ASC researchers compete with hESC researchers for grant funding and that "those working on more promising adult stem cell research will no doubt be deprived of opportunities for funding." Plaintiffs' Motion for Preliminary Injunction at 38. This loss, according to plaintiffs, cannot be remedied after the fact and "will harm their personal and professional interests in pursuing their lifelong work." *Id.* at 39. There is no support for these statements. Nor do they make much sense. Under plaintiffs' theory, any university that engages in research that involves stem cells will be competing against itself. That is simply not the way the process works.

a. Plaintiffs Have Not Established Any Concrete Injury

A potential loss to two plaintiffs' personal or professional interests in pursuing their work at some unspecified future time does not confer standing on them:

To seek injunctive relief, a plaintiff must show that he is under threat of suffering "injury in fact" that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury. ... This requirement assures that "there is a real need to exercise the power of judicial review in order to protect the interests of the complaining party," Where that need does not exist, allowing courts to oversee legislative or executive action "would significantly alter the allocation of power ... away from a democratic form of government,"

Summers v. Earth Island Institute, 555 U.S. ___, 129 S. Ct. 1142, slip op. at 4-5 (2009) (citations omitted).² Here, plaintiffs allege in a single conclusory sentence that NIH's Guidelines "will result in increased competition for the limited resources that are available to fund human stem cell research, threatening [his] ability to obtain federal funding for [his] adult stem cell research" and that without such funding, he "would likely be unable to continue [his] research."³ Sherley Decl. ¶ 4. *See also* Deisher Decl., ¶ 4. Dr. Deisher, however, does not have any NIH funding. *See id.* ¶ 3 (stating: "I am currently in the process of applying for NIH funding, and I will continue to seek funding for adult stem cell research in the future.").

Neither declaration is sufficient to support a "concrete injury," let alone an actual or imminent one, whether through competition or not: a single clause in a single declaration is "too thin a reed to support" an order halting approximately \$130 million per annum of biomedical research. *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, slip op. at 15 (2008). In any event, the relief sought is overbroad. Plaintiffs' allegations would not justify an injunction applicable to all twenty-eight institutes, centers and offices at NIH. Dr. Sherley is listed as a principal investigator on awards issued by one institute (National Heart, Lung, and Blood Institute), one center (National Center for Research Resources), and the Office of the Director. *See* <http://projectreporter>.

² In addition to these constitutional requirements, under the Administrative Procedure Act, parties must establish that their claims fall "arguably within the zone of interests to be protected or regulated by the statute in question." *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 488 (1998) (internal quotation marks omitted); *see also Amgen, Inc. v. Smith*, 357 F.3d 103, 108 (D.C. Cir. 2004). By their own admission, plaintiffs do not and will not use hESC, so the guidelines were not aimed at them and they do not fall within the zone of interests to be regulated or protected.

³ Plaintiffs have never demonstrated that there is a single zero-sum fund for stem cell research. There is no single fund and no single appropriation for stem cell research. *See* pp. 10, 13-14, *infra*.

nih.gov/reporter_searchresults.cfm?&new=1&icde=5414554&loc=2&CFID=20643284&CFTOKEN=59627114 (last viewed Sept. 19, 2010). Even there, that interest is not personal to him. Neither plaintiff is a direct recipient of any NIH grant. And, finally, plaintiffs incorrectly presume that if federal funding of hESC research were to cease, then UC and other institutions would refrain from seeking federal support using whatever tools the government has not banned. Thus a favorable decision is not likely to redress his perceived injury.

b. Any Injury Alleged By Plaintiffs Is Not Personal to Them

Neither plaintiffs' complaint nor this Court's decision in *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010) ("*Sherley I*") addressed the distinction between a grantee, such as UC or Boston Biomedical Research Institute ("BBRI"), and its employees, including principal investigators. That distinction goes to the heart of the district court's jurisdiction to entertain this suit. "Employees[, such as Drs. Sherley and Deisher] have generally been denied standing to enforce competition laws, because they lack competitive and direct injury." *Air Courier Conference of Am. v. Am. Postal Workers Union*, 498 U.S. 517, 528 n.5 (1991). This applies with equal force to NIH research grants where the principal investigator is not a party to the grant, does not control the grant, does not own the intellectual or tangible property developed under the grant, and does not administer the grant. While principal investigators may have sweat equity in a grant application, that does not translate into economic equity to support standing.

