

Testimony of Duane Roth, CEO of CONNECT

before the House of Representatives Committee on Oversight and
Government Reform

regarding “Federal Policies Affecting Innovation and Job Growth in the
Biotech and Pharmaceutical Industries.”

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Chairman Issa, thank you for this opportunity to testify to the Committee regarding “Federal Policies Affecting Innovation and Job Growth in the Biotech and Pharmaceutical Industries.” My name is Duane Roth and I am the Chief Executive Officer of CONNECT. CONNECT has assisted in the formation and development of more than 2,000 companies and is widely regarded as the world's most successful regional program linking inventors and entrepreneurs with the resources they need for commercialization of innovative products in high technology and life sciences. The key to our success has been the unique "culture of collaboration" between industry, capital sources, professional service providers and research organizations. CONNECT has been recognized by Time, Inc. and Entrepreneur magazines and was recently awarded the 2010 Innovation in Economic Development Award from the U.S. Department of Commerce for creation of Regional Innovation Clusters.

I have submitted more extensively written testimony but I'd like to briefly comment on a few issues that are critical to this Committee's review of this important topic.

First, the Committee must remember that the federal government, through its many science and technology related agencies, is the largest single investor in research in the United States, currently at almost \$150 billion annually. Over the past 30 years, these federal investments in research have led to the formation of innovative product-focused start-up companies that translated technology discoveries into commercial products. These products have been exported around the world and have contributed to better healthcare, increased security, more nutritious food, a cleaner environment and better communications. In the process, these companies also transformed the U.S. innovation economy and provided the majority of new high-paying jobs. The start-up model was financed primarily by venture capital (VC) investments in early-stage development with follow-on financing (often pre-revenue) from the public equities market through initial public offerings (IPOs).

Recently, this financing model has been challenged, especially in the biotech and pharmaceutical industries, primarily due to the disappearance of the IPO market for pre-revenue stage companies. The long, uncertain and expensive FDA approval process is a significant contributing factor in this financing challenge. As a result, it is increasingly difficult to fund start-ups to develop new innovative therapies since the VCs now have to fund these entities to profitability or to an exit through merger and acquisition. Therefore, many innovative discoveries end up in the so-called "Valley of Death," where there is no funding source available to support the early translation of research discoveries into products. To address this gap, foundations, advocacy groups and even government funding agencies have stepped in to try to provide this funding, but these investments are

generally inadequate to bridge the discovery to follow-on VC funding. If this investment gap is not addressed, the U.S. could lose its competitive advantage in commercializing innovation due to increasing global competition. To address this issue, it is imperative that the U.S. develop new financing and business models that provide incentives to bring investment into this pre-venture. Roth and Cuatrecasas recently described one such financing model in a publication by the Kauffman Foundation which is attached to my written testimony. I will focus my comments today on 1) capital formation for early-stage investments 2) addressing the regulatory challenges for innovative new medical products.

Capital Formation

Congress needs to aggressively look at various capital formation policies and quickly move to modernize them to support our changing innovation economy. These include among others, modernizing the SBA Loan program and continuing support of the SBIR and STTR programs. The recent Start Up America program has several helpful features including re-instating the small business investment companies (SBIC) and creating SBA-guaranteed bonds which will match private capital raised by privately-owned and managed investment funds. However these programs will not provide the massive infusion of capital we will need for America to remain the number one innovation economy in the world. Our global competitors have created clever economic development strategies that capitalize on our innovations, tax policies and shortages of certain skilled workers such as engineers. Countries such as Singapore and Malaysia have become

proficient at enticing American manufacturing and production in their countries.

Multiple sources have noted that U.S. companies are sitting on over a trillion dollars in foreign profits that are subject to an additional tax if these funds are repatriated to the U.S. Presently, these profits are subject to an incremental tax equal to the U.S corporate tax rate of 35% minus the tax rate they paid in the country where they earned the profit. Since the U.S. has the second highest corporate tax rate in the world, this policy acts as a deterrent to bringing that capital back to the U.S. and expanding research and development or manufacturing facilities which create jobs. Not only is the repatriation tax a bad policy on its face, but the policy is anti-competitive as it encourages American companies to build new facilities and develop new products overseas to avoid the high tax rate, thus allowing jobs and innovation to be created outside the U.S. This policy in effect serves to directly finance our competitors.

