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DRIVING INNOVATION AND JOB GROWTH THROUGH THE LIFE SCIENCES INDUSTRY

HEARING

BEFORE THE

JOINT ECONOMIC COMMITTEE
CONGRESS OF THE UNITED STATES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

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CONTENTS

VerDate Nov 24 2008 10:46 Aug 24, 2011 Jkt 067182 PO 00000 Frm 00003 Fmt 5904 Sfmt 5904 C:\DOCS\67182.TXT SHAUN PsN: DPROCT

DRIVING INNOVATION AND JOB GROWTH THROUGH THE LIFE SCIENCES INDUSTRY

WEDNESDAY, MAY 25, 2011

CONGRESS OF THE UNITED STATES,
JOINT ECONOMIC COMMITTEE,
Washington, DC.

The committee met, pursuant to call, at 9:31 a.m. in Room 216 of the Hart Senate Office Building, the Honorable Robert P. Casey, Jr., Chairman, presiding.

Senators present: Casey, Klobuchar, and Lee.

Representatives present: Brady, Mulvaney, Maloney, Cummings.

Staff present: Will Hansen, Colleen Healy, Andrew Wilson, Jesse Hervitz, Jessica Knowles, Jayne McCullough, and Robert O'Quinn.

OPENING STATEMENT OF HON. ROBERT P. CASEY, JR., CHAIRMAN, A U.S. SENATOR FROM PENNSYLVANIA

Chairman Casey. Well thanks, everyone, for being here. We are still starting early, but we are grateful you are here. I am proud to be joined by Vice Chairman Brady and our witnesses.

I will give an opening statement, and then I will turn the microphone to Congressman Brady, and then what we will have is, for Members who are here, maybe brief opening statements and then of course we want to get to our witnesses.

I am pleased to be joined by Vice Chairman Brady at this hearing. We are going to examine today the key roles that are played by the life sciences, and life sciences companies in driving innovation and job creation throughout our country.

We hope to shine light on the opportunities created by this vibrant sector and explore new policy actions that can incentivize additional research and development in the life sciences industry, and have a broader conversation about the role the Federal Government plays in supporting R&D.

As we consider that role, it is useful to remember the inspirational leadership of President Kennedy. Today is the 50th anniversary of the day when he challenged the country to put a man on the moon in his historic speech to a joint session of Congress.

That speech drove new breakthroughs in science exploration—or space exploration, I should say, and major advances in technology. On July 20th, 1969, eight years and two months after President Kennedy addressed the Nation, Neil Armstrong became the first person to walk on the moon.

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Today, 50 years after President Kennedy laid out that bold vision of the successful Apollo 11 Mission, that is a reminder of what our country can achieve when we set ambitious goals and commit ourselves to reaching them.

The anniversary is also a fitting backdrop to today's hearing on R&D and the life sciences industry R&D that will lead to next-generation drugs and devices that can dramatically improve quality of life and will enable us to address challenges that seem beyond our grasp even today.

Life sciences include, as you know, fields such as biotechnology, microbiology, and genetics. Among the very different types of life sciences companies are firms that research and produce pharmaceutical drugs, medical devices, and of course surgical equipment.

These firms play a critical role in our economy, employ approximately 1.2 million workers across America, and provide innovation-fueled economic growth, and job creation. The life sciences industry is particularly R&D intensive and is home to high rates of innovation.

Pharmaceutical companies alone, just one piece of this industry, account for 16 percent of the firm-powered R&D in the country employing just about 115,000 workers.

While employment in the health care sector is generally viewed as recession proof, life sciences employment actually declined by 28,000 from its high from October of 2008 to February of 2011. That is something we should note and discuss.

The role of the Federal Government of course is to spur innovation through policies and encourage or enable innovation, creating investment and research that would not otherwise occur in the private sector. This can be done through the government stepping in to fund research directly through grants to universities, for example, or by using the tax code to incentivize the private sector to carry out the investment.

These different tools can help to address when there is market failure in the private sector when, if it is left to its own devices, may underinvest in research and development.

In the past three decades, total R&D spending, both public and private, has remained relatively flat between 2.5 and 2.8 percent of GDP. Recently, the U.S. has lagged behind the rest of the world in the growth and the growth of R&D spending.

From 1996 to 2006 U.S. spending on R&D as a share of GDP grew by just .1 percent. China, on the other hand, grew by .9 percent during the same time period. A continuation of this trend can have significant negative effects on our long-term competitive position.

We know that in the post-World War II period there has also been a change in how R&D is funded. Federally funded R&D has been declining during this period, while industry-funded R&D has been increasing.

In 1980, industry-funded R&D surpassed federal R&D funding and, by 2008, the most recent comparative data available, the gap had grown substantially, with industry spending a little more than $267 billion on R&D, compared to the Federal Government's R&D spending of just $103 billion.

However, the Federal Government continues to play a significant role in funding basic research. That research increases our general base of knowledge and creates the building blocks for future products. Indeed, the Federal Government funds over half, 57 percent, of the basic research in the United States, the majority of which is conducted in universities.

In addition to the government funding of basic research, there are other federal policies that promote innovation. Tax credits that reduce the cost to the private sector of conducting R&D in the U.S. is one such policy. The Research and Experimentation Tax Credit, first introduced in 1981, and recently extended through 2011 as part of the bipartisan agreement on taxes in late 2010, is yet another prime example.

Businesses have long argued that the lack of a permanent credit leads to uncertainty from one year to the next about whether or not the credit will exist, and has limited the credit's effectiveness. A permanent credit would give business the certainty that they need to make R&D investments, thereby boosting R&D spending, innovation, and job creation.

The President's 2012 budget proposed making the R&D credit permanent, and expanding it by about 20 percent. So policymakers can also provide targeted incentives to encourage R&D in specific industries, amongst certain-sized businesses.

