

UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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JAMES L. SHERLEY, DR., <i>et al</i> ,	)	
	)	
Appellees,	)	
	)	
v.	)	No. 10-5287
	)	
KATHLEEN SEBELIUS, in her official	)	
capacity as Secretary of the Department	)	
of Health and Human Services, <i>et al.</i> ,	)	
	)	
Appellants.	)	

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MOTION FOR LEAVE TO INTERVENE ON APPEAL AS OF RIGHT

The Regents of the University of California, by its undersigned attorneys and pursuant to Rule 27 of the Federal Rules of Appellate Procedure and Circuit Rule 27 of the Rules of this Court, hereby moves for leave to participate in the above captioned matter as an intervenor. In support of this motion, the following is submitted.

1. The University of California is a public trust organized under the Constitution of the State of California and is governed by the Board of Regents. The University of California System (“UC”) comprises ten campuses, and its five medical centers support clinical teaching programs in medicine and health sciences, provide health care services in their communities, and develop and test

new diagnostic and therapeutic techniques. That research includes human embryonic stem cell (“hESC”) research, funded by the State of California, private sources and numerous Institutes, Centers, and Offices of the National Institutes of Health (“NIH”), as well as the NIH Common Fund. *See* Declaration of Steven V.W. Beckwith, Ph.D. (“Beckwith Decl.”) at ¶¶ 1-3; Declaration of Arnold R. Kriegstein, M.D., Ph.D. (“Kriegstein Decl.”) at ¶ 3.

2. As the single largest NIH grantee in the Nation whose grants are directly affected by this action, the Regents of the University of California seeks to intervene as of right.

3. Although the Federal Rules of Appellate Procedure explicitly provide for intervention only in direct reviews of agency decisions under Fed. R. App. P. 15, the Supreme Court has recognized that intervention on appeal is not precluded in other cases and is to be governed by the criteria in Fed. R. Civ. P. 24. *See International Union v. Scofield*, 382 U.S. 205, 217 n.10 (1965). This Court has identified the following four factors that must be considered in determining whether intervention on appeal as of right is appropriate: (1) the party must have an interest relating to the property or transaction which is the subject of the action; (2) the disposition of the case may impair or impede the party's ability to protect that interest; (3) the existing parties do not adequately represent the intervenor's interest; and (4) the motion must be timely. *See Building and Const. Trades Dep't*

*v. Reich*, 40 F.3d 1275, 1282-83 (D.C. Cir. 1994). This motion satisfies each of these requisites.

4. First, the University of California has a property interest in the subject matter of this litigation. It receives millions of dollars in grant funds for research to understand and develop better treatments for heart, lung and blood diseases, chronic dysfunction of the digestive tract, kidney, and liver, neurodegenerative diseases, both in children and older adults (including Alzheimer's Disease), diabetes, as well as other genetic disorders too numerous to list. *See Beckwith Decl.* at ¶¶ 3-8. Human embryonic stem cells are an important tool in this research as well as in research that uses adult stem cells because they serve as an important control mechanism. *Kriegstein Decl.* at ¶ 3. The NIH-funded research does not involve any derivation work; cell lines are acquired from other sources just like any other specimens but subject to the relevant federal guidelines. *See Kriegstein Decl.* at ¶ 4.

5. Second, the preliminary injunction issued by the district court has adversely affected the University of California. The impact of the preliminary injunction is not limited to only those grants that involve newer hESC lines. It has a profound impact that extends to far more programs. It disrupts not only the processing of grant applications currently under review by NIH, but it disrupts many of its currently funded grants, and it has already threatened ongoing

programs to educate physicians and physician-researchers. *See* Beckwith Decl. at ¶¶ 9-15; Kriegstein Decl. at ¶¶ 4-6.

6. The reach of the preliminary injunction also extends beyond a single medical center, and beyond those within the University's health sciences departments. It affects UC programs, faculty, and staff, as well as programs underway at other institutions with which the University is formally affiliated. And it affects scores of graduate students and trainees. The loss of funding imminent as a result of the injunction will result in loss of programs, the loss of hours and thus, the potential loss of jobs and fellowships. *See* Beckwith Decl. at ¶ 9-11; Kriegstein Decl. at ¶¶ 4, 6.

