PREPARED STATEMENT OF RHYS L. WILLIAMS, WITNESS BEFORE

THE U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE AND TRANSPORTATION,

SUBCOMMITTEE ON COMPETITIVENESS, INNOVATION, AND EXPORT PROMOTION,

To appear at a hearing addressing: "Innovation in America: Opportunities and Obstacles."

Scheduled for June 22, 2010

My name is Rhys Williams, and I would like to thank Sen. George LeMieux (R.–Florida) and the other Honorable Members of the U.S. Senate Subcommittee on Competitiveness, Innovation, and Export Promotion for this opportunity to share ideas from the frontlines of both entrepreneurship and early stage venture finance. I am a businessman from southeast Florida, and I wear two closely-related hats. My primary occupation is that of biotechnology entrepreneur; I am President of an early stage R&D firm (iTherapeutics) developing pharmaceutical drug candidates in partnership with academic researchers from the region's leading academic institutions. Additionally, my all-consuming avocation is serving as President of Florida's largest and only state-wide angel investor group (New World Angels), whose individual members invest collaboratively in what they hope will be the region's next entrepreneurial business success stories.

Members of the Subcommittee are very aware of the critical role that entrepreneurial management plays for our nation's competitiveness and the quantity and quality of innovative technologies and companies our economy produces. They may be somewhat less aware of the role of so-called "angel investors," who in most years either match or exceed the total level of early stage venture funding provided by institutional investors such as venture capital funds. The Center for Venture Research estimates that U.S. angel investors invested $19 billion in 55,000 deals (in about 35,000 small businesses) in 2008. Figures for 2009 (same source) comparing the activity of angel investors with that of institutional venture capital funds is highly instructive. In that year, ~259,500 individual angel investors invested $17.6 billion as part of 57,000 deals, 47% of which were in early stage ventures. By contrast in that same year, 794 institutional venture capital funds invested the same amount ($17.69 billion) as part of only 2,800 deals, only 9% of which were considered as investments in early stage companies.

Angel investors may invest individually, in small groups of two or three fellow investors, or as part of structured angel investor groups, whose number may range from 25 to 100. The metrics furnished by the Angel Capital Association regarding the profile of structured angel groups are instructive (see www.angelcapitalassociation.org). The prototypical angel group investor has been an angel investor for 9 years, has made an

average of 10 angel investments during that time, have themselves founded 2.7 new ventures during a 14.5 year tenure as an entrepreneur, is 57 years of age, has earned a masters degree, and directs fully 10% of his/her net worth to angel investments as an asset class. Such members are themselves either current or former successful entrepreneurs, and they also place investment bets on early stage companies run by other entrepreneurs, since they are more familiar with the challenges and the opportunities within the early stage ventures which comprise this asset class.

Early stage investment in high-growth, technology-based ventures is critical to commercializing technological innovations, to promoting our nation's competitiveness, and to robust job creation. For the 25 year period from 1980 to 2005, firms less than 5 years old accounted for all net job growth in the U.S. (Business Dynamics Statistics Briefing: "Jobs Created from Business Start-ups in the United States," Jan. 2009). A representative list of firms initially funded by angel investors include Google, PayPal, Starbucks, BestBuy, Amazon, Myspace.com, facebook, Costco.com, Yahoo!, Alcoa, and Cisco Systems.

From both perspectives (those of early-stage entrepreneurs, and the angel investors who back them), there are several areas where the federal government can take positive action to increase and accelerate both new business creation and private funding thereof. Equally important, there are areas where the federal government's best policy would be to take no action at all and let private matters remain private.

