Statement of

W. Mark Crowell

Before the

House Science, Space and Technology Committee

Subcommittee on Technology and Innovation

on

"The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs"

March 31, 2011

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**Testimony before the House Science, Space and Technology Committee's Subcommittee on Technology and Innovation on "The Role of Small Business in Innovation and Job Creation: The SBIR and STTR Programs" by**

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Chairman Quayle and Ranking Member Wu, thank you for the opportunity to testify before the House Science, Space and Technology Committee's Subcommittee on Technology and Innovation on the important topic of the SBIR and STTR programs – and their role in facilitating the formation and growth of small businesses which, in turn, create jobs and help grow the innovation economy.

My name is Mark Crowell, and I am the Executive Director and Associate Vice President for Innovation Partnerships and Commercialization at the University of Virginia. Founded by Thomas Jefferson in 1819, the University of Virginia is committed to its founder's ideal of developing leaders who are well-prepared to help shape the future of the nation through our initiatives in education, discovery and innovation advancement. In fiscal year 2010 the University received research awards totaling over $375.34 million from all sources (federal and state agencies, industry and private foundations). Of this amount, $276.47 million, or 73 percent, came from federal grants and contracts. I should also point out that the University of Virginia has been a partner on approximately 32 SBIR or STTR awards since the program's inception; over the last five years, we have partnered on about eighteen (18) awards for a total of more than $5.7 million. The program is becoming increasingly important to us in our efforts to translate innovations and discoveries developed at our institution into new businesses and products.

***The first question you asked me to address was to provide my views on the role of the university in the SBIR and STTR programs – and how it relates to technology transfer.*** I have been a director of technology transfer since 1987 – at Duke University, at North Carolina State University, at the University of North Carolina at Chapel Hill, at the Scripps Research Institute, and now at U.Va. In the decade prior to September 11, 2001, it seemed that if the university had a patent application on file, a preliminary business plan, and an interested faculty inventor, it was possible to land a reasonable Series A round of venture funding. Today, our friends in the venture capital industry remain important partners in our innovation and commercialization efforts, but anyone involved in innovation-based business development knows that shorter term return horizons, higher levels of risk-avoidance, and the need to invest at higher levels to accelerate innovations toward the market have moved most venture capitalists much further downstream than where most university deals tend to be. The availability of SBIR and STTR funding to help launch and grow companies, to facilitate important collaborations between such start-ups and universities, and to de-risk such start-up companies in preparation for the downstream venture capital investors is more important than ever in universities' efforts to launch, grow and sustain new ventures to commercialize their research discoveries and to connect their innovation pipeline in ways which help to create wealth and generate new jobs.

Perhaps a brief word about how universities benefit from SBIR and STTR funding would be helpful before proceeding. It is important to note that universities may not apply for SBIR or STTR funding; applicants must be companies. SBIR applicants may partner or subcontract less than one-third of the work to a university or other entity; STTR requires applicant companies to team with a not-for-profit research institution, and partnering and commercialization arrangements must be worked out in advance. Up to 60% of the work can be subcontracted, and

the principal investigator can be from the partnering research institution. Under both programs, and especially under STTR, universities are able to participate in a very meaningful and strategic way as the small company develops its research and development strategy for commercializing their technology.

I'd like to provide examples of how SBIR and STTR funding has helped to accelerate amazing growth, opportunity, and potential societal benefit around research developed at U.Va. Adenosine Therapeutics was founded in 1999 based on research emanating from U.Va.'s School of Medicine. The company's development pipeline included promising compounds for treating cancer, diabetes, CNS diseases, arthritis, and COPD. In less than nine years – rocket speed in the drug development world – Adenosine was acquired by a larger, public company, Clinical Data, Inc. The Company maintains a significant presence in Charlottesville even as this growth has occurred. Several of Adenosine's promising compounds are now in various stages of FDA testing and pre-market approval, including a potential best-in-class coronary vasodilator for cardiac stress testing. Adenosine was the recipient of numerous SBIR/STTR awards beginning in 2000 through 2007. We have no doubt that this funding significantly accelerated the development of the technologies, the growth of the company, the value to the company's investors, and the pace of introducing to the market potential life-saving and life-enhancing treatments.

Another example is Directed Vapor Technologies International, Inc. (DVTI). The company was formed in 2000 to capitalize on U.Va. patents associated with the creation of a new coating method, Directed Vapor Deposition (DVD), a novel physical vapor deposition tool for applying coatings to high performance materials (such as turbine engines, batteries, and liquid crystal displays) which allow them to be made faster, cheaper, and with less waste. This new

small business operates a 6,000 sq. ft. manufacturing facility in Albemarle County, VA, and maintains its relationship with the University and the region, often hiring interns, recent graduates and alumni. Development of the technologies behind DVTI was supported by grants from the National Science Foundation and the Department of Defense, including numerous SBIR/STTR awards.