A grant is a contract between the grantee, usually an institution, and the grantor, such NIH. *See* 42 C.F.R. pt. 52; *Dartmouth Coll. v. Woodward*, 17 U.S. 518, 627 (1819) ("It can require no argument to prove, that the circumstances of this case [including a grant from the crown] constitute a contract."); *see also*

United States v. City & County of San Francisco, 310 U.S. 16 (1940); *Am. Hosp. Ass'n v. Schweiker*, 721 F.2d 170, 182-83 (7th Cir. 1983); *United States v. County Sch. Bd., Prince Georges County, Va.*, 221 F.Supp. 93 (E.D. Va. 1963). Dr. Sherley, as a principal investigator, is not “a party to ... the [g]rant[.]” and has no legal standing with respect to any grant that funds or could possibly fund the research on which he is employed to work.⁴ *Gen-Probe Inc. v. Center for Neurologic Study*, 853 F.Supp. 1215, 1219 (S.D. Cal. 1993). Instead, the principal investigator is “designated” as such “by the grantee,” and normally is an employee of the grantee institution. 42 C.F.R. § 52.2(b); see e.g., UCLA Policy 900: Principal Investigator Eligibility (May 7, 2009), at <http://www.adminpolicies.ucla.edu/pdf/900.pdf> (last viewed Oct. 10, 2010); University of Michigan Research Administration, http://www.drda.umich.edu/proposals/principal_investigator.html (last viewed Oct. 10, 2010); Yale University Policy 1310 (Feb. 1, 2008), <http://www.yale.edu/ppdev/policy/1310/1310.pdf> (last viewed Oct. 10, 2010).

Courts have consistently recognized that unless an employee has a legal interest that is distinct from his employer, he lacks the standing necessary to challenge government policy. In *J.F. Shea Co., Inc. v. City of Chicago*, 992 F.2d 745, 749 (7th Cir. 1993), for instance, a government contractor based outside of Chicago and its project superintendent challenged Chicago’s “local business preference rule,” that gave preferential treatment to Chicago-based businesses. In affirming the dismissal of the project superintendent’s claims, the court noted that

⁴ The standard NIH grant application does not even have a place for the proposed principal investigator to sign. See PHS Form 398 <<http://grants.nih.gov/grants/funding/phs398/phs398.html>>. The only signature required is that of the designated institutional official, usually the grantee’s Vice President for Research. Similarly, the Notice of Award Letter, the NIH document confirming that the grant sought has in fact been awarded, is directed to the institutional official and not the principal investigator. NIH Revised Notice of Award Letter, available at <<http://grants.nih.gov/grants/guide/notice-files/not-od-07-060.html>> (last viewed Oct. 17, 2010).

“employees generally do not have standing to assert claims of the corporation because they lack direct injury.” *Id.* The fact that an employee may lose his employment as a result of the challenged government policy is insufficient: lost employment is “merely incidental to the corporation’s injury.” *Id.* (quoting *Warren v. Mfrs. Nat’l Bank*, 759 F.2d 542, 545 (6th Cir. 1985)); *see, e.g., Adams v. Pan Am. World Airways, Inc.*, 828 F.2d 24 (D.C. Cir. 1987), *cert. denied sub nom. Union de Transports Aeriens v. Beckman*, 485 U.S. 934 (1988) (denying standing to former airline employees to assert antitrust claim that airline allegedly drove their former employer out of business); *Curtis v. Campbell-Taggart, Inc.*, 687 F.2d 336 (10th Cir.), *cert. denied*, 459 U.S. 1090 (1982) (same).