I. Regulatory Arena (Food and Drug Administration)

In recent years, the Food and Drug Administration has gone through extended periods without formal, resolute leadership. Political considerations in the wake of high-profile drug safety incidents have left regulators at all levels hamstrung, afraid to make any decision whatsoever during the long drawn-out process of regulatory review of new drug candidates, medical devices, and "combination" technologies. In such an environment, entrepreneurs lose years in their product development timelines and must spend additional capital in order to pursue preliminary, and ultimately final, approvals of the technologies they seek to bring to market. As a result, early stage investors increasingly altogether avoid making investments in areas with greatest technological promise, for the following reasons:

- with extended (and some would say indeterminate) development timelines, is it not possible to predict what the risk-adjusted return on investment (ROI) might be for a given technology
- investors believe that given the internal culture of the FDA, regulators are incented not to make approvals in any case (for fear they may get it wrong)
- with the "regulatory risk" so great, angel investors are incented to make investments in other equally promising sectors and technologies which are not required to pass through regulatory scrutiny at all (e.g. wireless, social media, entertainment software, business process services, etc.). The chilling effect of regulatory delay and/or indecision is palpable from an investor standpoint.

Recommendations:

- Fill critical vacancies at the FDA as quickly as possible
- Charge the FDA leadership to send clear, consistent policy signals as part of its regulatory pronouncements, so that both entrepreneurs and early stage investors will understand the FDA's expectations, requirements, preferences, timelines, etc., within specific biotechnological/medical sub-sectors; enhance the agency's communication function.
- Speed up regulatory review at all stages of the FDA application and regulatory process
- Perform a cost-benefit analysis to compare societal benefits resulting from a "calculated risk" policy, vs. a "zero-defect" policy as pertains to new drug reviews and approvals. Common wisdom within the biotechnology and pharmaceutical industries is that there is no such thing as a "safe drug"; there are drugs whose safety profiles offer substantial benefits to the overwhelming majority of patients who understand and personally accept the risks of a particular drug, undertaken with the guidance of their physicians.

II. U.S. Patent and Trademark Office (USPTO).

Similar to characteristic delays resulting from FDA regulatory review, the U.S. Patent and Trademark Office (USPTO) is significantly backlogged in its the patent application review and patent issuance processes. It is a common thread of discussion within the entrepreneurial community that the USPTO is facing up to a 3.5 year backlog in processing applications. This delay not only adds to a company's developmental timeline requirement, but increases the legal costs that must be born by early stage ventures. Entrepreneurs and the angel investors who back them require more timely information regarding whether a particular venture's technologies will receive patent protection; patents are often one of the few assets an early stage venture can acquire. Relatedly, an early stage venture is required to know whether it has "freedom to operate" within a particular intellectual property landscape (i.e., a general analysis that it is not likely violating other patent-holders' rights). Entrepreneurs are often told by investors to "call me when you have received your patent allowance" from the USPTO; however, the entrepreneur is not able to keep the doors open until that time. Given the significant gating factor that the patent application process represents, entrepreneurial managers must make decisions regarding allocation of time, capital, technology, and skilled labor, often under total uncertainty. To the extent the timeframe of this uncertainty can be minimized, from a patent perspective, the more efficient and efficacious the venture creation economy will be.

Finally, U.S. ventures often perceive little value in filing patents in strategic foreign jurisdictions, since there is little guaranty that local enforcement mechanisms are available or effective. Consequently, entrepreneurs often forego pursuing patent filings in foreign jurisdictions with poor or questionable enforcement mechanisms. Intellectual property is thereby abandoned for purposes of commercialization within that foreign territory.

Recommendations:
- Consider implementing a USPTO policy of "expedited review" for those technologies in strategic sectors of the U.S. and international economies (e.g., biotechnologies, wireless technologies, clean technologies, renewable energy, etc.)

- Significantly expedite the review process and approval of patent issuances, whether this might require re-allocating existing resources or increasing staff levels to handle workload, or outsourcing backlogged workflows to private vendors at key thresholds.
- Continue to push for reciprocity for and enforcement of intellectual property rights within foreign jurisdictions
- Study potential changes to the U.S. patent regime, whereby U.S. patent rights might begin from the time of award, not from the time of filing or disclosure. This would "toll" the patent application period and allow companies to exploit the full potential 20 year life of a patent. It would also increase the economic value of the patent for the firm and from the perspective of early stage investors.