The Small Business Innovation Research Program, for example, provides grants to small businesses, helping them in the early stages of their research to navigate the so-called "Valley of Death" where their concept is too high risk for private-sector support.

The Life Sciences Jobs and Investment Act, which I am proud to be co-sponsoring with Vice Chairman Brady, will double the R&E credit from 20 percent to 40 percent on the first $150 million of R&D in life sciences, providing a new incentive for small and medium-sized businesses to invest in R&D funding.

We want to ensure that the United States is preparing our students in science, engineering, and other skills they need to compete in this new economy. That is not the focus of today, but we know this is a priority for other hearings and other discussions.

We are fortunate today to have a distinguished panel of experts who bring with them vast experience as inventors, innovators, job creators, and experts on the important role that tax incentives can play in spurring new research, new innovation, and new jobs.

With that, I will turn to our Vice Chairman, Congressman Brady.

OPENING STATEMENT OF HON. KEVIN BRADY, VICE CHAIRMAN, A U.S. REPRESENTATIVE FROM TEXAS

Vice Chairman Brady. First, Mr. Chairman, I would like to thank you for holding today's hearing on the life sciences industry. I would also like to welcome all of today's witnesses, especially my fellow Texans, Dr. Arthur Sands and Thomas Kowalski—both highly respected in their fields—and thank you for taking time out of your busy lives to testify.

America's life sciences industry leads the world with innovations in biomedical science, biotechnology, agriculture, and medical devices. This industry's products help Americans live longer and

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healthier lives. It employs 1.4 million Americans and accounts for one-third of all research and development expenditures by private U.S. firms.

The Joint Economic Committee is holding this hearing today to discover what steps the U.S. Government may take to help the life sciences industry prosper and strengthen its competitiveness both here and abroad.

Investment in research and development in life sciences creates good, high-paying jobs; keeps the United States on the cutting edge of global competitiveness; and enhances the quality of life not only for Americans but for people everywhere.

Yet the up-front cost of investment in this industry is extremely high. Companies spend years researching and testing, pouring millions and at times billions of dollars into the research, testing, and trials of medical ideas that may never make it to market. Yes, the return can be high, but the investment is highly risky as well.

In this vital area of the economy, America is falling behind. Other countries are increasing their incentives for R&D in an aggressive effort to attract investment and the high-paying jobs that go with it. America's share of the world's research and development pie is shrinking as our global competitors are taking a page from our playbook and beating us at it. In 1981, America led the world as the first to create an R&D tax credit. By 2009, we ranked 24th out of 28 countries in the strength of our R&D incentives.

We need to rethink our approach to incentives. It is time we modernize the R&D tax credit; strengthen it to encourage companies to make even more substantial investments in research and hiring; and make it permanent so businesses and investors have the confidence to make long-term decisions.

At the same time, we should reform the way our overall tax structure operates by lowering the rate and simplifying the code. At 35 percent, the United States has one of the highest corporate tax rates in the world. Our complicated tax structure puts Americans at a disadvantage when competing at home and abroad. More than $1 trillion in capital earned by American companies and workers is stranded overseas because our tax code strangely penalizes companies for bringing profits home.

As an interim step, we have an opportunity to temporarily lower tax barriers to incentivize companies to bring these profits back home for investment. The right form of repatriation measure would lower the tax gate and allow private capital to flow back to the United States to be used to create jobs, to expand businesses, and to invest in research.

Additionally, we should examine ways we can help boost incentives even more for the life sciences industry, given its unique structure and the benefits it adds to our health and way of life. This could include further strengthening the R&D tax credit, and allowing life sciences companies to claim research expenses paid to universities.

However, we should not limit our considerations of tax provisions only to those benefiting the life sciences industry. The competitive challenges which federal policies pose to life sciences firms merely reflect the tax, trade, and regulatory impediments that all American companies face when competing in global markets.

VerDate Nov 24 2008 10:46 Aug 24, 2011 Jkt 067182 PO 00000 Frm 00008 Fmt 6633 Sfmt 6633 C:\DOCS\67182.TXT SHAUN PsN: DPROCT

To begin, we must look at fundamental reform of business taxation:

We must lower the federal corporate income tax rate to a competitive level so that both American and foreign firms will make new investments in the United States, creating more and better paying jobs for American workers.

We must also lower the after-tax cost of making new business investments by moving toward expensing new investments in equipment and software and significantly shortening the tax depreciation schedules for buildings and other structures.

Finally, we must enact a permanent and generous tax credit for research and development.

Beyond business tax reform, we must continue to open new markets to American exports of goods and services. I continue to call on President Obama to submit the pending free trade agreements with Colombia, Panama, and South Korea to Congress for approval. And we must ensure that intellectual property rights, such as those developed by firms before us today, are fully respected by all countries.

Finally, we must reform our regulatory structure to assure that the goals we all share for product safety and a clean environment are achieved in a cost-effective way that does not place undue burdens on American companies or their workers.

With that said, Mr. Chairman, I look forward to hearing today's testimony.

[The prepared statement of Representative Kevin Brady appears in the Submissions for the Record on page 34.]

Chairman Casey. Thank you, Vice Chairman Brady.

Next, by order of appearance, which is the way we do things here, Senator Klobuchar.

OPENING STATEMENT OF HON. AMY KLOBUCHAR, A U.S. SENATOR FROM MINNESOTA

Senator Klobuchar. Well thank you very much, Mr. Chairman, and thank you for holding this hearing. I think it is very important.

I first wanted to mention, my in-laws are here today, Bill and Marilyn Hassler, from Mankato, Minnesota. My father-in-law taught science biology for most of his life, and I am happy to have them here.

