

**Testimony by Clinton T. Rubin, PhD,**

**Subcommittees on Contracting & Workforce and Research & Technology**

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Good morning, and thank you to Chairman Knight and Chairwoman Comstock, Ranking Members Murphy and Lipinski, and members of the Subcommittees on Contracting and Workforce, and Research & Technology, for inviting me to testify today regarding the impact that the NIH Research, Evaluation and Commercialization Hub (REACH) program has had to catalyze technology development, SBIR/STTR initiatives and company formation from within our University communities. It is also an honor to join colleagues from the Small Business community, who work so hard to build companies around innovation and technology, and who harness the SBIR programs so effectively.

My name is Clinton Rubin, and I am a SUNY Distinguished Professor & Chairman of the Department of Biomedical Engineering at Stony Brook University in New York. While I am, by most any measure, a dyed-in-the-wool academic whose research is targeted towards the treatment of osteoporosis, obesity and diabetes, I have devoted a significant portion of my professional career to fostering the translation of academic-based, biomedical innovation into the commercial sector where it can ultimately improve human health.

I have personally founded three biomedical-centric companies (Juvent, Exogen, Marodyne), one of which has gone public, and have experienced firsthand the challenges and frustrations of bringing academic-based innovation into the commercial sector; securing intellectual property and financing, attracting experienced management, and navigating regulatory pathways. While the SBIR/STTR programs are powerful programs designed to catalyze, augment and accelerate the growth of small companies and add value to the

technologies on which they are built, it is also critical to recognize that there is a huge, untapped reservoir of discovery based engineering and science within academic centers that could become a next generation therapeutic, diagnostic or medical device, but instead languishes in university labs because it lacks the “proof-of-concept” necessary to attract the interest of the commercial sector. I am here to discuss the NIH-REACH proof of concept centers as one such means of helping to drive federally-funded basic science into the commercial sector, accelerate the path to new treatments for disease, create high-value jobs, and foster bio-based company formation. Translating bio-based discoveries from the academic benchtop to the bedside to improve health must embrace the commercial sector, a goal which must attract the attention of the entire academic community. REACH has helped enormously to achieve that goal.

Please note, I also serve as the Director of the Long Island Bioscience Hub, one of the three, NIH-designated Research Evaluation and Commercialization Hubs (REACH), established in accordance with Section 5127 of the 2011 SBIR/STTR Reauthorization Act (P.L. 112-81). The Long Island Bioscience Hub (LIBH) represents a regional partnership between Stony Brook University, Brookhaven National Laboratory, Cold Spring Harbor Laboratory, and the Feinstein Institute at Northwell Health Systems. Our REACH hub, like the ones at the University of Minnesota and the University of Louisville, is devoted to translating biomedical discoveries made at these institutions into new therapies, diagnostics, medical devices and research tools, and building upon these discoveries as the foundation for new company formation.

While the REACH program is only two-years in existence, it has already had major impacts at our institutions, fostering new intellectual property, increasing credibility with the investor community, promoting a shift in the academic culture, attracting new licensing opportunities, and most importantly, catalyzing the formation of new companies – some of which have

successfully secured SBIR funding. Please note: REACH is a program that does not compete w/ small business, nor does it dilute a basic science mission of the university, but instead fuels the growth of the small business community around university centers, and drives science towards successful new treatments for disease. REACH is synergy, and REACH is a bridge.

We were fortunate to receive the NIH designation in large part due to our thirty plus-year history as a New York State Center for Advanced Technology in Medical Biotechnology. The “Center for Biotechnology,” as we are commonly referred to, is a university-based economic development organization that capitalizes on the innovation capacity and infrastructure of NY State’s research universities to drive economic growth. Based at Stony Brook University, the Center serves as the lead organization for the Long Island Bioscience Hub (NIH-REACH) mentioned above, providing a platform for expansion of the critical infrastructure necessary to develop university discoveries into potential commercial products. Over the course of the Center’s history we have contributed to the development of dozens of commercial products and start-up companies, contributing more than \$80M annually to the New York State economy. Not only are we driving the formation of companies past the starting line, we proactively guide these companies forward, through mentorship programs, investor partnering, follow-on funding, and access to university facilities and scientists who understand the bioscience industry.

