WRITTEN TESTIMONY OF

Dr. Erik Lium

Assistant Vice Chancellor for Innovation, Technology & Alliances

University of California, San Francisco

BEFORE THE

Subcommittee on Research and Technology,

Committee on Science, Space and Technology

U.S. House of Representatives

HEARING ON

"*Improving Technology Transfer at Universities, Research Institutes and National Laboratories*"

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Mr. Chairman, Ranking Member Lipinski, and Members of the Subcommittee, my name is Erik Lium and I currently serve as the Assistant Vice Chancellor for Innovation, Technology & Alliances at the University of California, San Francisco (UCSF). I am here to testify on my own behalf. Thank you for the opportunity to appear before you today to discuss the very important issue of translating federally funded basic research into commercial applications for public benefit.

In my current role, I am responsible for the UCSF Office of Innovation, Technology & Alliances ("ITA") which serves to streamline the creation of public-private research partnerships, the transfer of UCSF technologies to the commercial marketplace and the education of budding entrepreneurs. I am a molecular biologist by training, and as a prior co-founder of a venture capital backed enterprise software company, an entrepreneur.

UCSF is widely regarded as one of the world's leading universities in the biological and health sciences, and as the birthplace of the biotechnology industry. UCSF's mission is to advance health worldwide through innovative health sciences education, discovery and patient care. Our graduate Schools of Medicine, Pharmacy, Nursing, and Dentistry are ranked among the very best schools nationwide, our Medical Center among the nation's premier hospitals for the 12th consecutive year, and our research enterprise received over $1 billion in research funding in 2012 of which $521 million was from the National Institutes of Health (NIH). UCSF's faculty

includes five Nobel Laureates, ten recipients of the Albert Lasker Award, four recipients of the Shaw Prize in Life Sciences and Medicine, four recipients of the National Medal of Science, 44 members of the National Academy of Sciences and 89 members of the Institute of Medicine.

My comments today will be focused on three issues:

- First, early-stage life science companies are struggling. They are in desperate need of funding to reach technological proof-of-concept ("PoC"), a critical value inflection point required in today's marketplace to attract private investment funding.
- Second, it is reasonable and appropriate for the Federal Government to play a role in funding PoC research given the prerequisite in today's marketplace to substantially de-risk early-stage discoveries in order to attract investment; and,
- Third, the proposed legislation to expand the use of STTR funds to support innovative approaches to technology transfer will increase commercialization of federally funded basic research. Notably, it will enable agencies to fund programs to de-risk early-stage discoveries at universities without the requirement for a commercial partner. The Act correctly requires data collection to facilitate the identification of best practices, though steps should be taken to ensure that such requirements are not an impediment to participation.

I will address these issues through my responses to the three questions the Committee has specifically posed for my testimony.

The first question I was asked to address today is, "What innovative practices does the University of California at San Francisco employ to develop federally funded research projects that have commercial opportunities?"

Federal funding is the lifeblood of basic research and enables our scientists to pursue potentially groundbreaking innovative research. The challenge is translating the fruits of this basic research into commercial applications for public benefit, a goal that is strongly supported by UCSF leadership. UCSF has established an innovation ecosystem to address this challenge, and I will describe a few noteworthy elements of this ecosystem in my testimony.

The ***UCSF Clinical & Translational Science Institute (CTSI)*** provides infrastructure, services and training to support clinical and translational research, and seeks to facilitate the rapid translation of research to improvements in patient and community health. Established in 2006, the CTSI was among the first of the now 60-member Clinical & Translational Science Awards consortium funded by the NIH. To advance early-stage discoveries, it established the Early Translational Research Program to connect researchers with industry executives, business leaders and funding resources. This innovative program provides pilot grants and tailored mentoring to advance early-stage discoveries.