III. Federal Tax Policy.

The 15 percent capital gains rate has been cited as one of the most important reasons for the increase in angel investment levels in the last six years. Any significant increase in capital gains rates will significantly curtail the number of investments made in this high-risk asset class. At a time when all other economic indicators point to less available capital for small business at the same time that the sheer number of potential investors has plummeted with the economic downturn, it would be counterproductive to increase capital gains taxes for individual investors who embrace great financial risk to directly support innovative, start-up companies.

Additionally, federal ordinary income tax credits for angel investments in small business start-ups would also improve the flow of angel capital to small businesses in communities throughout the country. Twenty-plus states and several foreign countries have instituted income tax credits over the last decade. These credits are generally offsets against other investor tax liabilities and enhance the attractiveness of early stage, high-risk investments in early stage enterprises. A <u>federal</u> tax credit could ensure that innovative small businesses would benefit from such investor credits, irrespective of state of domicile. A nationwide credit would enhance the benefits offered by states that already have such programs as offsets to state taxes (federal ordinary income tax obligations are greater than state tax liabilities). In addition, a tax credit with a nationwide footprint could help encourage more syndication among and between angel groups in different states, which is increasingly the manner by which entrepreneurs are able to raise larger rounds of financing. Several state-level precedents are instructive. A 2008 study of Wisconsin's angel tax credit program and related initiatives found that overall investment in Wisconsin small businesses increased by 43 percent from 2006 to 2007. Wisconsin-based angel groups increased their investments by 57 percent and more than doubled the number of small businesses that benefited from Wisconsin's policy initiatives during the same period.

Beyond the realm of angel investors, recently proposed legislation to tax "carried interest" earned by venture capital fund managers at ordinary income tax rates rather than at capital gains rates will significantly reduce the number of institutional venture capital funds being raised and consequently the amount of capital deployed to the most deserving entrepreneurs. In normal cyclical fashion, the venture capital industry expands

by two-thirds during “boom” times, and then contracts by two-thirds during “bust” cycles. During bust cycles, venture capitalists “retreat upstream” and pursue later-stage companies whose risk/reward profile is lower than that of early stage companies. Thus, there is already a strong cyclical contraction underway; to reduce the compensation earned by venture capital fund managers will substantially exacerbate this already challenging trend. Venture capitalists will forego or abandon their involvement in the discrete asset class of venture capital, and instead pursue other areas within the investment professions, such as traditional mutual fund management, asset management, commodities and/or currency trading & arbitrage, where the risk/reward profile will appear more attractive. The “drying up” of early stage venture capital sends an extremely discouraging signal to early stage entrepreneurs (particularly within the biotechnology arena), and it has the very tangible effect of channeling both capital and managerial talent into other industries and technology sectors which require less total capital, over fewer years, and which do not include “regulatory risk” as part of their investment profile. Unfortunately, such industries are of less strategic importance to the nation’s competitive standing (e.g., niche consumer products now receive investor capital vs. pharmaceutical development; entertainment media deals are funded vs. clean energy technologies).

Recommendations:

- Encourage Congress to keep capital gains tax rates for angel investments in truly early-stage businesses at 15 percent <u>or less</u> when it renews tax legislation for long-term capital gains this year.
- Given current economic conditions, Congress consider complementing a lower capital gains rate for successful early-stage investments with a tax credit for investments in innovative small businesses. Federal ordinary income tax credits for individual angel investors in small business start-ups would also improve the flow of angel capital to small businesses in communities throughout the country. The Angel Capital Association could serve as a resource to advise legislators and policy makers on best practices gleaned from the twenty-plus states who have implemented state-level individual tax credit programs to promote growth of small businesses that create high-paying jobs.
- Resist calls for changing the taxation of carried interest for venture capital fund managers from capital gains to ordinary income. Such a policy would greatly reduce the already shrinking pool of available venture capital and result in a significant drop-off in new venture funds being raised.
- Beyond ordinary income tax credits for individuals, <u>corporate</u> tax credits for small firms could be linked to levels of outside capital investment attracted, employment gains made by small firms, capital equipment purchased, or some combination of these measures. There has been experimentation in this area at the state level as well. The effectiveness of this proposed policy however is admittedly lessened for those early stage technology-based firms which operate for several years without meaningful revenues (which is not uncommon).