In November of 2016, we were very fortunate to also receive an i6 Challenge award from the Economic Development Administration to provide early-stage companies and faculty with in-depth training to compete successfully for SBIR/STTR funding. A major objective of the award is to develop efficient mechanisms that will help faculty and early-stage management utilize SBIR/STTR funding to foster company formation and accelerate the development of academic innovations into products that providers can use in clinical practice.

Team mentorship of new entrepreneurs is also a key component of the strategy. We believe that programs such as REACH not only catalyze company formation, but create an innovative climate on campuses to drive entrepreneurship, creating the very ecosystem that will nurture the companies that vie for SBIR-type support... it is the beginning of growth, and the definition of sustainability of the tech sector. Research-intensive universities are supersaturated with promising technology, and just like rock-candy, placing a string in that solution... providing a structure such as REACH, catalyzes new company formation, framed around cutting edge technology. It is true that universities are powerful economic engines for their communities, both locally and globally. But more effectively rooting the research and the technology into our communities, and harnessing the potential of the university for the creation of therapeutics and diagnostics, is certain to make our world a better, healthier place.

I am hopeful that my experience as an academician, entrepreneur, and director of academic-based technology development initiatives, may shed some light on the opportunities and challenges that face your committees, in areas related to the SBIR/STTR program in general, and relative to the NIH REACH program in particular. REACH fuels technology discovery, development and translation into the commercial sector, while the SBIR program enables these technologies and companies to thrive.

### **Universities as Economic Engines**

Major advances at the interface of medicine, biology, engineering, and the computational and physical sciences have positioned the 21<sup>st</sup> century to witness profound technological advances destined to vastly improve human healthcare.<sup>1</sup> Smart drugs that target specific organs and treat specific diseases.<sup>2</sup> Vaccines and vaccine delivery to reduce the spread of debilitating illnesses. Bio-interactive materials to accelerate the regeneration and healing of tissues.<sup>3</sup> Patient-

specific designer drugs with the potential to recognize an explicit genomic profile, and new medical devices which will permit early recognition of disease pathogenesis, improving diagnosis and treatment of crippling conditions. Such advances in biomedical science and engineering have far-reaching implications for our academic research enterprise, the characteristics of our industrial sector and its relationship to academia, and on human healthcare through the advent of translational medicine.

The National Institutes of Health (NIH) is the key driver of biomedical innovation. With an annual budget of more than \$33B,<sup>4</sup> the federal government, through NIH (and not counting \$B's of R&D investment by other federal agencies such as NASA, DOE, DOD, NSF, etc.) provides the scientific infrastructure of basic science and technology development for the future of biomedicine. Research universities within the United States have since played a critical role in generating the discoveries that have led to commercially-available technology with large societal impact. Drugs including ReoPro<sup>®</sup> (Stony Brook University) to prevent heart attacks, Remicade<sup>®</sup> (NYU) for the treatment of autoimmune diseases, Gleevec (Oregon Health & Science University), for the treatment of blood cancer, Enbrel for the treatment of rheumatoid arthritis,<sup>6</sup> and devices including the Pacemaker (University of Minnesota) to regulate heart rhythms, and the MRI (Stony Brook University) and CAT Scan (Georgetown University) for medical imaging,<sup>7</sup> all have their roots in academia, and all have transformed healthcare. But how to augment this translation of science into medicine?