Congress should incentivize the investment of those foreign profits back to the U.S. in a way that will infuse capital into early-stage innovation and emerging technologies, which have especially struggled in the sputtering economy. Fortunately, there is a bill in Congress that will do this and it was introduced by San Diego Congressman Brian Bilbray. H.R. 1036, the Job Creation and Innovation Investment Act of 2011, allows the repatriation of foreign profits back to the U.S. at a 0% tax rate IF those funds are used for the following limited purposes:

- Research & Development—internal and external, sponsored or purchased

- Expansion of facilities
- Funding Proof of Concept Centers
- Early-stage VC investment (including original investment)
- Manufacturing start-up costs (including plant, equipment, infrastructure and contract manufacturing).

The bill allows the return of repatriated funds at a 5.5% rate otherwise.

Bringing this money back to the U.S. will move American profits out of places like Singapore, Malaysia and South Korea and into places like San Diego, Maryland and Utah. Congress CANNOT wait for comprehensive tax reform legislation to move before bringing this money back to the U.S. and creating a private sector stimulus that creates no new federal program and creates no new burdens on taxpayers.

FDA Reform

The current regulatory system for approval of medical products creates a “no win” situation as the parties in the room negotiating approval cannot objectively assess risk and benefit. The regulator is inherently influenced by the risk that the drug or device may not be safe, while the maker of the drug or device is inherently influenced by the benefits that can be realized by the patients. Numerous attempts have been made over the past several decades to try to address these built in biases through new rule making including the Prescription Drug User Fee Act (PDUFA I) of 1992 and follow on renewals (PDUFA II-IV) and the FDA Modernization Act of 1997. The results of these attempts have not been successful to date in that it takes longer, costs more and fewer new innovative products have

reached the market despite an explosion of investment in research from both government and industry.

Recently, the Hastings Center Report, a trusted authority on ethics in medicine and bioethics, published an article I drafted based upon my over four years' service on the oversight board of the California Institute of Regenerative Medicine where the board of twenty-nine members includes ten patient advocates. My remarkable experience of working with these advocates led me to suggest a new paradigm on how the regulatory approval process may be re-engineered to remove the inherent biases and build trust into the system through a shared responsibility.

What I realized is those directly impacted by the disease or impairment have a unique perspective in evaluating risk and benefit. It is their disease, not the industry's nor the FDA's. I suggest that it is unethical to exclude them from the room in which literally life and death decisions are made in a two-way, biased negotiation between the FDA and the company. There is precedent for direct patient involvement in the regulatory process.

Following the unfolding of the HIV epidemic in the early 1980s, patient advocates persuaded the FDA and industry to include their perspective in the approval process for anti viral medicines by allowing their input into the approval process. These efforts lead to the first protease inhibitor approval in 1995 in just 97 days, a drug that changed AIDS to a chronic disease from a fatal one. To this day if you talk with those directly involved in the review they will tell you it worked remarkably well and all are extremely proud of what they together accomplished. Unfortunately

instead of institutionalizing this shared responsibility as a formal part of the approval process for innovative therapies, it became a “one-time” event.

I suggest that we should consider incorporating patient mediators in the review process for innovative new products as a routine. The FDA review team would remain, as now, the final decision maker in all review processes. The company team would, as now, have responsibility to generate the data to prove safety and efficacy. The patient team would help both parties view risk and benefit through their lens. In my paper I suggest that we create a pilot program to test this process. The patient mediator team would need to be directly impacted by the disease (they or their immediate family) and be certified that they have the appropriate background and experience (knowledge of regulatory law, statistics, clinical trial design, manufacturing and controls, etc.) Such a three way shared responsibility would have the potential to change everything for U.S. led innovation that would directly benefit patients providing a higher quality of life and lower overall healthcare costs.

My written testimony includes the full text of the Hastings Center Report article and provides more extensive discussion and analysis of this proposal.

Thank you.