7. Third, the University's interests are not adequately represented by the existing parties. An NIH research grant is a contract between two parties--the grantor (*i.e.*, NIH acting on behalf of the Secretary) and the grantee (usually a university or research institution). *See Dartmouth College v. Woodward*, 17 U.S. 518 (1819); 42 C.F.R. pt. 52. The parties to the current litigation represent only one of the perspectives relevant to the award and operation of research grants. The grantor is a party to the litigation and is represented by the Department of Health and Human Services, NIH's parent agency, and the Department of Justice. No grantee, however, is represented in this litigation; yet grantees are the most directly and immediately affected non-federal parties by the equitable relief sought by the

plaintiffs. The plaintiffs are two individual researchers who are neither grantors nor grantees. Thus, UC's interests are not represented in this litigation.

8. Finally, this motion is timely. The Regents seek to intervene at this juncture because it is only with the district court's decision on August 23, 2010, granting a preliminary injunction, that its interests have been affected. Prior to that time, there was little likelihood that plaintiffs' lawsuit would have any impact on the relevant communities. The district court had held that the plaintiffs did not have standing to challenge the use of hESC in federally funded research and the Regents believe that plaintiffs' standing now that the case has moved beyond the initial motion to dismiss still has not been established. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). And, the plaintiffs' theory--that they individually somehow competed against other grant applications for NIH funding--was not only inaccurate as a factual matter, but even if true, it would not justify an injunction applicable to all twenty-eight institutes, centers and offices at NIH. Here, neither plaintiff is a direct recipient of any NIH grant. One of the two plaintiffs (Sherley), currently is listed as 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.nih.gov/reporter\\_searchresults.cfm?&new=1&icde=5414554&loc=2&CFID=20643284&CFTOKEN=59627114](http://projectreporter.nih.gov/reporter_searchresults.cfm?&new=1&icde=5414554&loc=2&CFID=20643284&CFTOKEN=59627114) (last viewed Sept. 19, 2010).

Moreover, plaintiffs incorrectly presume that if federal funding of hESC research were to cease, then UC and other institutions that successfully have applied for such funding in the past would refrain in the future from seeking federal support for their projects using whatever tools the government has not banned.

9. Between the time this Court reversed the district court's order of dismissal on June 25, 2010, and the time the district court issued its August 23, 2010 preliminary injunction, the University evaluated whether its interests could be adequately represented by defendants. The district court, however, did not request any filing or hear any argument on plaintiffs' substantive claims before or following this Court's decision. It was not until September 7, 2010, when the district court denied NIH's motion to stay the injunction that the direct and indirect effects of the lower court's decision were felt by University of California and the lack of focus on or consideration of extramural research by the parties or the court became clear. The Regents acted quickly thereafter.

10. Additionally, no party is prejudiced if this motion for intervention is granted. This litigation is still at a preliminary stage. UC's participation does not delay or disrupt these proceedings in any way. This motion does not inject new issues into the case. Rather, it presents a perspective directly relevant to the Court's consideration of the balance of harms. As the largest NIH grantee in the nation, the University's interests are significant and significantly affected by a

preliminary injunction that broadly enjoins NIH from implementing, applying or taking any action or other funding research involving hESC as contemplated in the Obama Administration's hESC guidelines.

11. If this motion were to be granted, the University would abide by the current scheduling order and file its merits brief on the dates set for the appellants.

12. For all of these reasons, this motion satisfies the requirements for intervention on appeal as of right.

13. Counsel has contacted the attorneys for Drs. Sherley and Deisher as well as the attorneys representing the Secretary. Counsel for both Appellants and Appellees declined to consent, but neither provided any reason.

WHEREFORE, for the reasons set forth above, the Regents of the University of California respectfully requests that it be permitted to intervene and be admitted as a party in this proceeding, with all rights appropriate to that status.

Respectfully submitted,

s/Robert P. Charrow  
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CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2010, a copy of the foregoing Motion for Leave to Intervene on Appeal As of Right 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 parties both electronically and by first-class mail, postage prepaid:

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s/Robert P. Charrow  
Robert P. Charrow



University of California System is the single largest recipient of research grant and cooperative agreement funding from the National Institutes of Health (“NIH”).