According to the [AUTM Licensing Survey: FY 2015](#), 879 new products were commercialized and 1,012 new companies launched by universities in 2015 (up 11% from 2014). Seventy-two percent of these new businesses remain in the home state of the institution from which they licensed the technology, offering a compelling economic development justification for supporting

commercialization activities. Yet university technology transfer offices, and university-based proof-of-concept centers like our own Center for Biotechnology, will acknowledge that these outcomes *represent but a small fraction of the innovation taking place at our nation's research universities*. Entrepreneurial faculty have the motivation and the know-how to protect their discoveries, but unfortunately they represent only a very small percent of the total faculty on campus. With only a small cohort of faculty recognizing the path to commercialization, only a fraction of the research in universities will lead to new biomedical products. The majority of potentially valuable discoveries remain unprotected and out of sight in academic laboratories across the country, representing a vastly untapped, and tremendously under-realized opportunity to impact human health and the economy. Programs such as REACH help foster cultural shifts in faculty, spurring patent disclosures, attention to applied science, attraction of investors and capital, and a goal of translating their research into the commercial sector. Programs such as REACH directly drive technology development (e.g., patents), fuel economic growth (e.g., royalty returns and leveraged funding), and create jobs (i.e., company formation).

### **Barriers to Commercialization**

There are several issues that have impeded the ability to translate academic innovation into commercial opportunities that can improve human health and fuel economic growth. While many universities – including the LIBH partner institutions - benefit markedly from the income secured through the return of royalties, on closer inspection the great majority of these fees are derived from the licensing of an astoundingly few technologies. No mechanism currently exists to adequately bridge the gap between early stage discoveries common to research universities and the point in time when a commercial partner would reasonably be willing to license or invest in the next stages of technology development. As a result, the shelves of tech transfer offices

are stacked with high-risk, early-stage technologies that still lack proof-of-concept or any commercial context that would address the market, competitive landscape, regulatory pathway, or appropriate business models necessary to attract commercial interest. And remember, the intellectual property most typically comes from a select few faculty oriented towards that path, and is blind to the great majority of academics – and their science - who stand unaware of this opportunity. Programs such as REACH not only catalyze new companies, they shift awareness at Universities to recognize the importance of innovation and entrepreneurship to empower their science by translating it into the commercial sector.

In parallel with this academic frustration, the commercial sector, and in particular the pharmaceutical/biotech industry, is shifting its attention to the acquisition and development of later stage assets. The cost to bring a single drug to market is now estimated at \$2.6B and has more than doubled in 10 years,<sup>8</sup> The cost incorporates the failure rate of drugs that begin, but do not successfully complete, the clinical trial process, and the lengthy regulatory approval process required to move a drug through the clinical trial process. Ninety-percent of drugs fail in clinical trials, and seventy-five percent of drug costs are related to this failure. It is estimated that just one out of five thousand compounds that begins the preclinical development stage will actually reach market.<sup>9</sup> As new drugs become more expensive to produce, pharmaceutical research dollars and investment capital have shifted away from support for early-stage innovations to the acquisition and development of later-stage, blockbuster drugs that hold promise for significant market returns. The path of discovery to market is changing in the biomedical arena, and the pipeline for new drugs and devices is thinning. Pharmaceutical and biotech companies are looking to the academic centers for the ‘next big thing,’ but the early stage nature of most academic technologies discourages investment.

Compounding these challenges is a cultural divide between the academic and commercial sectors. The culture of research universities is driven by a focus on basic science that expands our fundamental understanding of the world. The primary objective is the pursuit of knowledge for the sake of knowledge. Furthermore, the faculty tenure and promotion process is based upon the ability to publish basic research findings in highly regarded scientific journals like *Science*, *Cell* and *Nature*, and on securing funding from federal, state and private agencies to further basic research programs. There is no doubt that the basic science that is pursued with passion in academic centers represents the basis for next generation technologies, but there must be a means to move it into the commercial world. REACH provides that path, and creates that engine.

Not only is there a cultural divide between the goals of the basic research enterprise and the commercial sector, there is also a fundamental lack of knowledge and a skepticism by many faculty about the commercialization process. It is a missed opportunity: not only to form a company around a platform technology, but to bring a promising therapeutic, diagnostic or medical device into the real world where it can positively impact public health.