Plaintiffs, apparently aware of the “employee-standing” conundrum, blur the distinction between the grantee and the principal investigator, and endow the principal investigator with authority not contemplated by either the Public Health Service Act or its implementing regulations. For example, plaintiffs assert that referring to “Dr. Sherley as not being the grantee conveys an inaccurate impression, because Dr. Sherley is the principal investigator” and “the individuals who develop and submit grant applications and administer the awarded grants are referred to as ‘principal investigators.’” Appellees’ Opposition to UC’s Motion for Leave to Intervene at 10. As plaintiffs themselves recognize, there is a regulatory distinction between a grantee and principal investigator. *Compare* 42 C.F.R. § 52.2(e) *with id.* § 52.2(b). While the principal investigator may develop the idea for the grant, the principal investigator neither owns nor administers the award, and does not even submit the application. An NIH grant is, by definition, awarded to the grantee, not the principal investigator (*see* 42 C.F.R. § 52.2(e)); the grantee, not the principal investigator, is responsible for administering the grant and ensuring compliance with its terms and conditions (*see e.g.,* 42 C.F.R. § 50.601 *et seq.*; 42 C.F.R. pt. 93; 45 C.F.R. pt. 74), and “[o]nly the Authorized Organizational

Representative (AOR) has the authority to submit applications[,]" not the principal investigator. *See* http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm (last viewed Oct. 11, 2010).

Plaintiffs' complaint also blurs the distinction between employer and employee. Plaintiffs allege that "Dr. Sherley applied for NIH funding approximately 41 times." Complaint, ¶ 6. But plaintiffs also state that Dr. Sherley "work[s] at the Boston Biomedical Research Institute." *Id.* Both the public record and plaintiffs' subsequent filings with this Court establish that BBRI is the grantee of the NIH awards that fund Dr. Sherley's research and that Dr. Sherley is an employee of BBRI. Dr. Sherley, as an employee, has no independent right to assert competitive injury to his grantee-employer especially when BBRI has announced on its website that "BBRI fully endorses the funding of research programs by the National Institutes of Health (NIH) across the country, including those involving human embryonic stem cells" and that "Dr. Sherley's position on this issue neither represents nor reflects that of BBRI." <<http://www.bbri.org/index.php/statement/articles/statements.html>> (last viewed Oct. 17, 2010).

Grantees, such as UC, treat scientific research as a collaborative effort among their faculty and scientific staff, recognizing that in science everyone stands on someone else's shoulders. University grantees, such as UC, therefore promote all avenues of inquiry and seek funding for ASC, iPSC and hESC research simultaneously. These grantees do not compete for ASC funding to the exclusion of hESC funding, but rather seek funding for all. Therefore, the concept of competition over research types makes no sense when viewed from perspective of the employer-grantee. To the contrary, plaintiffs are really asking this court to intercede in their employment relationship by precluding their employers from seeking hESC funding.

Thus in *Sherley I*, when this Court found that plaintiffs had established competitive standing sufficient to withstand a motion to dismiss because they “will have to invest more time and resources to craft a successful grant application” and “[t]hat is an actual, here-and-now injury,” *Sherley I*, 610 F.3d at 74, the Court was not fully informed. The distinction was neither fully briefed or addressed by the Court at that time. Plaintiffs are not investing their own resources, but rather the resources of their absent employers. Nor are they investing their own time; that investment too is underwritten by their absent employers. Nothing in the record suggests that either plaintiff is developing grant applications outside the scope of their employment and nothing suggests that plaintiffs’ continued employment hinges on NIH grants.