3. The University of California System (“UC” or the “University”) has devoted substantial resources to research involving human embryonic stem cells (“hESC”), adult stem cells, and induced pluripotent stem cells (“iPSC”). UC employs scores of scientists, technicians, and other staff, and educates undergraduate, graduate and medical students in these fields. Research involving hESC is performed across disciplines, across departments, across schools, and in some instances, across institutions. The University has dedicated substantial effort to hESC research reflecting the strong consensus in the relevant scientific communities, in the State, and among University leaders that hESCs are a powerful research tool that can be used and are being used to better understand fundamental cellular biology and eventually, to improve the health of our citizens. Many scientists believe that hESCs hold the hope for developing cures for heretofore untreatable and fatal ailments such as amyotrophic lateral sclerosis (Lou Gehrig’s Disease), autoimmune diseases such as type I diabetes, and crippling spinal cord injuries. They believe that hESC research also promotes advances in adult stem cell and iPSC research.

4. The most promising stem cell research at the University has been made possible by support from numerous sources. These include donations from private

benefactors and California State funding that became available after California voters approved Proposition 71 on November 3, 2004. Proposition 71 authorized the State to raise \$3 billion through bond issuances for stem cell research to be disbursed over a ten-year period, giving priority to research with the greatest potential for therapies and cures.

5. In addition, University of California faculty and researchers have applied for and received NIH grant funding for hESC research under both the Bush Guidelines and the Obama Guidelines. The University of California, as the grantee, has been awarded a significant number of grants using or involving hESC from many of the institutes within NIH, as well as the NIH Common Fund. Many of these grants are for three to five years. An NIH three-year grant involves an initial application and award followed by two nearly automatic annual renewals. A five-year grant involves an initial application and award followed by four nearly automatic annual renewals. Many of the grants fund specific projects and usually involve a principal investigator and several additional researchers and technicians. Others are large program-project grants employing scores of researchers and supporting staff members, often across multiple disciplines. The University of California has been awarded NIH research grants, program-project grants and other forms of grants to conduct research and undertake graduate educational programs involving hESCs. The University of California, however, has not sought from NIH and has not been

awarded by NIH any NIH Small Business Innovation Research grant with respect to any stem cell research.

6. Between the Los Angeles campus (*i.e.*, UCLA) and the San Diego campus (*i.e.*, UCSD) alone, UC has been awarded thirty (30) NIH grants for research involving hESC from thirteen (13) institutes and centers within NIH, totaling \$16 million per annum. Additional grant applications are pending. Pending applications and those up for renewal that propose using hESC as a research tool have been adversely affected by the preliminary injunction.

7. UC, through its UCLA campus, for example, currently is the grantee of sixteen NIH grants with annual awarded budgets of approximately \$8.7 million that use or involve hESC from nine different institutes as follows: (1) National Cancer Institute; (2) National Institute of Allergy and Infectious Diseases; (3) National Eye Institute; (4) Eunice Kennedy Shriver National Institute of Child Health and Human Development; (5) National Heart, Lung, and Blood Institute; (6) National Institute of Mental Health; (7) National Institute of Arthritis and Musculoskeletal and Skin Diseases; (8) National Institute of General Medical Sciences; and (9) National Institute of Neurological Disorders and Stroke.

Collectively, these grants fund the work of 46.5 researchers and staff. This number does not reflect the far greater number of individuals engaged in some manner in hESC research, but instead refers to the number of full-time equivalent (“FTE”)

salaries supported by the NIH grants. Moreover, the NIH grants indirectly support many more individuals across the campus engaged in grant administration and other support activities.

8. UC, through its San Diego campus, currently is the grantee of fourteen NIH grants with annual awarded budgets of approximately \$7 million that use or involve hESC from five different institutes as follows: (1) National Heart, Lung, and Blood Institute; (2) National Institute of Biomedical Imaging and Bioengineering; (3) Office of the Director; (4) National Institute of Diabetes and Digestive and Kidney Diseases; and (5) National Institute on Alcohol Abuse and Alcoholism. Collectively, these grants fund the work of 17.17 researchers and staff. As at UCLA, many more individuals are engaged in research activities in connection with the funded projects, and these grants indirectly fund other support activities.

9. The research budgets, including hiring decisions, at UC's ten campuses are based in significant measure on approved grant funding taking into account the term of each grant. The University reasonably relies on projected grant funding from its awarded grants when making decisions concerning construction, allocation of space, acquisition of equipment, hiring and promoting faculty and researchers, and admitting graduate students. It has done so here with respect to

the funding from awarded NIH grants involving hESC that would be effectively “de-funded” by the preliminary injunction.