IV. Federal and State Securities Regulations.

Federal rules require individual investors who seek to invest in an early stage company to meet certain threshold requirements of either wealth or income level. As the economic

downturn has decreased the number of individuals able to meet these thresholds, consideration should be given to lowering one or both the standards.

Additionally, the federal government should continue its beneficial policy of permitting the exemption of early stage company stock from the usual securities and exchange listing requirements under Regulation D of the 1934 Act. This exemption saves early stage companies and their investors significant time and money, which are at a premium for such enterprises.

Recommendations:
- Preserve, and potentially lower, the traditional definition of "accredited investor(s)" for securities and tax law purposes. Conversely, raising the threshold definitions will vastly reduce the number of angel investors eligible to make investments in early stage companies.
- Continue to protect the "Reg. D" exemption under the '34 Act for the offering of stock in early stage ventures.
- Study the potential benefits of simplifying the complex patchwork of all federal regulations within the area of securities issuance exemptions.
- Pursue harmonization of federal laws with the patchwork landscape of the states' own "Blue Sky" securities regulations. This would provide regulatory and financial relief to early stage firms, which often must incur onerous legal cost to ensure compliance in numerous state jurisdictions.

V. Programs Promoting the Development and Integration of Local/Regional Infrastructure and Critical Resources for the "Entrepreneurial Ecosystem."

Two programs showing early promise and worthy of promotion at the Federal level are as follows:

A. The Florida Institute for the Commercialization of Public Research (FICPR).

The Florida Institute for the Commercialization of Public Research (FICPR) matches commercially-viable technologies originating from the states' public and select private research institutions with (i) experienced start-up managers (entrepreneurs) and (ii) private investor capital (angel investors, venture capitalists, and corporate development partners). FICPR is an unprecedented collaborative effort of the technology licensing and commercialization offices of Florida's eleven state universities as well as those private research institutions within the state that receive public funding. These partners are the gatekeepers charged with licensing technologies to startups for commercial product development leading to company growth and job creation. A nonprofit organization formed by the Florida Legislature in 2007, FICPR's mission is to create new, innovation-based companies and jobs by supporting entrepreneurship and commercialization of publicly-funded research in the life sciences, aviation/aerospace, clean energy, homeland security, and information technology sectors.

In addition to the aforementioned "matchmaking function," FICPR expands access to early stage capital by administering Florida's newly authorized Commercialization Matching Grant Program, which provides matching state funds to qualified Phase I and Phase II SBIR federal grant and STTR federal grant awardees. The multiplier effect of this program significantly expands the initial award of federal grant monies with new sources of both state funding and private investor capital.

Finally, FICPR expands and strengthens the connectivity among the state's technology business incubators, local innovation networks, prototyping facilities, strategic workforce training agencies, angel investor groups, and other entities through which additional training, communication, financing, and relevant support services are provided to early stage ventures. In this role, FICPR leverages existing assets and infrastructure, connecting the dots in a state often characterized by regional and institutional insularity.

In the near future, FICPR aspires to foster even greater connectivity among the many separate elements of the entrepreneurial ecosystem by leveraging requested federal funding with other state and locally-funded initiatives and programs. The collaborative model implemented by FICPR represents a successful precedent that is worthy of study and replication, both regionally and nationally.