I told Senator Casey it was "Bring Your In-Laws To Work Day," but——

[Laughter.]

But he did not really believe me. I am very excited about this hearing because my State has really built its reputation on innovation. Our unemployment rate is at 6.5 percent, one of the lower in the country, and that is because of innovation.

We brought the world everything from the Pacemaker to the Post-It Note. 3M started as a little sandpaper company up in Two Harbors, Minnesota, and now employs 75,000 people. Medtronics started as a garage—in a garage. Target started as a little dry goods store in Nicollet Mall. So we have always believed in moving ahead.

I think this country needs to move ahead, and that the heart of our progress should be an innovation agenda. It is what Tom Friedman, who writes for The New York Times, who is a Minnesota native called, "Nation building in our own Nation."

This innovation agenda, we've got part of it in a bill that I introduced with Senator Scott Brown, that is co-sponsored by Lamar Alexander and Mark Warner, called Innovate America, and I think first of all we start with education, doubling our number of STEM high schools and making sure that we are training students to go into the jobs that are actually available in the marketplace today, including technical schools, and making sure that we have students trained to run the high-tech assembly lines of the day.

The second thing, which has been mentioned by my colleagues and certainly applies in the life sciences, is this idea of making sure the R&D tax credit is good, and stable, and that we are not playing a game of red light/green light with that tax credit, like we have been; that we do things to close loopholes and lower rates.

I think the Deficit Commission had some good ideas there in terms of lowering the overall corporate rate, but closing some of the loopholes and looking at our revenues, as well. Certainly doing something about our debt will be helpful for market investment in every new kind of product.

Third, immigration reform: looking at the H–1B Visas; realizing that we are basically having to contract with people in other countries because we've made it so hard for them to come over here. When students graduate that study at our great universities, that we give them that time to get a job so that they start the next Google in the United States and not in India or some other place.

The idea of making sure that we do something about red tape. Minnesota is the mecca for the medical device industry, and I was just reading a statistic from a study that came out today out of Chicago that showed, because of problems with the FDA approval process, two-thirds of small medical device companies engaged in developing new products are obtaining approvals in Europe first. Only 8 percent of the 300-some companies surveyed felt that the U.S. approval pathway was the most predictable in the world; 72 percent found that information requested by the FDA reviewers was beyond necessary requirements. That is a big problem. We are working to address it every single day, but it is basically we are putting up a sign that says: Go put your money elsewhere. And I think that has to change.

Last, exports is the key to this in terms of getting out of our slump. The President has called for a doubling of our exports in the next five years. I think that is doable. And I think a lot of the way it is doable is the research that you will be talking about, the work in the life sciences, as well as medical device and other areas.

But this has to be an around-the-world effort. Our embassies have to be focused on assisting companies in getting contracts in other countries, because certainly the embassies in other countries is what they're devoted to all the time, and we have to make sure that our small- and medium-sized companies have an opportunity through the foreign commercial service to find out about those customers and potential markets. Because there is this growing group

of customers across the world that we have not appropriately accessed with our small- and medium-sized companies.

So in sum, Mr. Chairman, I truly believe that we are not going to grow as a Nation in the life sciences, or in any of our innovative industries if we are simply a country that focuses on churning money on Wall Street, and importing our way, and building debt.

We have to be a country that thinks again, that makes things, that invents, that exports to the world. So I thank you for holding this important hearing.

Chairman Casey. Thank you, Senator Klobuchar.

Senator Lee.

OPENING STATEMENT OF HON. MIKE LEE, A U.S. SENATOR FROM UTAH

Senator Lee. Thank you, Mr. Chairman. Utah is also a state with a strong interest in the life sciences. We have got 600 different life sciences companies in Utah, employing over 25,000 people. We have got two institutions in the State of Utah that have helped to facilitate this, along with our universities.

One is an organization known as the Bio-Innovations Gateway. Another is known as USTR, the Utah Science Technology Research Initiative. And so these are both programs that work with our institutions of higher learning to help recruit top-level talent to the State of Utah and to its universities so that we can patent and develop and produce more life sciences technology.

And I wish I could claim that the Post-It Note was invented in my state, but alas Minnesota beat us to the punch.

[Laughter.]

But we are out there looking for the next life sciences iteration of the Post-It Note. Maybe we will find some medical device delivery system that is a removable adhesive strip like the Post-It.

Senator Klobuchar. Dream on. Dream on.

Senator Lee. Yes. Exactly. I have to dream. So I welcome the witnesses and look forward to your testimony.

Chairman Casey. Thank you, Senator Lee.

We will now move to our witnesses. I will provide a biographical sketch, brief though it will be, of each witness. And then of course we will start with Dr. Tang for his testimony.

Let me start with Dr. Stephen Tang. He is the President and CEO of the Science Center in Philadelphia. Before coming to the Science Center, Dr. Tang served as Group Vice President and General Manager with Olympus America, where he led U.S. operations for the company's Global Life Sciences business. Dr. Tang earned a Doctorate in Chemical Engineering from Lehigh University. We're happy about that. An MBA from the Wharton School of Business in the University of Pennsylvania, also a Pennsylvania institution, and a B.S. in Chemistry from the College of William and Mary. So, Dr. Tang, welcome, and we look forward to your testimony.

Tom Kowalski is the President and CEO of Texas Healthcare and Bioscience Institute, a statewide public policy research organization promoting medical research, development, and manufacturing in the State of Texas. Prior to his appointment as President of THBI, Mr. Kowalski served as Executive Director of the National Associa-

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tion for the Support of Long-Term Care, as well as a senior staff member to Governor Bill Clements of Texas; and Senator John Tower of Texas. Mr. Kowalski, welcome to you.