Nor have plaintiffs pleaded or articulated any right, independent of their employer institution, to compete for federal grant funds, as none exists. The Public Health Service Act §§ 301, 401, 42 U.S.C. §§ 241, 282, which authorizes the Secretary through NIH to fund biomedical research, creates no such right.⁵ *See also Rubinstein v. Mayor and City Council of Baltimore*, 295 F.Supp. 108 (D. Md. 1969) (finding no vested right of a co-investigator on an NIH grant who sought to preclude the transfer of a grant from the Baltimore City Hospitals, where he was employed, to Yale University).

The lack of a recognized individual right to compete for federal funding is reflected in the longstanding judicial reluctance to interfere in NIH grant funding decisions. Permitting putative grantees to challenge agency funding decisions or policy not only undermines the peer review system, but also places courts in the

⁵ The only statutory nod to principal investigators is the requirement that the NIH director “ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health[.]” 42 U.S.C. § 282(b)(7)(iii)(III).

awkward position of having to second-guess scientific policy in areas where they have been understandably reluctant to enter. *See Grassetti v. Weinberger*, 408 F. Supp. 142, 150 (N.D. Cal. 1976) (“[C]ourts are simply not competent to step into the role of a medical research scientist.”). *See also Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 600 (1993) (Rehnquist, dissenting) (“I defer to no one in my confidence in federal judges; but I am at a loss to know what is meant when it is said that the scientific status of a theory depends on its ‘falsifiability,’ and I suspect some of them will be, too.”). In fact, hypothesis creation and falsifiability are the hallmarks of the scientific method and they form the basis of most fundamental research funded by NIH.

c. Plaintiffs Have Failed to Identify the Relevant Market

In any case predicated on a competitive standing theory, the plaintiff must plead--and establish--the relevant market. *See Illinois Tool Works v. Independent Ink*, 547 U.S. 28, 32 (2006); *U.S. v. Microsoft Corp.*, 253 F.3d 34, 82 (D.C. Cir.) (“Plaintiffs have the burden of establishing barriers to entry into a properly defined relevant market.”), *cert. denied*, 534 U.S. 952 (2001). Here, there are twenty-eight distinct funding markets--each with its own appropriations and each with its own Federal Advisory Committee Act council that recommends which grants are to be funded and which are not. *See* PHS Act § 406, 42 U.S.C. § 284a. In addition, NIH operates nearly 180 regular study sections that initially review each grant application.⁶ Plaintiffs have failed to plead, let alone introduce evidence, as to which of the twenty-eight markets they compete in; they have never alleged that they compete in all twenty-eight. Absent such a showing, plaintiffs have failed to

⁶ NIH also operates an additional 230 special-emphasis study sections. Robert Charrow, *LAW IN THE LABORATORY: A GUIDE TO THE ETHICS OF FEDERALLY FUNDED SCIENCE RESEARCH* 18 (Univ. Chicago Press 2010).

satisfy the requisites to establish competitive standing sufficient to hold all funding hostage.

In addition, the notion of competitive standing requires some connection or effect on commerce. Thus the Court must consider the nature of the activity to determine whether it is commercial. *See* Areeda, P. and Hovenkamp, H., ANTITRUST LAW § 260 (1999). This Court already has held that research is not a commercial activity. *See Washington Research Project, Inc. v. HHS*, 504 F.2d 238, 244-45 (D. C. Cir. 1974) (“it defies common sense to pretend that the scientist is engaged in trade or commerce” unless there is some commercial interest or application evident), *cert. denied*, 421 U.S. 963 (1975). Nor is competition for research a commercial activity where, as here, plaintiffs have alleged no commercial interest or application and none is evident. This too precludes reliance on their competitive standing theory at this juncture. Finally, plaintiffs have not alleged, let alone shown, the connection between any increase in competition and harm now or in the future. Since Dr. Deisher has never applied for or received an NIH grant and only intended to apply for one at some time in the future, she has not and cannot allege any imminent or concrete harm. If Dr. Sherley is unsuccessful in obtaining grant applications, it is not because there is more competition, it is because his proposals lack merit. Even under the court’s decision at the motion to dismiss stage, a mere increase in competition without some showing of any actual effect or injury in fact is not sufficient to confer competitor standing. *Sherley I*, 610 F.3d at 73 (“the basic requirement common to all our cases is that the complainant show an actual or imminent increase in competition, which increase we recognize will almost certainly cause an injury in fact.”). The Court’s recognition of “almost certain” injury by an allegation of an increase in competition may have been sufficient when considering the motion to dismiss, but it is not sufficient at the preliminary injunction stage.