10. The impact of the preliminary injunction, even though in effect only briefly, was significant. If reinstated, the preliminary injunction will have profound adverse consequences for the University System, its faculty, staff, and students. The preliminary injunction upset settled expectations and undermined budgetary decisions. If the current stay is lifted, non-faculty scientists hired to conduct research under an awarded NIH grant subject to the preliminary injunction will be in jeopardy of losing of their positions, as will technicians and staff hired to support these projects.

11. The effect of the preliminary injunction transcends those who are conducting NIH funded hESC-related research full-time. Without the stay, individuals whose time is split between hESC research projects and non-hESC research projects will be jeopardy because their salaries, benefits, and overhead are based on the assumption that each will conduct funded research full-time. If a non-tenure tracked researcher’s or a staff member’s funded time is cut by forty-percent, for example, it may not be possible to retain that individual.

12. The budgetary and personnel impact described above is based on the terms and amounts of awarded grants most directly affected by the preliminary injunction and does not factor into account the many more grant applications that have been

submitted and would have been evaluated but for the preliminary injunction. The University of California Davis alone had at least eight affected applications pending at the time of the preliminary injunction.

13. For example, I have been informed that at least one pending hESC grant application was removed from the relevant study section prior to review as a direct result of the preliminary injunction and that it will not be reviewed until at least November, assuming the injunction is stayed pending appeal. Thus, the preliminary injunction precluded altogether consideration of that UC grant application during the most recent funding cycle.

14. The preliminary injunction, if reinstated, also will have profound adverse consequences for the University's various training programs. For instance, at UCSF alone, eighty-eight students receive training grant stipends from NIH through the agency's Medical Scientist Training Program ("MSTP"). In the typical M.D.-Ph.D. training grant, the applicant institution lists each of the faculty mentors who would be involved in the training program. Some of our mentors undertake privately funded or State-funded research involving hESC, but unrelated to the mentorships. We have been advised that it is NIH's position that if an awarded training grant lists any mentor who undertakes any hESC research, then, pursuant to the injunction, that individual would not be eligible to act as a mentor under the training grant and since it is not possible to ascertain whether the

reviewers based their decision to award the grant on the presence of that mentor, the entire grant will no longer be funded. Such an interpretation coupled with a preliminary injunction would soon eliminate training stipends that are essential to some programs, and thereby undermine the University's efforts to train many promising physician-researchers.

15. The preliminary injunction also imperils the independence and integrity of the peer review process by which federal grants are awarded. As we understand it, the plaintiffs believe that their proposed research may not be capable of competing favorably with other research proposals and therefore, they have asked the courts to help improve their chances of obtaining federal research funding by reducing the number of scientists eligible to compete against them. Their view of the peer review process and the way in which grants are awarded is incorrect. We understand that NIH has no separate line item in its budget for hESC research. Even if UC researchers were precluded from using hESC as a tool in their projects, there is no change in competition; the researchers, through the University, will continue to pursue grants using the remaining tools available to them. The injunction, in other words, does not increase the likelihood that plaintiffs' applications will be awarded. Science funding is based on a meritocracy where proposals which are deemed to be the best and which hold out the most promise of advancing our knowledge are the most likely to receive funding. The peer review

system promotes this independent, knowledge-based decision-making. Court intervention to prop up otherwise wanting proposals is inconsistent with the peer review system, the independence of the scientific enterprise, and the meritocracy that it seeks to promote.

16. The University acted as quickly as possible following the August 23, 2010 order to evaluate the impact of the preliminary injunction on patients, students, employees, and faculty at the ten campuses and to evaluate whether our interests could be appropriately represented by any of the defendants. Given our position as a grantee and need for the court to consider the impact of equitable relief on the extramural community, we decided that intervention was essential to protect our interests and inform the court. It is on the basis of that evaluation, which is summarized above, that the University decided on September 15, 2010, to seek to intervene on appeal and to bring to the attention of the Court the impact of the preliminary injunction on the largest NIH grantee in the Nation.

I declare under penalty of perjury that the foregoing is true and correct.