### **Bridging the Gap Between Discovery & Commercialization**

The SBIR/STTR Reauthorization Act of 2011 recognized that this science represented a robust pool of next generation technologies, and authorized the NIH to provide funding, education, and resources to facilitate the conversion of NIH-funded basic science discoveries into commercial technology development opportunities and start-up companies. In March of 2015, the Long Island Bioscience Hub was awarded, following a highly competitive process, a designation as one of just three, Research, Evaluation, and Commercialization Hubs (REACH) in the country. The other two designated Hubs are at the University of Louisville and the University of Minnesota.

The REACH Hubs join the National Heart, Lung, Blood Institute's three, consortia-based, NIH Centers for Accelerated Innovation (NCAI), forming a network of proof-of-concept centers across the country focused on developing best practices for the translation of academic innovation into the commercial sector, and proactively establishing the means to bring basic biomedical science into the commercial realm. Collectively, the network represents the innovation capacity of more than thirty academic institutions, creating a critical mass of technologies capable of attracting the sustained interest of strategic partners and investors. While in existence for only a short time, the impact of these REACH Hubs and NCAI Centers is tangible and very real, with new intellectual property filings, new companies formed, some of which are now funded by the SBIR/STTR program. The impact is real, it is beneficial, and it is growing by the moment.

### **REACH & NCAI Impacts**

While it is early in the context of biomedical product development to be expecting commercial outcomes, early indications are that the Hubs and Centers are having the desired impacts. Since their inception, the Centers and Hubs have evaluated more than 850 early technologies to determine their commercial potential, emphasizing that faculty at these intuitions are 'listening'. From this process, 144 projects have been selected for funding, creating a pipeline of therapeutic, diagnostic, device, and research technologies at various stages of development. It is important to note that the funding is in no way a surrogate for a 'research grant.' These are technology development programs, with very specific milestones (e.g., disclosures for IP, securing of industry or SBIR/STTR funding, formation of company). And in this short time, thirty-two of these technology development projects have been completed. Each has benefited from the industry style project management approach of the REACH Hubs,

and from the commercial expertise each Hub brings to bear through its close partnerships with industry. This approach has resulted in 11 companies formed, 17 licenses and option agreements executed, and \$45 million in follow-on funding raised, including five SBIR/STTR awards being issued. The REACH and NCAI programs have caught the imagination of the university ecosystem, and a priority for the basic science brimming at our benchtops is becoming its translation into the commercial sector. THIS is a principal path by which our science can benefit health and society, can create companies and can create jobs. These are new programs, but their impact is very real.

Equally important, the Hubs and Centers are working side-by-side with faculty innovators and students, exposing them to commercialization strategies, applying milestone driven project management objectives to the technology development process, and engaging industry representatives and investors in all aspects of their activities. Not only has the expertise represented by the Hubs and NCAIs improved efficiency and the likelihood that these innovations will reach market, but it has taught the faculty inventors and their teams of students and postdocs how to stage-gate research toward development of an actual commercializable product. This hands on approach to helping faculty understand the commercialization process is augmented by the innovative NSF I-Corp curriculum, which has been tailored to support the biomedical technology development environment, and incorporated in the Hub's and Center's training programs. It is wonderful evidence of the power/synergy of federal agencies working together. Further, the Hubs and NCAIs thrive from the active collaboration with each other, from the partnership with the NIH and our federal partners including the US Patent and Trademark Office (USPTO), the Food & Drug Administration (FDA), the Centers for Medicare and

Medicaid Services (CMS), and Kaiser Permanente, and from our commercial partners in the investment community and established industry. This comprehensive hands-on, side-by-side teamwork approach to technology development has begun to fuel the entrepreneurial culture within our universities, eroding some of the resistance, and lack of understanding that has existed in the past, and has catalyzed a new era in bringing science to the marketplace, as a critical step in improving healthcare.