Plaintiffs also misunderstand how funds are awarded. The tools of research normally do not determine the NIH unit that will fund the research;⁷ the funding unit is determined by the ailment or body system targeted by the research. Plaintiffs' standing hinges on two factual assumptions, neither of which is supported by evidence. First, plaintiffs tacitly assume that if a researcher is precluded from seeking NIH funding for a project involving hESC, that researcher will not seek funding from NIH for any research, including stem cell research. The evidence is to the contrary. *See* Beckwith Decl., ¶ 15. Second, there is no evidence of "head to head" competition other than the letter submitted to the D.C. Circuit by plaintiffs' counsel prior to oral argument where counsel stated that Sherley's "chief competitor for this funding is Geron Corp., a biotechnology company that engages in similar research using human embryonic stem cells." Counsel's statement was inaccurate. Sherley does not compete with Geron for NIH funding. Geron received significant NIH funding in the past, but has no active NIH funding, is no longer a "small business" for SBIR purposes, and thus no longer qualifies for the SBIR grant program under which Sherley sought funding.⁸ It also would be wishful thinking on Dr. Sherley's part to believe that he competes for any funding with Geron. Geron already has started clinical trials of an hESC product to treat those paralyzed due to spinal cord injury. *See* n.8, *supra*.

⁷ There are limited exceptions not relevant here. For example, a significant segment of research that focuses on imaging technology (*e.g.*, MRI, CT scan, PET scan) is funded by the National Institute of Biomedical Imaging and Bioengineering.

⁸ On October 11, 2010, the Washington Post reported that Geron was initiating a clinical trial of an hESC-based article to treat spinal cord damage. *See* Rob Stein, First patient treated in stem cell study, *The Washington Post* (Oct. 11, 2010) at <http://www.washingtonpost.com/wp-dyn/content/article/2010/10/11/AR2010101102946.html>; *see also* <http://www.clinicaltrials.gov/ct2/show/NCT01217008?lead=Geron&rank=2> (last viewed Oct. 13, 2010). In 2009, Geron reported revenues in excess of \$1.7 billion with 172 employees. *See* Geron's 2009 Annual Report at <http://www.geron.com/investors/factsheet/reports.aspx> (last viewed Oct. 14, 2010).

The preliminary injunction sought by plaintiffs would preclude NIH from funding basic research that can lead to these types of advances for otherwise untreatable conditions, ailments or diseases. In short, plaintiffs' lawsuit comes at the expense of patients' health and well-being.

3. Either Plaintiffs Cannot Establish Redressability Or They Have Waited Too Long to Seek Relief

It is unclear whether plaintiffs' alleged competitive injury is redressable, a prerequisite for standing. *See Lujan*, 504 U.S. at 561. If plaintiffs are truly challenging the 2009 Guidelines, then their standing would hinge on (i) pleading and proving that the incremental difference in hESC funding between the Bush policy and the 2009 Guidelines was injuring their competitive position, and (ii) showing that absent the Guidelines, their competitive position would improve. They have done neither and can do neither.

First, as to incremental injury, since plaintiffs never reveal the difference in hESC funding under the two policies, they have not even taken the first step toward proving that the incremental funding difference injures their competitive position.