B. Promote the Establishment and Growth of Private Angel Investor Groups and Networks.

Since angel investors have most recently accounted for roughly half of all early-stage funding last year (also consistent with the long-term trend), entrepreneurs and the early stage businesses they start would benefit from an expansion of organized angel investor activity. One challenge facing policymakers is that angel investing is, by its very nature, an inherently private sector matter. Providing private investors with exposure to best practices and a roadmap for how they may organize collaborative angel investment activity at local and regional levels is perhaps the best manner of promoting private investment activity in early stage companies. The Angel Capital Education Foundation (ACEF), a national source of education and research on angel investing, serves as a resource and repository available to assist private investors, entrepreneurs, support organizations, legislators, and policymakers who seek to understand, pursue, access, and/or promote angel investment activity (www.angelcapitaleducation.org).

Recommendations:
- Federal agency heads and federal legislators should become familiar with the programmatic successes of both the Florida Institute for the Commercialization of Public Research (FICPR) and the Angel Capital Educational Foundation (ACEF). Where possible, the programs and initiatives developed by both entities should be supported, replicated, extended, and also integrated into existing federal programs (as relevant).
- Specific consideration should be given to funding the FICPR's upcoming grant application to the *i6 Challenge Grant* program (sponsored by the US Department of

Commerce's Economic Development Administration, in partnership with the National Institutes of Health (NIH) and the National Science Foundation (NSF).

VI. SBIR and STTR Programs.
The federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs have been a staple of early stage company formation and advancement for many years. While the time and scope of this testimony do not permit a sufficient overview of each program, the core takeaways are as follows:
- SBIR and STTR grants provide key financing for early stage companies seeking to bridge the "valley of death" between initial seed capital (most often provided by entrepreneurs themselves, their "friends and family," and/or angel investors), and later, larger financing rounds from institutional investors (e.g. venture capital funds and large pharmaceutical firms).
- SBIR/STTR grants serve an important "validating" function for later investors, signaling that the science supporting the technology under development by an early stage firm has gone through peer-review during the grant award selection process.
- SBIR/STTR grants are often the sole source of funding for "highest risk/highest reward" projects which seek to demonstrate the first "proof of concept" for a given technology.

In recent years, funding for the SBIR and STTR programs has been threatened by larger corporate and institutional investor interests, who would prefer to see federal funding steered toward later-stage, larger enterprises. However, SBIR and STTR grants, primarily intended for small and mid-size enterprises, are literally the "seed corn" for much of this nation's most innovative private research and development efforts.

Recommendations:
- Preserve federal funding support for both the SBIR and STTR programs
- Protect SBIR and STTR programs from encroachment by larger firms which seek to displace earlier stage firms from grant award funding, potentially by imposing ceilings on the size of enterprise that may be eligible for grant funding.

VII. Conclusion.
Again, I would like to thank Senator George LeMieux (R.– Florida) for the opportunity to share these observations and recommendations with the Honorable Members of this Senate Subcommittee. Federal policies supporting (i) entrepreneurs, (ii) the early stage ventures they launch and grow, and (iii) the early stage investors who back them, all contribute to an ecosystem that is part of a virtuous cycle of high-wage job creation, increased tax revenue (over the long-term), dynamic innovation, and robust competitiveness on the global stage. By the same token, as suggested earlier, restraint at the federal level is often the best available policy option.

Sincerely,

Rhys L. Williams

Contact information:

Rhys L. Williams, J.D., M.B.A.
President
New World Angels, Inc.
3701 FAU Blvd., Ste. 210
Boca Raton, FL 33431
561-542-1380 (cellphone)
561-620-8494 x14 (office)
RhysWilliams@newworldangels.com
www.newworldangels.com

Rhys L. Williams, J.D., M.B.A.
President
iTherapeutics Corp.
3701 FAU Blvd.
Suite 210 – 112
Boca Raton, FL 33431
(561) 638-7714 office
(561) 542-1380 cellphone
(561) 638-6305 fax
rwilliams@itherapeutics.com