### **The Long Island Bioscience Hub (LIBH) Impacts**

To help highlight the impact the Hubs and Centers can have on their individual communities, I would like to focus a bit on our own experience at the Long Island Bioscience Hub. The Long Island Bioscience Hub represents a true government, university, industry partnership. The \$3 million investment made by the NIH in our Hub has allowed us to leverage an additional \$6M from our institutional partners (Stony Brook University, Brookhaven National Laboratory, Cold Spring Harbor Laboratory, and the Feinstein Institute for Medical Research), NY's Empire State Development, and the Research Foundation of SUNY. Our industry colleagues, including such companies as Pfizer, Lilly, Novartis, GE, and Canon, and the investment community represented by Orbimed, Canaan Ventures, and Pappas Ventures, to name just a few, are providing invaluable guidance at the technology evaluation and early development stages, and are actively encouraged by the outstanding quality of the projects they are reviewing and the faculty they are mentoring. These industry experts serve on our Strategic Advisory Board, our External Review Board, as advisors on individual projects, and as mentors to our start-up companies. Whether they become commercial development partners remains to be seen, but their contributions to the community and enrichment of the ecosystem have been substantial, and their curiosity has turned into very real interest in the next steps of the program.

In terms of technology development here at LIBH, in two years we have funded 33 projects across thirteen different departments and four institutions. These projects represent an investment of \$2.1 million, and have resulted in 8 patents filed, 2 license and 3 option agreements executed, with 3 additional option agreements in negotiation. Fifty-two SBIR/STTR applications have been submitted by small company clients of the Hub since its inception in March 2015, 5 of which are focused on the development of technologies that were actually funded by the Hub. Our i6 Challenge award, launched in December of 2016, has offered SBIR/STTR training to thirty companies, faculty members, and students, and resulted in 7 SBIR/STTR applications for the April 2017 deadline. We are also proud to say we launched our first company in January as a direct result of the i6 Challenge, and anticipate more will follow. A somewhat novel initiative of our Hub is our Bio-Entrepreneur-in-Residence (BEIR) initiative, which offers serial entrepreneurs milestone-based compensation to evaluate the intellectual property portfolios of our partner institutions for the sole purpose of identifying technology that will support company formation. With the LIBH's technology and business development staff serving as a virtual start up team, the BEIR is expected to launch a company and exit the program as CEO of a newco. So far 8 BEIRs have been retained and 11 companies started. These BEIRs are responsible for 11 of the 52 SBIR/STTR applications. A transformation of our region is unfolding, and it is driven by the translation of biomedical science into commercial ventures. REACH has seeded a transformation of how academic discovery reaches the bedside.

## **Conclusion**

In summary, we have only begun to realize the potential of the NIH REACH/Long Island Bioscience Hub to transform our region into a vibrant, self-sustaining ecosystem that will fuel bioentrepreneurship and economic growth, to form companies to benefit the community, and

to develop technologies to improve health. It is early but our outcomes are real, our momentum is palpable, and exciting signs of a cultural shift within our partner institutions is evident. We are becoming a cornerstone of our region's and our state's economic development strategy, we are harnessing the exceptional basic science of our institutions towards new diagnostics and therapeutics, and the productivity and impact of our collaborative relationship within our partner institutions continues to grow. It would have been hard to anticipate the far-reaching impact the REACH investment has had on the Long Island Bioscience Hub, and we look forward to continuing to implement our shared vision with our federal, state, institutional, and industry partners.

Thank you again for your attention, and for the opportunity to testify. The REACH program, targeted to catalyze innovation, is innovation at its core. It is spawning technologies, fueling job growth, and catalyzing company formation. I urge you to consider reauthorizing it, and expanding its scope. I would be happy to answer any questions you may have.

Respectfully submitted:



**Clinton T. Rubin, Ph.D.**

SUNY Distinguished Professor and Chair  
Department of Biomedical Engineering  
Director, Center for Biotechnology & Long Island Bioscience Hub  
Bioengineering Building, Room 217  
Stony Brook University  
Stony Brook, New York 11794-5281

Phone: 631-632-8375  
FAX: 631-632-8577  
e-mail: [clinton.rubin@stonybrook.edu](mailto:clinton.rubin@stonybrook.edu)  
BME: [www.bme.stonybrook.edu](http://www.bme.stonybrook.edu)  
CfB: [www.centerforbiotechnology.org](http://www.centerforbiotechnology.org)

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