The ***UCSF Office of Innovation, Technology & Alliances ("ITA")*** was created in 2011 to streamline the development of collaborative public-private research partnerships and facilitate the commercialization of UCSF discoveries. The ITA integrates business development, industry contracting, alliance management, technology transfer and entrepreneurship training, optimizing the support of UCSF researchers and discoveries, and catalyzing the connections, relationships and educational resources required to advance discoveries. UCSF has over 1,600 active inventions and 679 active patents. Thirteen UCSF drug candidates and medical devices are in clinical development, 97 commercial products were derived from basic research performed at UCSF.

UCSF has hundreds of active research partnerships with industry that often serve to advance basic federally funded research. A few noteworthy examples include the UCSF-Pfizer Center for Therapeutic Innovation, which is developing novel small and large molecule drugs, a partnership with Sanofi U.S. to support and extend highly innovative breakthrough biomedical research and the UCSF-Onyx Pharmaceuticals Oncology Innovation Alliance which seeks to develop novel treatments for cancer.

The ***Entrepreneurship Center at UCSF***, a division of the Office of Innovation, Technology & Alliances, offers pragmatic courses on essential aspects of commercialization, educational programs featuring top-tier members of the entrepreneurial ecosystem, a network of investors, entrepreneurs and service providers and experienced industry mentors to coach fledgling entrepreneurs in the creation of new ventures. The Center, headed by an experienced industry veteran, Stephanie Marrus, serves as an essential bridge between the UCSF researchers and clinicians and the Silicon Valley/Bay Area entrepreneurial ecosystem. Our flagship

entrepreneurship course, now in its 13th year, employs team-based experiential learning to educate new entrepreneurs on the essential requirements for a commercially viable life science venture culminating in a presentation of their business plans to Silicon Valley venture capitalists. This course can be transformative, opening the eyes of scientists and inventors to new career paths. I would like to share two noteworthy stories form this course.

The first is about a doctoral candidate bioengineer at UCSF performing groundbreaking research on brain mapping, an essential procedure performed at the beginning of brain surgeries to map the functional areas of a patient's brain thereby enabling a surgeon to plan their path to a successful surgery while minimizing impact on healthy functional tissue. Patients are conscious during the mapping process, which traditionally relies on the surgeon manually stimulating areas of the patient's brain while requesting feedback on the effect. Brain mapping using this technique is a long and arduous process, often requiring several hours to be completed. In collaboration with a UCSF neuroscientist, this doctoral candidate has developed a mapping approach using novel software and largely existing FDA approved devices that substantially reduces the time required for the procedure, is less painful, lowers the risk of infection, and is more accurate.

From a nascent idea on the first day of class to a mature business concept at the final competition, this researcher attracted a team, explored all aspects of creating a venture, developed a commercialization plan, presented to investor judges and won $15,000 in funding. She is now following the entrepreneurship path with hopes of commercializing a basic research discovery, and is preparing an application for a SBIR grant.

The second story is about a clinical urology resident who conceptualized a novel approach to address geriatric urinary incontinence. The management of incontinence represents a substantial economic burden to the U.S. health care system with annual costs estimated at $20 billion. In addition, urinary incontinence in older adults is humiliating, disabling, and causes stress and depression. Research on urinary incontinence demonstrates that an effective management strategy is frequent clearance. The physician designed a device to detect the volume of urine in an individual's bladder in real-time, and notify the individual and nursing staff when the volume is approaching a level that may cause spontaneous clearance. The urologist's venture, which

seeks to commercialize an easy-to-wear sensor integrated with an intuitive mobile application, is initially seeking to serve patients within nursing homes.

An exciting addition to the UCSF Entrepreneurship Center is the NSF's Innovation Corps (I-Corps) program, an experiential educational program designed to increase the commercialization of NSF funded research. UCSF, UC Berkeley and Stanford University have partnered to create the Bay Area Node of the NSF I-Corps, and have received an NSF grant to support this highly innovative program. UCSF is leading the development of life sciences/healthcare-specific curriculum within the I-Corps framework in preparation for launching a life Sciences/healthcare-specific course in late 2013.