Second, even if they are challenging the 2009 Guidelines, plaintiffs' arrows are aimed at the wrong apple. Guidelines do not, and cannot as a matter of law, authorize NIH to fund hESC research or any other type of research for that matter. Guidelines can only announce a general policy imposing restrictions on how the government funds research authorized elsewhere.⁹ Here, the Public Health Service Act authorizes funding by requiring the Secretary to support research "relating to the causes, diagnosis, treatment, control, and prevention of physical and mental

⁹ The Guidelines issued by NIH cannot authorize NIH to fund. Authorizations, by definition, must come from higher authority, in this case Congress through the Public Health Service Act.

diseases and impairments of man” and authorizes the Secretary to “make grants-in-aid to universities [and others] ... for such research projects as are recommended by the advisory council of the entity of the Department supporting such projects.”

PHS Act § 301(a), 42 U.S.C. § 241(a).

Invalidating the Guidelines will merely leave NIH in the position that it was in before President Bush issued his August 9, 2001 policy statement and Executive Order 13,435 (June 20, 2007), when research using hESC was within the NIH authorization and could be freely funded subject to the Dickey-Wicker Amendment. *See* JA 161 (Rabb Memorandum). NIH’s default policy is to fund research unless Congress or the Executive imposes limitations through statute, Executive Order or regulation and those funding and allocation decisions are “committed to agency discretion.” *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993). In short, invalidating the Guidelines does not automatically preclude federal funding of research involving hESC.

If plaintiffs’ actual complaint is with the NIH’s general policy to fund hESC research, plaintiffs waited too long to bring this action and are now barred by the six-year statute of limitations that applies to actions against the Government under the APA. *See* 28 U.S.C. § 2401(a).¹⁰ *See also Daingerfield Island Protective Soc’y v. Babbitt*, 40 F.3d 442, 445 (D.C. Cir. 1994). The limitations period begins to run from the time of “final agency action.” *Sw. Williamson County Cmty. Ass’n v. Slater*, 173 F.3d 1033, 1036 (6th Cir. 1999) (citing 5 U.S.C. § 704). Here, the final agency action was the decision reached during the Clinton

¹⁰ Section 2401(a) provides that “[e]xcept as provided by the Contract Disputes Act of 1978, every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues.” For actions under the APA, the right of action under section 2401 can accrue before a plaintiff suffers any injury. *See Pennsylvania v. United States Dep’t of Health and Human Servs.*, 101 F.3d 939 (3d Cir. 1996) (Alito, J.).

Administration to fund research that involved hESC, that was reaffirmed in President Bush's August 2001 policy statement, his 2007 Executive Order and implementing Guidelines, and again in President Obama's 2009 Executive Order and the implementing 2009 Guidelines. While science moves quickly, these two scientists have not.¹¹

B. The District Court Misunderstood the Term "Research" in the Dickey-Wicker Amendment

The Government's reading of the Dickey-Wicker Amendment is so natural and robust that it leads to the same interpretation no matter how "research" is defined. Dickey-Wicker is not a monograph on the philosophy of science, the meaning of "research," or the scientific method. Rather it uses the language of the appropriators to limit how funds can be spent and in that regard, the pragmatics of appropriations and grant funding intersect. NIH funds biomedical research projects. The metes and bounds of each project are determined by the grant application, including the budget, and the subsequent Notice of Award Letter. If an activity is included within the proposed project and is funded by the NIH grant, then, by definition, that activity is part of the funded research. If the activity is not included in the request for funds, no NIH funds are made available for that activity, no NIH grant funds are used for that activity, and, by definition, the activity is not part of the funded project. Thus, if grantees do not request funds for the derivation of hESCs or the creation of hESC lines and NIH does not award funds for those activities, by definition, NIH has not funded any research in which embryonic stem

¹¹ *Felter v. Kempthorne*, 473 F.3d 1255, 1260 (D.C. Cir. 2007) ("[u]nlike an ordinary statute of limitations, § 2401(a) is a jurisdictional condition attached to the government's waiver of sovereign immunity," quoting *Spannaus v. DOJ*, 824 F.2d 52, 55 (D.C. Cir. 1987)). The Government cannot be deemed to have waived this defense since they have not yet filed an answer to plaintiffs' complaint. See *Sherley v. Sebelius*, Civ., No. 09-01575 (D.D.C. filed Aug. 19, 2009).

cells are derived or propagated. This pragmatic definition of “research” looks to what is being funded in light of underlying authorization and allows agencies, Congress and the grantee community to apply for funding without having to be concerned with Popper, Kant, or Bacon.