Dr. Arthur Sands is the President and CEO of Lexicon Pharmaceuticals, a company he co-founded. Dr. Sands pioneered the development of large-scale gene-knockout technology for use in drug discovery. Prior to founding Lexicon, Dr. Sands served as the American Cancer Society's Post-Doctoral Fellow at Baylor College of Medicine. He received his BA in Economics and Political Science from Yale University and his M.D. and Ph.D. from Baylor College of Medicine. Dr. Sands, thank you very much for being here, as well.

Mark Heesen is the President of National Venture Capital Association, which is engaged in public policy issues surrounding information technology, life science, and clean technology investing. Prior to his work in the NVCA, Mr. Heesen—He-sin? Hee-sen, I'm sorry. I'm pronouncing that wrong. He was an aid to former Governor Thornburgh in Pennsylvania. He received a Law Degree with emphasis in taxation from Dickinson School of Law. Thank you very much for being here, as well. So we will start with Dr. Tang.

And I should mention for the record, your full testimony, each of your testimonies, will be included in the record in full. We will try to keep each of you to five minutes, if you can do that, in your opening.

Thank you.

STATEMENT OF DR. STEPHEN S. TANG, PRESIDENT AND CEO, UNIVERSITY CITY SCIENCE CENTER, PHILADELPHIA, PA

Dr. Tang. Thank you, Chairman Casey, and Vice Chairman Brady, and Members of the Committee:

I am Steve Tang. I am President and CEO of the University City Science Center in Philadelphia. It is an honor and a privilege to speak to this distinguished Committee today. And may I say, I have had the honor of living in both Pennsylvania and Texas, and doing business in each of your States, during my career.

Science and innovation are in my blood and are part of my heritage. I am the son of two Chinese-born scientists. I was born with high expectations from parents who sought, and largely achieved, the American Dream.

My background is in both science and entrepreneurship. As Senator Casey mentioned, I have an undergraduate degree in Chemistry from the College of William and Mary and a Ph.D. in Chemical Engineering from Lehigh University; as well as an MBA from the University of Pennsylvania's Wharton School. So with my over-education in full view of the Committee, I want to wish everyone Happy Nerd's Pride Day.

[Laughter.]

Senator Lee, as a graduate student, I founded and ran my own technology assessment consulting firm, while at the same time pursuing my doctorate and managing Lehigh University's Biotechnology Research Center.

After I obtained my MBA, I served as a management consultant to two international firms, focusing on projects in the chemical, environmental, health care, and pharmaceutical industries.

VerDate Nov 24 2008 10:46 Aug 24, 2011 Jkt 067182 PO 00000 Frm 00012 Fmt 6633 Sfmt 6633 C:\DOCS\67182.TXT SHAUN PsN: DPROCT

I then served as CEO of a hydrogen fuel cell company, guiding its growth as it moved beyond its start-up phase, completed a successful initial public offering, and attracted subsequent investment and financing.

Next, as Senator Casey mentioned, I ran Olympus America's Life Science Division, overseeing operations, finance, strategy, and product and business development.

Since 2008, I have had the privilege of leading the University City Science Center. I was motivated to take this position by my passion for science and technology, and their ability and potential to make the world a better place. As a newly appointed member of the U.S. Commerce Department's Innovation Advisory Board, I welcome the opportunity to contribute to the national discussion on innovation and economic competitiveness, particularly as it relates to life sciences.

The Science Center is a private, nonprofit research park and business incubator in Philadelphia. Located in the city's heart of the city's "meds and eds" community, we have existed at the intersection of innovation and economic development for close to 50 years. We are the Nation's oldest and largest urban research park, with 15 buildings on 17 acres containing over 2.0 million square feet of lab and office space. More than 8,000 people come to work each day on our campus.

We are home to innovative programs such as the QED Proof-of-Concept Funding Program, which pulls technologies out of the labs and into the marketplace by pairing scientific researchers with experienced business advisors.

At the Science Center we firmly believe that our multi-institutional QED program is a unique and model "public-private partnership" that can be replicated across the Nation to help promising ventures cross the "Valley of Death" in funding.

I am proud to report that QED achieved a funding milestone on its own last month when we received a two-year, $1 million grant from the U.S. Economic Development Administration. This federal funding is currently being leveraged with funding previously awarded to QED by the Commonwealth of Pennsylvania and the William Penn Foundation of Philadelphia, plus additional funding from the Science Center and the 19 institutions participating in this program.

The Science Center is owned by 32 of the leading colleges, universities, hospitals, and nonprofit institutions throughout Pennsylvania, New Jersey, and Delaware, including the University of Pennsylvania, Drexel University, the Children's Hospital of Philadelphia, the University of Delaware, and Rutgers University.

More than 350 companies have passed through our doors since we were founded in 1963. The 93 that remain in the Greater Philadelphia Region account for over $9 billion of annual sales and 15,000 current direct jobs. These jobs pay an average of $89,000 per year, a remarkable figure considering today's economy.

Our campus features two business incubators, collectively known as "the Port," that are home to more than 30 start-up companies in life sciences, cleantech/greentech and information technology.

These companies are at the cutting edge of scientific innovation. To give you an example, one of our start-up residents—Invisible

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Sentinel—is working on a fast, efficient way to detect food contamination. Another—BioNanomatrix—is using nanotechnology to decode the human genome. And a third—Enzybel International—a Belgian company, is dedicated to the production and commercialization of sustainable compounds derived from nature.

In our 48 years of operations, we have helped to create the model for the modern research park and high tech business incubator. Our graduates include Centocor, the maker of Remicade, to treat rheumatoid arthritis; global software giant Bentley Systems; and financial services powerhouse SEI Investments.

