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.	No. 10-5287

DECLARATION OF STEVEN V.W. BECKWITH, PH.D.IN SUPPORT OF THE REGENTS' MOTION TO INTERVENE ON APPEAL

I, Steven V.W. Beckwith, Ph.D., declare as follows:

1. I am the Vice President for Research and Graduate Studies at the University of California and as such, set the general research policies for the ten campuses that comprise the University of California System. My office supports research and graduate education across the University of California System and at affiliated national laboratories.

2. The University of California is a public trust organized under the Constitution of the State of California and is governed by a Board of Regents. The

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

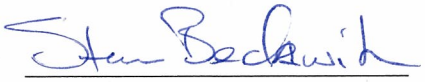
reviewers based their decision to award the grant on the presence of that mentor, the entire grant will no longer funded. Such an interpretation coupled with a preliminary injunction would soon eliminate training stipends that are essential to some programs, and thereby undermine the University's efforts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