II. The Concrete Harm to Defendants and the Public Outweighs Any Amorphous and Speculative Harm to Plaintiffs

The harm alleged but not established by plaintiffs must be balanced against the actual harm to current grantees and the public. In this balancing, it is not even a close case. UC is the single largest recipient of research grants and cooperative agreement funding from NIH. It has received NIH grant funding under both the Bush Guidelines and the Obama Guidelines. Beckwith Decl., ¶ 5. It has been awarded at least thirty grants involving hESC from thirteen different institutes and centers within NIH. Beckwith Decl., ¶¶ 6, 7, 8. UC has been awarded research grants, program-project grants and other forms of grants involving not only hESC, but ASC cells and iPSC. Beckwith Decl., ¶ 3. UC has devoted substantial resources to research involving all stem cells, including hESC. Beckwith Decl., ¶ 3. UC employs scientists, technicians and staff, and educates undergraduate, graduate and medical students in these fields. Beckwith Decl., ¶¶ 3, 7, 8. Its budgeting determinations, including hiring and promotions, construction, allocations of space and equipment, and graduate student admissions, are based in large measure on approved grant funding. Beckwith Decl., ¶ 9. The brief period in which this funding was enjoined had a significant impact on UC. The effect of a preliminary injunction going forward will be profound on the University, its faculty, staff, and students. Jobs of non-faculty scientists, technicians and staff hired to conduct research under or to support an awarded NIH grant will be jeopardized. Beckwith Decl., ¶¶ 10, 11, Kriegstein Decl., ¶ 4. The impact is not

limited to those who perform research using hESC alone; a preliminary injunction will have an impact on dozens of researchers and students, affecting programs across UC's campuses and departments, including programs that do not even perform any non-federally funded derivation work, but acquire hESC lines from other institutions outside of California. Kriegstein Decl., ¶ 4.

The adverse consequences are also felt in UC's Medical Scientist Training Program ("MSTP") as well as the Neuroscience Training Program and Developmental Biology Training Program. Beckwith Decl., ¶ 14, Kriegstein Decl., ¶ 6. More than eighty students at UCSF alone receive MSTP training grant stipends from NIH. If the training grant lists any faculty mentor who undertakes hESC research, that faculty member will not be eligible to act as a mentor and without those faculty mentors' participation, the entire grant will no longer be funded. The loss of those stipends will undermine UC's efforts to train many promising physician-researchers and will halt the research in which they are engaged. Beckwith Decl., ¶ 14, Kriegstein Decl., ¶¶ 5, 6.

And, as important, the adverse consequences will be felt by the public. UC has devoted substantial resources to hESC research based on its belief, shared by a strong consensus in the relevant scientific communities, the State of California, and among the University's leaders, that hESCs are a powerful research tool that is and can be used to better understand fundamental cellular biology and to improve health. Beckwith Decl., ¶ 3; Kriegstein Decl., ¶ 3. That research holds the potential for developing cures and treatments for brain disease and injuries, including Parkinson's Disease, amyotrophic lateral sclerosis (Lou Gehrig's Disease), and autoimmune diseases, such as type I diabetes, and spinal cord injuries. *Id.* The use of hESC also serves as an important standard against which the fidelity of other types of stem cells can be measured and thus promotes advances in adult stem cell and iPSC research. *Id.*

III. The Preliminary Injunction Should be Vacated Because Plaintiffs Failed to Join as Necessary Parties hESC Grantees, Such as UC

Although grantees are the only non-federal actors with a direct legal interest in the Guidelines and grant awards, plaintiffs declined to name or serve any grantee, including their own employers. When UC sought to intervene on appeal, plaintiffs argued that UC had waited too long. Grantees, though, are necessary parties and plaintiffs were obligated to name and serve them in their complaint. *See* Fed. R. Civ. P. 19.