One of our latest incubator success stories—Avid Radiopharmaceuticals—exemplifies America's potential for innovation and entrepreneurship in the life sciences. Avid was founded by Dr. Dan Skovronsky, a neuropathologist at the University of Pennsylvania who had an idea for a technology that would revolutionize the ability to diagnose Alzheimer's and other diseases at an early stage.

In 2005, Dan moved his brand-new company into the Science Center's incubator with one employee—himself. Over the next 4 years, Avid refined its technology and added jobs. By 2009, the payroll had grown to 37 people. The company outgrew its space in our incubator and moved into custom-fitted, full-price office and lab space on our campus. Since then, the company has grown to more than 50 employees.

Last fall, Avid was acquired by one of our Nation's leading pharmaceutical companies, Eli Lilly, for $300 million in cash up front, plus another $500 million in additional payments over the next few years based on the achievement of certain milestones.

We were thrilled to learn that Avid currently plans to remain at the Science Center, continuing to bring new jobs and economic growth to Philadelphia and our region.

Avid represents a classic example of how research and development in the life sciences are essential to our Nation's economic recovery.

Let's take a step back and look at the economic impact of the life sciences in the Science Center's home State of Pennsylvania.

As noted in the State Bioscience Initiative 2010 Report from Battelle and BIO, the biosciences sector in Pennsylvania employs 81,000 workers in the state at an average salary of $82,000—for a total of $6.7 billion in wages. With a multiplier effect of 4.38, the industry has a total employment impact of 354,000 people.

On a national level, according to the same report, total employment in the U.S. bioscience sector reached 1.42 million in 2008. When you figure in a multiplier effect of 5.8, the total employment impact of the bioscience sector is 8 million jobs nationwide.

These are tough numbers to ignore. Yet the life sciences industry does more than create well-paying jobs. Scientists and researchers are dramatically improving treatments, therapeutics, and ultimately patient care and the quality of life.

Think back to our Port business incubator tenant, Invisible Sentinel. Their work in detecting food contamination may also have applications in the detection of pathogens associated with hospital-acquired infections, as well as in cancer detection, and homeland security.

At the Science Center we look forward to helping our residents advance science and technology and invent new products that will change the world, while creating jobs and economic growth along the way.

I invite you to visit Philadelphia and learn more about us, our track record of success in nurturing entrepreneurs and their ventures, and our unique self-sustaining business model.

In closing, I would like to express my strong support, along with the Chairman and Vice Chairman, for the proposed Life Sciences Jobs and Investment Act. This legislation will help strengthen the biosector's culture of innovation, discovery, education, and job creation across the Nation.

The Life Sciences Jobs and Investment Act will offer tax incentives for small and medium-sized businesses to invest in life sciences research and development on a targeted basis. It will also ensure the availability of an educated, skilled workforce that will sustain our pipeline of bioscience innovations, companies, and jobs over the long term.

One out of every six jobs in the Greater Philadelphia region can be traced back to life sciences. The Life Sciences Jobs and Investment Act is key to the long-term success of this crucial industry sector. This is the kind of proactive legislation that we need to maintain our competitive edge as we ensure that biotech in the region—and the entire country—continues to grow and thrive.

Thank you for your kind attention, and I welcome your comments and questions.

[The prepared statement of Dr. Tang appears in the Submissions for the Record on page 35.]

Chairman Casey. Thank you, Dr. Tang. Dr. Kowalski.

STATEMENT OF MR. THOMAS R. KOWALSKI, PRESIDENT, TEXAS HEALTHCARE AND BIOSCIENCE INSTITUTE, AUSTIN, TX

Mr. Kowalski. Thank you, Chairman Casey, Vice Chairman Brady, and the entire Joint Economic Committee, for inviting me here today.

I am Tom Kowalski, President of the Texas Healthcare and Bioscience Institute. The Institute was created in 1996. We are located in Austin, Texas. Our national partners we consider are Pharma, BIO, and Agrameds, so it covers a whole spectrum of the life science industry.

Our organization's mission is to research, develop, and advocate policies and legislation that promote biomedical science, biotechnology, agricultural and medical device innovation in Texas. We have been at this a long time.

The issues you are considering here today—how targeted tax incentives can be used to enhance medical innovation, life sciences education, and job creation here in the United States—is of great interest to me and of vital concern to our industry.

The impact of the life sciences industry on the U.S. economy is significant. It advances medical knowledge, develops products that keep our country at the cutting edge of global competitiveness, and supports millions of high-quality paying jobs.

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As important as the direct benefits to our Nation's economy, the innovations produced by these companies are also helping Americans live longer, healthier lives.

I would like to share with you the positive impact the life sciences industry has had in Texas, both in improving the health of Texans as well as creating a robust job sector. And much of this development has occurred because of the very vital investments that Texas has been willing to make into the life science sector.

We have a dynamic biotechnology marketplace with an estimated economic impact of $75 billion. The State has many national top-10 rankings in biotechnology and is home to over 4,100 biotechnology, biomedical research, business, and government consortia, medical manufacturing companies, and world-class universities. We employ over 104,000 people at an average annual salary of over $67,000.

A significant number of top global biotechnology and pharmaceutical companies have Texas locations, underscoring the State's vitality.

There are significant factors pointing to the robust growth, and I would like to point out two:

First, University research is the lifeblood of our State's innovation, medical treatments, and job creation. The Texas Life Science Centers in the State, they are the crown jewels by which all of this activity centers around.

Secondly, there has been a significant investment from the State into the life science industry which has enabled research technology transfer and commercialization to successfully occur. Much of the state's investments require academic and private sector collaborations, and that has been key. And the Life Sciences Investment Act will complement these efforts by the potential infusion of industry research dollars and future collaborations which extend to increase workforce, which goes into the entire R&D process.

The State is ready to be able to work with these companies because of these two programs—because of the problems I am about to talk to you about, and focusing on the collaborative efforts.