In its first two years of existence, the I-Corps has facilitated the creation of numerous startups that are working to commercialize discoveries made through federally funded research. Based on analyses to date, ventures that have participated in this program receive SBIR funding at a rate 3-times higher than those that have not.

The final element of the UCSF innovation ecosystem highlighted in this testimony is the ***California Institute for Qualitative Biosciences (QB3)***, a three-UC campus organization that includes UCSF. QB3 maintains crucial incubator space for biotech startups, provides support for incorporating new companies, training on SBIR/STTR grant writing and has a small seed-stage fund to help entrepreneurs emerging from the University of California.

The second question I was asked to address today is, "Please provide your thoughts on whether you think it would be beneficial to dedicate a portion of Small Business Technology Transfer (STTR) program funding to proof-of-concept and other technology transfer programs at universities, research institutions and national laboratories."

It is more than beneficial; it is essential. UCSF innovations, which predominantly fall within the drug, medical device, diagnostic and research tool markets, require substantial funding in the form of risk capital for commercialization – funding that has rapidly disappeared as venture capitalists have become increasingly risk averse since 2008.

Early-stage life science ventures desperately need funding to reach technological proof-of-concept ("PoC"), a prerequisite to attract private investment. The funding environment has

changed dramatically in recent years. Small, innovative drug companies were once able to secure tens of millions of dollars of funding through venture capitalists or public markets to advance early-stage discoveries to human clinical trials, at which point the enterprise became an attractive partner or target for acquisition. In recent years, venture financing for life science companies has dropped sharply as private capital has shifted to lower risk markets that deliver faster returns. Today, few investors are willing to risk investing in early-stage life science ventures. Why invest hundreds of millions of dollars in a business that often will not provide returns for a decade, if ever, when the funds can be invested in a smartphone application or social media company that may attain that value in three to five years?

Initial financings of U.S. - based biotechs are down an alarming 30% from their peak in 2007. Most funding is directed to existing companies with products in late-stage development, not to startups. According to Fenwick & West, only $2.5 billion, or 12.5% of funds raised by venture capital firms in 2012, is likely to be deployed in the life sciences, which stands in stark contrast with the $7.8 billion that was invested in 2008. The dearth of risk capital is discouraging even seasoned entrepreneurs from attempting to develop innovative medicines. In our classes at UCSF, we see a significant reduction in proposed therapeutic ventures and an increase in ventures, such as digital health, requiring limited time, limited funding and that offer substantially less regulatory risk.

The implication for the U.S. is sobering: there will be few truly innovative medicines and our leadership in innovation is at risk. Medical devices and diagnostics are similarly challenged: little funding is available. Thanks to a difficult U.S. regulatory environment, reimbursement issues and lack of risk capital, many medical technology ventures are moving offshore. Consider this story from an experienced device entrepreneur. When looking for investors to fund trials for an implantable heart device, his search took him far from Silicon Valley and Boston to Asia, courting investors in Singapore, Hong Kong, Thailand, and Malaysia. “Companies like ours with very promising technology that in years past would have been funded very richly, are struggling to find money to even stay in business.” As he explained, his last company raised $50MM in 2007 for a cardiac device and “it never would have even crossed my mind to look to Asia.” Since then, funding from U.S. venture capital firms for medical devices has dropped 35% to approximately $2.4 billion last year, according to the National Venture Capital Association.

We need a new model to attract private investment capital into biotechnology, medical devices and diagnostics to once again fuel the commercialization of federally funded basic research and to preserve the U.S.'s dominance in these fields.

The gap between the development of intriguing but unproven innovations, and the investment to commercialize those innovations, is characterized as "the Valley of Death." The U.S. lags behind other nations in not having a national funding program to cross this "Valley," placing us at a disadvantage.