Under Rule 19(a)(1)(B)(i), a plaintiff is obligated to join all parties with an interest in the property that may be “impair[ed] or impeded[ed]” by the litigation. This litigation and the preliminary injunction it seeks were designed in part to void existing grant contracts between NIH and the unnamed and unserved grantees. *See* p. 7, *supra* (indicating that grants are contracts). Where a third-party seeks to upset the contractual rights of other parties, those other parties are “necessary” and must be joined. *United States ex rel. Hall v. Tribal Dev. Corp.*, 100 F.3d 476, 479 (7th Cir. 1996) (joinder is necessary where “a judicial declaration as to the validity of a contract necessarily affects, ‘as a practical matter,’ the interests of both parties to the contract.”); *see also Martin v. Wilks*, 490 U.S. 755, 767-68 (1989) (where the Supreme Court found joinder required in a suit by a group of employees who sued their employer seeking promotion to positions superior to those of other employees who were not parties to the suit); *Nat’l Union Fire Ins. Co. of Pittsburgh, Penn. v. Rite Aid of S. Carolina, Inc.*, 210 F.3d 246, 251 (4th Cir. 2000) (finding joinder of a parent corporation required when the parent was a party to a challenged agreement); *Professional Hockey Club Cent. Sports Club of the Army v. Detroit Red Wings, Inc.*, 787 F. Supp. 706 (E.D. Mich. 1992) (in an action between two hockey clubs for tortious interference with contract, absentee hockey player was a

necessary party because holding that his contract with plaintiff was invalid would mean no contract existed with which defendant could have interfered). It was inappropriate for plaintiffs to seek and for the district court to grant a preliminary injunction without joining all affected grantees.

Nor is it enough that one party to the contract can in theory adequately represent the interests of all absent parties. The “impair or impede” clause of Rule 19 does not contain the “unless” clause found in Rule 24, *e.g.*, “unless existing parties adequately represent that interest.” Only where the interests are identical or where one party will undoubtedly make all of the absent parties’ arguments will courts permit the case to proceed without the absent party. *See Washington v. Daley*, 173 F.3d 1158, 1167-68 (9th Cir. 1999) (using a multiple factor test); *Tell v. Trustees of Dartmouth Coll.*, 145 F.3d 417, 419 (1st Cir. 1998) (interests must be identical); *Ohio Valley Env'tl. Coalition v. Bulen*, 429 F.3d 493, 504-05 (4th Cir. 2005) (same). No one has argued that the government’s interests are identical to the grantees: the interests may be aligned but they cannot be identical. For this reason too, a preliminary injunction affecting grantees should not have issued without joining the grantees as parties in the proceedings below.

CONCLUSION

For the reasons set forth above, the district court’s decision should be reversed and the preliminary injunction should be vacated.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I hereby certify that this brief complies with the type-volume limitations set forth in that rule. This brief contains 6,606 words (exclusive of the cover, table of contents, table of authorities and glossary). I relied on my word processor, Microsoft Word 2003, to obtain the count.

In addition, this brief complies with the typeface requirements of Fed. R. App. P. 35(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2003 in Times New Roman 14 pt.

s/Laura Metcoff Klaus

Laura Metcoff Klaus

CERTIFICATE OF SERVICE

I hereby certify that on October 17, 2010, a copy of the foregoing Brief Amicus Curiae of the Regents of the University of California was electronically filed with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by the appellate CM/ECF system and by hand-delivery. Service was made this date on the following by the CM/ECF system:

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