The Texas Emerging Technology Fund is one of these programs. It is known as the ETF. It has allocated more than $193 million in funds to 131 early stage companies, and nearly $173 million in grant, matching, and research superiority funds to Texas universities. And by "research superiority," we are going out and actually recruiting talent to the State of Texas with the ETF dollars.

Investments by the TETF attract additional investment capital to emerging technology companies. Since the fund's inception, more than $407 million in private capital has been invested in ETF companies—in ETF-funded businesses, which is more than double the state's contribution.

Another key program in Texas has been the creation of the Cancer Prevention and Research Institute of Texas. It is known as CPRIT. The Texas Legislature and the Governor authorized the program in 2007. It has funded 256 grants totaling more than $382 million for cancer research, commercialization and prevention in 46 academic centers. More than $500 million including matching funds have been invested in Texas' extraordinary efforts to lead the Nation in cancer research.

CPRIT has become one of the largest cancer research grant-making organizations in the Nation. Our focus in Texas has been to create a strong environment. How do we grow our own? How do we keep the companies we are creating? How do we attract additional companies into the State? And, more importantly, how do we put our grads that we are graduating to work into these companies?

The industry has enjoyed a strong growth rate of 14 percent from 2003 to 2008. These programs have added stability during the last two years to enable our companies to continue to raise capital and invest that capital into the R&D process. This is what has been helpful for us during this economic recession.

While individual states can do much to support the growth of the life science industry, continued and increased support at the federal level is paramount.

The biotech industry directly provides hundreds of thousands of good-paying jobs for American working families. However, over the last decade, America's leadership in the life sciences industry has begun to erode.

To retain those jobs and to create new ones, the success and growth of the industry's basic research efforts, as well as innovations in effective treatments and associated technological advancements, must remain in the U.S. where they will contribute to our Nation's future economic growth and international competitiveness.

Unfortunately, as the cost of developing new biotech products in the U.S. continues to rise, companies are under great pressure to find lower-cost locations to conduct their research and development.

We can adjust our tax policies and remain the international leader in biotech research, development, and manufacturing, or we can watch the industry move overseas like so many before it.

Narrowly tailored tax incentives aimed at ensuring investment in domestic biomedical research and development will create a demand for highly skilled workers, promote higher education in the life sciences, encourage greater scientific collaboration, and improve our Nation's overall economic well-being and health.

Thank you for the opportunity to be here today.

[The prepared statement of Mr. Kowalski appears in the Submissions for the Record on page 36.]

Chairman Casey. Thank you, Mr. Kowalski. Dr. Sands?

STATEMENT OF DR. ARTHUR T. SANDS, M.D., PRESIDENT/CEO/DIRECTOR, LEXICON PHARMACEUTICALS, INC., WOODLANDS, TX

Dr. Sands. Thank you. Good morning, Chairman Casey, Vice Chairman Brady, Members of the Committee, ladies and gentlemen:

I am President and Chief Executive Officer of Lexicon Pharmaceuticals, and I am honored to be appearing before the Committee today on behalf of the Biotechnology Industry Organization, BIO.

BIO represents more than 1,200 companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.

When I founded Lexicon in 1995, we were a small, privately funded research-stage company. We now employ 290 individuals,

and we have 7 drugs in development. Currently there are thousands of similar companies throughout the United States—each one with molecules and drug candidates that could change the face of modern medicine.

Biotechnology may hold the answer to medical problems that face America from the devastation of cancer and AIDS, to the personal losses of Alzheimer's and Parkinson's Disease, and to the spiraling costs of health care associated with diseases that are reaching epidemic proportions such as Type II diabetes.

Additionally, the biotech industry is a thriving yet I'd say constantly struggling industry. It is a growth engine directly employing 1.4 million Americans in high-quality jobs, and indirectly supporting an additional 6.6 million workers.

Despite these windows of opportunity that face us in biotechnology, the research and development effort is truly a difficult, arduous, and very long process. It takes an estimated 8 to 12 years for one of these breakthrough companies to bring a new therapy from discovery to market, costing between $800 million and $1.2 billion.

These are estimates that of course there have been many studies on, which we have all read. I have to say, we are actually living these numbers, and we are having to raise the capital associated with all these figures. Through this time, Lexicon has raised up to about $1.2 billion. We have done that through private investment. We are very fortunate to have strong investors, but it is a very difficult thing, to consistently raise capital like that over 15 years with the hope of bringing forward the medicine that we've created. So those are very real numbers.

Due to this capital-intensive process, biotechnology has turned to the private-sector investors, and we are publicly traded, as well, and collaborative agreements to finance the early stages of therapeutic development. We have done over $450 million worth of collaborations. We've reached out to bigger companies, such as Genentech and Bristol-Myers Squibb to help fund our discovery process, but now we are trying to develop innovative therapies on our own.

However, I would say the current economic environment has made private investment dollars extremely elusive, especially during the recent financial crisis. It has been a very difficult time, resulting in life-saving therapies for patients being delayed or shelved. We've actually seen some of this happen at our company.

Early and midstage companies have been hit the worst; last year, Series A initial funding deals brought in half of what they did in 2009.

As U.S. biotech companies face financial uncertainty, other countries are moving ahead, including China and India, and we have seen business moving to these countries. This lag puts us at risk to lose our competitive edge.

There are certain steps Congress has taken to maintain the American leadership in biotechnology. Last March Congress enacted the Therapeutic Discovery Project, an important $1 billion tax credit program designed to stimulate investment in biotechnology research and development.

Under this program, small biotech companies received an infusion of capital to advance their innovative projects and create and sustain American jobs. Congress should expand and extend this program.