For Adenosine, DVTI, and other high growth potential companies we are prepared to launch, support, and nurture, SBIR and STTR funding is extremely important to U.Va.'s efforts to help launch start-up companies. Like many universities across the country, the University of Virginia takes seriously its role in translating research results into products, companies, and jobs. The SBIR and STTR programs are key weapons in our arsenal. And as venture capital moves further down-field, and as companies large and small increasingly look to universities to be their source of innovation, it is more important than ever that we continue to have access to tools like SBIR and STTR funding. The President referred to the innovation imperative as our Sputnik moment; the Congress and our governors are focusing more and more on innovation-based economic development and job creation; and universities like U.Va. are ready to answer the call. But, we need help to bridge the valley of death, and SBIR and STTR funding has been and remains a critical resource for us.

***A second question you asked me to address focuses on my views of the current percentage of funding allocated to the SBIR and STTR programs; and whether venture-capital backed small companies should be eligible to participate in the programs.*** At the University of Virginia, we strongly support funding for the current SBIR and STTR programs. That being said, we also believe there is no compelling justification or need for increasing the percentage set aside amounts. A close review of success rates within the Phase 1 SBIR and STTR grants will reveal that the funding success rates for these grants is equal to, and in many cases – such as with NIH funding – higher than the success rates for other equally important grants for basic research. Any increase in the current SBIR and STTR set-aside would

come at the expense of other peer-reviewed basic and applied research – the seed corn for the innovation pipeline.

We are particularly concerned about shifting funding away from basic research and into the SBIR and STTR programs at a time when we are likely to see flat, if not declining funding for basic scientific research programs as the Congress looks to address the growing budget deficit. While basic research is an essential piece of the innovation process, the long-term horizon of most scientific research performed at universities is viewed by industry as too risky for significant private sector investment. This is why the continued federal support for basic scientific research is vital. As the Congressional Joint Economic Committee has stated, "Despite its value to society as a whole, basic research is underfunded by private firms precisely because it is performed with no specific commercial applications in mind."

We also support the eligibility of companies backed with significant venture capital investments to apply for funding under the SBIR and STTR programs. Companies which have secured substantial venture backing, by definition, will have undergone significant due diligence evaluation by investors and could be assumed to be on a more certain path to success. In today's financial climate, sharing risk and leveraging investments are a market reality for even the most promising start-up companies. Depriving promising companies an opportunity to compete for sources of co-investment or de-risking capital seems contrary to common sense and public policy, and we recommend removing any restrictions on the ability of such companies to apply. Further, companies which traditionally have the need for much greater amounts of funding – such as biopharmaceutical companies – are particularly disadvantaged if there is a disconnect between SBIR/STTR-backed companies and venture capital backed companies.

In fact, a publication by BIO, the Biotechnology Industry Association, states that almost 33% of companies that brought biotherapies to market between 1982 and 2005 had SBIR funding. In this era of intense focus on innovation-based economic development, it would be

wise to remove or revise this restriction so that more fast-growth, job-creating companies can benefit from SBIR and STTR funding.

***The final question I was asked to address concerns what recommendation I would make to improve the SBIR and STTR programs.*** We note that the Association of American Universities (AAU), which represents 61 leading U.S. research universities including U.Va., along with other organizations, has recommended more rigorous evaluations of the SBIR and STTR programs. We support this recommendation and therefore support the recommendation made by the National Research Council to increase the amount of the current set aside percentage by .03 to .05 percent of total program funding, with the increase to be directed for program assessment and management. This could be a critical component in continuing to improve and to fine tune the program for future growth and impact given the renewed emphasis on innovation and economic development in the national discussion.

Maximum per award funding amounts allowed under SBIR/STTR Phase I and Phase II awards should be increased as well to reflect renewed importance on this initiative, as well as to reflect the effects of inflation over the years. Phase I awards should be at least $150,000, and Phase II should be $1 million. We also would recommend incorporating sufficient flexibility in determining the precise award amounts so that SBIR/STTR program officers would have the freedom to increase each award up to 20% of the published cap when exceptional circumstances and high impact opportunity are deemed to be represented in a particular funding award.

Restrictions related to conflict of interest should be examined and, where feasible, flexibility should be added that make it easier for researchers with disclosed and manageable conflict of interest to participate in SBIR/STTR-backed start-up companies. Consistent with

efforts to encourage, recognize and reward faculty interest in research commercialization, onerous conflict of interest policies which discourage faculty from working with industry or developing innovative technologies should be examined. U.Va. and other universities have policies which focus on identifying and avoiding completely unacceptable and unmanageable conflicts, but which allow other conflicts to exist under appropriate management and monitoring committees and related mechanisms, especially where the potential benefit to society or to the institution from the proposed activity is deemed to be significant and consistent with other institutional priorities. Many institutions have in fact published policies and manuals for managing conflict of interest in the application and performance of SBIR and STTR projects; federal agencies administering SBIR and STTR initiatives should identify, incorporate and disseminate what they consider to be best practices in managing conflicts of interest in SBIR/STTR-based projects.