Steven V. W. Beckwith, Ph.D.  
September 20, 2010

UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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JAMES L. SHERLEY, DR., <i>et al</i> ,		)	
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Appellees,		)	
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v.		)	No. 10-5287
		)	
KATHLEEN SEBELIUS, in her official		)	
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		)	
		)	
Appellants.		)	
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**DECLARATION OF ARNOLD R. KRIEGSTEIN, M.D., PH.D. IN  
SUPPORT OF THE REGENTS' MOTION TO INTERVENE ON APPEAL**

I, Arnold R. Kriegstein, M.D., Ph.D, declare as follows:

1. I am the Director of the Eli and Edythe Broad Center of Regeneration Medicine and Stem Cell Research, the John G. Bowes Distinguished Professor in Stem Cell and Tissue Biology and a Professor of Neurology at the University of California, San Francisco ("UCSF"). I have applied for as principal investigator and been awarded through my grantee institutions twenty-five research and program-project grants from the National Institutes of Health an more from other funding sources. I have also served as an ad hoc reviewer for the National Institute of Neurological Disorders and Stroke ("NINDS") at the National Institutes of Health ("NIH") between 1997 and 2009.

2. My research at UCSF focuses on neurodevelopmental disorders including birth defects, schizophrenia, epilepsy, and learning disabilities. Twelve to fifteen scientists and three technicians or staff members are involved in research at my laboratory at UCSF. I am the principal investigator on two ongoing research grants funded by NINDS. I also am the co-principal investigator on an ongoing program-project grant funded by NINDS.

3. Our research uses electrophysiological, optical recording, and molecular biological approaches to study intercellular signaling and proliferation in the embryonic cerebral cortex during fetal stages of development. We use both adult stem cells as well as human embryonic stem cells (“hESC”). hESC serve as an important standard against which we measure the fidelity of other types of stem cells including adult and induced pluripotent stem cells. We recently demonstrated that radial glial cells, present only in the embryonic and fetal developing brain that were long thought to simply guide embryonic nerve cells during migration, are neuronal stem cells in the developing brain. This identification has helped to shift attention to the role of glial cells in the adult brain, and may lead to innovative therapies aimed at treating diseases of the brain and brain injuries. We also recently demonstrated that brain grafts consisting of a specific type of nerve cell, called an inhibitory interneuron, could be used to treat Parkinson’s disease. We are

now working to make these nerve cells from embryonic or induced pluripotent stem cells.

4. Many of my colleagues and I have been adversely affected by the preliminary injunction that halted NIH's processes for funding ongoing grants and for reviewing, scoring, and approving grant applications. Although much of the work associated with hESC is funded through the State of California, the amount of federally funded research in the University of California ("UC") System is significant and the impact of the preliminary injunction is disproportionate to the amount of federal funds received for this research. In addition to its impact on scientists, technicians and staff who are hired on a full-time basis for federally funded research, the University also employs researchers who split their time between multiple studies, some involving hESC and some that do not. Any loss of funding for the federal hESC projects will result in a loss of hours for these employees. In this way, the preliminary injunction has an impact on dozens of researchers and students, affecting programs across the UC campuses and across departments including programs that do not perform any derivation work, but rather, acquire hESC lines from other institutions outside of California.

5. In addition, UCSF operates a Medical Scientist Training Program ("MSTP") which combines graduate and medical curricula and leads to both M.D. and Ph.D. degrees. It is designed to produce highly qualified physician-scientists who will

pursue outstanding careers in academic medicine and research. The MSTP is sponsored jointly by NIH, the UCSF School of Medicine, and the UCSF graduate programs. MSTP provides financial support to cover all medical and graduate tuition and fees, and NIH provides a yearly stipend of \$28,000 (for the 2010-11 academic year) for students to participate in research activities. Currently, approximately eighty-eight students receive NIH MSTP grant funds. Mentoring by UCSF faculty is a critical part of the program and mentors are included in the grant applications submitted to NIH.

6. As a result of the preliminary injunction, NIH has held the NIH MSTP Grant in abeyance and has indicated that it will not renew funding because the grant included faculty members who were serving as mentors or advisors who also were involved in hESC projects even though those projects are not funded through the MSTP Grant. Because the applications were reviewed and scored based on the presence of those faculty members, we understand that the scientists cannot be replaced in order to permit continued funding of the NIH MSTP stipends. The preliminary injunction therefore threatens not only the vitality but the viability of this important program. Students in the program will lose their stipends and the research they perform, which is not only an integral part of their education, but an important part of our research that will thus be halted. A similar threat is hanging

over other NIH supported training programs at UCSF, including the Neuroscience Training Program, the Developmental Biology Training Program, and others.

I declare under penalty of perjury that the foregoing is true and correct.

A handwritten signature in black ink, reading "Arnold R. Kriegstein". The signature is written in a cursive style with a horizontal line underneath.

Arnold R. Kriegstein, M.D., Ph.D.  
September 20, 2010