There was a cutoff there of 250 employees to be included in the program. At 290 employees actually couldn't be included, just because we were 40 employees over the limit.

Additionally, Vice Chairman Brady recently introduced the American Research and Competitiveness Act which would support and foster the creation of high-wage jobs associated with R&D in the biotech industry by strengthening and making permanent R&D tax credits.

Chairman Casey has introduced a bill, the Life Sciences Jobs and Investment Act, which would allow biotech companies to elect an increased R&D credit for their life sciences research, or to repatriate up to 150 million in foreign earnings to invest in job creation. I definitely believe those should be passed.

Given the long R&D timelines and the truly arduous road to bring a therapy from bench to bedside, emerging biotech companies, which are not currently profitable, and that is most companies, are unable to immediately benefit from many of the current tax incentives, given the way that they are structured.

In the reduced capital gains rate for sale of qualified small business stock, IRC Section 1202, there is greater theoretical and practical impact on companies like ours, and throughout the biotech sector. This is due to the complexity of the rules, its limited scope, subsequent changes in tax rates and alternative minimum tax. Among other challenges, the section employs a test in which the corporation's gross assets must be less than $50 million in order to be eligible for the preferential capital gains treatment. When intellectual property is incorporated as an asset, small biotech companies are almost always over the $50 million limit, and we don't start in garages. We start in very expensive garages, okay, with our intellectual property.

So while modifications to Section 1202 would represent key improvements in the biotech environment, Congress has the opportunity to enact new tax incentives which would further encourage private investment in our industry.

Historically, Congress has provided tax incentives to high-risk industries as a means of encouraging investment in these new endeavors, which it deems important. Research and development in the biotech industry is an extremely high-risk undertaking. Small oil and gas exploration companies face similar challenges to biotech, and Congress responded by including provisions in the code allowing investors to take advantage of tax benefits accumulated by these high-risk companies.

If applied to biotechnology, these partnership tax incentives would encourage biotech investment.

In 2000, Lexicon completed one of the most successful IPOs in the biotech industry, raising $220 million. Companies today with science just as groundbreaking as ours are unable to access the capital markets, given the state of the public markets.

The U.S. biotech industry is a thriving and, as I said, continually struggling growth engine for the American economy, creating high-

quality jobs in every state, and improving America's health and well being.

Congress has the opportunity to encourage investment in this industry by both improving our current programs and incentives, and by creating new ones that will recognize the vital part the biotech industry plays in America's future.

Thank you very much.

[The prepared statement of Dr. Sands appears in the Submissions for the Record on page 38.]

Chairman Casey. Dr. Sands, thank you very much. Mr. Heesen.

STATEMENT OF MR. MARK G. HEESEN, PRESIDENT, NATIONAL VENTURE CAPITAL ASSOCIATION, ARLINGTON, VIRGINIA

Mr. Heesen. Thank you.

For the last four decades the venture capital community has served as a founder and builder of companies, a creator of jobs, and a catalyst for innovation in the United States.

According to a recent study conducted by Global Insight, companies that were started with venture capital since 1970 now account for 12 million American jobs and $3.1 trillion in revenue in the United States in 2010.

Nowhere has the power of venture-backed innovation been felt more strongly than in the life sciences sector. Approximately one-third of all venture investment is directed into biotechnology and medical device startups each year.

After funding companies such as Genentech, AmGen, and Medtronic, the venture capital industry has helped bring countless lifesaving medical innovations to market. In 2010 alone, venture capitalists invested nearly $6 billion in biotechnology and medical device startups.

Today I want to cover some important ways that you as policymakers can help ensure that our life sciences startup ecosystem can continue to prosper.

To begin, Congress must continue to encourage long-term—and I emphasize "long term"—investment through tax policy. Returns earned by venture capitalists and entrepreneurs as a result of successfully building companies should be taxed at a capital gains rate that is globally competitive and preserves a meaningful differential between ordinary income and capital gains.

This maintains proper incentives for investors who are dedicating more than a decade of capital and time to their companies. We appreciate the support of many Members of Congress, including Chairman Casey and Vice Chairman Brady, in recognizing this dynamic.

While the R&D tax credit is important to many midsized and large corporations, it is not a critical component for startup biotechnology and medical device companies. Our companies are typically losing money and thus cannot use a credit that is structured for companies that are profitable.

As lawmakers consider tax reform, we urge you to build a system that supports both emerging companies and multinational corporations. Certainly we believe that recent reports of possible proposals to force certain partnerships to pay corporate tax rates is a move in the opposite direction of such a system.

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We are also beginning to look towards protecting future sources of venture capital within our industry. Private and public pension funds currently represent 40 percent of all the institutional venture capital that we receive. At the same time, we are beginning to see a movement from defined benefit to defined contribution pension plans, particularly at the state and local level.

If this shift continues, the venture industry will risk losing a critical source of capital as there are currently no viable means by which a defined contribution plan can invest in the venture capital asset class. We hope to work together to develop viable solutions to this looming concern over the next several years.

We also must address problems at the end of the venture capital cycle. Studies show that more than 90 percent of job creation occurs after a venture-backed company goes public. In the last decade, however, the market for venture-backed IPOs has suffered due to unfavorable market conditions and ramifications of regulations that attempt to fit everyone into the same criteria.

The NVCA is actively engaging with Congress, the Administration, and regulators on ways to make the path to an IPO once again smoother, particularly for small-cap companies.

Regulatory barriers are also impacting medical innovation. In recent years, when evaluating new drugs and medical technologies, the FDA has become increasingly reticent to balance the benefits against the risks of new therapies and technologies for seriously ill patients, resulting in less and later access to life-saving products when compared to other countries.

We are calling for FDA reform that returns a balance to the review and approval process and reflects the importance that patients and health care providers place on access to new products in the United States.