Finally, we would encourage that additional flexibility be built into the SBIR and STTR programs. In particular, I would like to recommend that the STTR program be modified in a way that would enable agencies to use a certain proportion of these funds to directly support additional proof-of-concept work at universities. Specifically, we would encourage the Committee to consider allowing agencies to use a portion of STTR funds to support new demonstration projects that would support proof-of-concept grants to universities and their faculty members. Europe has recently launched just such a program, and I think it is important that we here in the U.S. also find a way to fill this existing funding gap in the innovation pipeline relating to a lack of proof-of-concept funds. Using a proportion of the STTR set aside as the mechanism by which to address this matter seems totally appropriate, especially if there were a decision made to increase the percentage STTR set aside.

It is important to note that the flexibility we are seeking is aimed mainly at allowing agencies such as the NIH and NSF to devote a proportion of their STTR funds for even earlier stage proof-of-concept research or prototype development research, the type of research that is best conducted in the settings where discoveries and innovations perceived to have commercial application are first developed, as opposed to later stage product development or for more applied pre-commercial research. Such funding should be allocated only after rigorous evaluation by carefully assembled panels of local experts in translational and proof-of-concept research – this is key to scaling success to the national level. Among the criteria for awards under this initiative should be the demonstrated willingness and capability of a university in engaging project management boards comprised of industry, start-up, venture capital, technical, financial, and business/market experts. Additionally, successful applicants for this funding should be required to prove their willingness and agility in managing translational projects stressing market-relevant milestones, in conducting rigorous oversight and management of such projects, and in their willingness to withdraw funding from projects failing to reach essential milestones so that funding can be re-allocated to projects with more potential. U.Va. is one university which has recently demonstrated tremendous success and impact in undertaking such proof-of-concept research, with audited results indicating tremendous success in return on investment of such funds.

We attribute U.Va.'s success in proof-of-concept research to the now nationally well-known Coulter process, involving a very diverse review board, in-person final review sessions, milestone-driven projects, quarterly reporting that is simple yet effective in re-directing projects, the "will to kill" projects or re-direct funds if insurmountable obstacles occur, and excellent networking to the venture capital and private sector. The Coulter program projects have

generated a 5-1 overall return on investment (ROI) in new follow-on funding, and 42-1 ROI for the top 10 percent of portfolio projects. The key differentiators of this process as we employ it at U.Va. versus most prior proof-of-concept funding mechanisms is the in person diligence on the involved people and ideas, dedicated project manager, the diverse composition of the board, the urgency of quarterly reviews and re-direction of projects, and will to re-direct funds as results emerge.

In closing, I would like to make a brief point about the patent reform legislation recently passed by the Senate (S. 23) and currently under consideration in the House. While not directly related to SBIR and STTR funding, patent reform is also critically important to universities seeking to translate their inventions into new products, new businesses, and new jobs. We strongly support the recently passed S. 23, but we are concerned about two provisions of the draft bill under consideration by the House Judiciary Committee: (1) greatly expanded prior user rights and (2) a lowered threshold for the initiation of *inter partes* review. Just as we believe that the SBIR and STTR programs are essential programs for helping universities facilitate the launch and growth of small companies, we also strongly believe that a predictable patent system which minimizes uncertainty for companies and investors is critical. The expanded prior user rights in the proposed House legislation would disadvantage universities, even with its university carve-out, and would create unpredictable, uneven, and anti-innovation impacts. As just one example – university researchers often publish their research results before filing for patents. While the grace period in S. 23 and prior House patent reform bills would protect inventors from others patenting their inventions, expanded prior user rights would have the opposite effect – i.e., competitors might be incentivized to perfect a competing trade secret product that would then be immune from infringement of the eventual valid university patent. We therefore respectfully

urge this Subcommittee to work with the House Judiciary Committee on this currently pending patent reform legislation – and especially on the prior user rights provision it contains – as a way of continuing to improve federal policy promoting the successful launch and growth of innovation-based start-up companies.

I would like to thank the Subcommittee, and especially the Chair and the Ranking Member, for your support of the SBIR and STTR programs in these tough budgetary times. While we understand that funding is greatly constrained, I hope that you agree that innovation and commercialization serve the public good while promoting the creation of new products, new companies, and new jobs. SBIR and STTR funding have proven to be tremendously effective in fueling these activities, and we at the University of Virginia, and throughout the university community, are highly indebted for your continued support of these programs.

Thank you again for the invitation to testify.