Recognizing the need to reduce technological, regulatory and market risks for early-stage life science and healthcare ventures, UCSF is leading the development of a life sciences/healthcare-specific curriculum within the framework of the NSF Innovation Corps program, a program supported by this Committee. This program aims to empower entrepreneurial teams to effectively identify the most promising ventures by thoroughly examining key elements of each, and adapting or terminating the venture accordingly, thereby reducing the overall failure rate, improving the utilization of capital and ultimately increasing investment in these markets.

UCSF is initially offering this life sciences/healthcare-specific curriculum in October 2013 for up 32 teams, and thereafter hopes to expand this program.

The third question I was asked to address today is, "Please provide comments and recommendations on the discussion draft of the "Innovative Approaches to Technology Transfer Act of 2013".

We enthusiastically support the proposed legislation that establishes STTR grant programs to support innovative approaches to technology transfer that increase the commercialization of discoveries made through federally funded basic research. In my role as Assistant Vice Chancellor, I routinely interact with bright and enthusiastic scientists and clinicians with early-stage discoveries with commercial potential who are struggling to secure essential PoC funding. For example, a successful senior investigator at UCSF has invented an implantable artificial kidney device in collaboration with scientists at the Cleveland Clinic, Vanderbilt University and University of Michigan. This device has a high probability of dramatically improving the health and well being of individuals suffering from kidney failure, freeing patients from numerous miserable dialysis sessions per week, extending lives and potentially dramatically reducing the

estimated $41.5 billion spent on dialysis per year in the US. Despite receiving numerous awards, substantial interest from potential corporate partners and being selected by the FDA as one of just three projects for a pilot program that will fast track the development of breakthrough medical devices, our entrepreneur has been unable to raise funds to support commercial development.

Grant programs created under the Act could address this crucial need for PoC funding. Such programs should not include a requirement for company participation, thereby removing the existing incentive to prematurely create startup companies for the sole purpose of qualifying for SBIR/STTR grants, and allowing funds to be used exclusively for reaching technical PoC. New requirements, such as matching industry funds, should also not be included in order to avoid potentially costly delays, as companies often require PoC as a prerequisite for investment.

We would welcome expansion of the NSF Innovation Corps program to additional agencies and the addition of phased PoC funding. This expansion would establish a means to validate and advance the development of a broader array of discoveries while providing entrepreneurs crucial training and PoC funding.

We enthusiastically support the proposed legislation, including the requirements for the collection and analysis of data on the performance of funded programs to identify those that may warrant expansion; however, we strongly caution against including excessively burdensome and costly administrative requirements that may inadvertently reduce the effectiveness of the program by reducing participation.

I hope that my testimony has provided background, context and recommendations that can help this Committee in its laudable goal of improving technology transfer and the innovation eco-system in the United States.

Thank you Mr. Chairman, Ranking Member Lipinksi and Members of this Subcommittee for the opportunity to discuss this important issue and I look forward to answering any questions you may have.

WITNESS BIOGRAPHY

ERIK LIUM, PH.D.

Dr. Erik Lium serves as the Assistant Vice Chancellor for Innovation, Technology & Alliances at the University of California, San Francisco (UCSF). He has held prior positions at UCSF of Assistant Vice Chancellor of Research, Director of the Industry Contracts Division and Interim Director of the Contracts & Grants Division of the Office of Sponsored Research, and Director of Business Development for the Diabetes Center & Immune Tolerance Network. Dr. Lium was President of LabVelocity Inc., an information services company focused on accelerating life science R&D processes prior to its acquisition in 2004. He served as a postdoctoral research scientist in the laboratory of Nobel Laureate J. Michael Bishop, MD at UCSF, earned a Ph.D. from the Integrated Program in Cellular, Molecular and Biophysical Studies at Columbia University in the laboratory of Dr. Saul J. Silverstein. Dr. Lium holds a B.S. in Biology from Gonzaga University.