The NVCA understands that these reform measures require an FDA that is adequately funded. While all agencies should root out waste, untempered resource reduction at the FDA will result in a reduction in innovation being delivered to the American people. We ask that Congress be mindful of the tradeoff here.

Maintaining America's global innovation advantage also requires continued federal funding of basic research and development. We understand the need for fiscal responsibility, but drastically reducing this research funding will be devastating long term to our global economic leadership.

Further, we remain extremely disappointed regarding the once-again stalled SBIR reauthorization bill. The ongoing lack of clarification regarding whether venture-backed companies can apply for SBIR grants has unquestionably hurt the innovation pipeline. We hope that another year does not go by in which the most promising, innovative venture-backed projects are not eligible to receive SBIR grants and subsequently die on the vine.

The venture capital industry remains committed to the long-term investment in our country's future. We look forward to working with Congress to ensure that our companies continue to grow and create significant economic value for years to come.

Thank you very much.

[The prepared statement of Mr. Heesen appears in the Submissions for the Record on page 42.]

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Chairman Casey. Mr. Heesen, thank you very much. I appreciate all of our witnesses' testimony. We will do a round of questions, and I will start.

I first of all wanted to ask—and this is not necessarily directed to any one of our witnesses; each and every one of you could provide perspective on it—it is the basic question about not just the divide between private sector investment in R&D versus public sector, but in particular if we can state, as I did for the record, about the investment of government dollars in basic research, which is still I guess around 57 percent. Moving away from that question, I would ask the panel: What are the most efficient uses of government resources in R&D? We know it is more predominant in basic research, but beyond that question, what is the best and most efficient use of federal dollars? We can start with Dr. Tang and go down the panel.

Dr. Tang. Certainly, Senator Casey.

I think you are absolutely right. There needs to be increased spending on basic research. That is, research that is pre-competitive. In other words, it is not yet to the point of commercialization.

I think we have become more enlightened about the innovation process, though, over the years. And I have to say that translational research is now known to be separate and distinct from basic research.

Chairman Casey. Can you define and distinguish the two?

Dr. Tang. Certainly. So in the life science area, translational research is what is known as the work that needs to be done to move it from bench, the laboratory bench, to the bedside.

That is a very different set of challenges. It involves a clinical approval from the FDA. It involves reimbursement definition from CMA. So there are several factors that go beyond what the government is funding.

This area of translational research, I think, has not been highlighted from a policy perspective as an area that needs more funding, and it certainly does. But it is also an area, I think, where there could be better public/private partnerships. In other words, the use of not only federal funds, but state funds, and regional economic development funds to help them along the way.

Chairman Casey. Anyone else on this? Doctor.

Dr. Sands. Yes. I think it would be interesting if the Federal Government could help fund clinical trials. For example, with our diabetes drug alone our Phase III clinical trial alone is $200 million. And this is given the rising hurdle that we face in diabetes to prove both safety and efficacy.

I know that the Federal Government does conduct a large number of its own trials, but I think it would be very interesting if companies could also be eligible for that kind of funding so that it's not necessarily conducted through the federal, you know, NIH and other investigational organizations, but actually if companies could apply for such grants.

Chairman Casey. Could you just walk through that for a second? Today, in terms of funding for clinical trials, how does that work? If you can just describe the process?

Dr. Sands. Yes. It is privately funded. We have to raise capital from investors, and then invest that money—spend the money on

clinical trials. We send the money to all of the research organizations to sponsor those trials. The money goes to numerous centers for each patient on a per-patient basis.

And I don't know of any methodology where companies can apply for grants to actually fund those trials. You can collaborate with NIH, but then the NIH is running the trial and that is a challenge. We are actually trying to get one of those going in schizophrenia with the NIH right now. They are very interested in funding that trial. It has taken a long time to get that established.

But I personally believe that more investment dollars by the government in translational research outside the walls of the government would be very important, in my view.

Chairman Casey. I am almost out of time. Mr. Heesen.

Mr. Heesen. Well from a business perspective, a venture capitalist is not going to put money into basic R&D. That's not the job of the venture capitalist. The job of the venture capitalist is to take data and research that's been done from the basic research and apply it, and help companies to grow in that regard.

However, there's also a point where government needs to be more effective. And I think the real highlight there is the SBIR program right now. The fact that a venture-backed company cannot take part largely in that program because it is getting venture dollars, these are companies that actually were vetted by venture capitalists who think that these companies actually have potential, and the government is saying, okay, well that means that you don't need any more money. So instead, we will invest in those companies that did not pass venture capital muster.

And that, to me, demonstrates that you need to be looking at companies that have a true potential for success at the end of the day. Many of our companies fail but at least give us a leg up because we've looked at these companies and we see what companies have real expertise, and a potential to move cancer, Alzheimer's, et cetera.

Chairman Casey. Thank you. Mr. Kowalski, and then I'll turn it over to Vice Chairman Brady.

Mr. Kowalski. A decade ago we were losing companies in Texas. And by the implementation of the two funds that I spoke about, the ETF, what those dollars did is it allowed the companies to leverage those state dollars, and to be able to take those state dollars and then bring in matching dollars and be able to invest those companies.

Let me just give you two figures. In the biolife sciences side, there were awards of $83 million given. They leveraged those dollars to $138 million. So there was a return on investment. On the research superiority where they were going out and attracting research—the best of the best, and the George Steinbrenner model, and recruiting them into Texas, there was $85 million in grants given. They leveraged that to $484 million.

So it was the way and the approach that these funds were set up that allowed that leveragability and, believe it or not, 10 years now we're keeping our companies in the state. And that is the best news.

Chairman Casey. Vice Chairman Brady.

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Vice Chairman Brady. The "George Steinbrenner model"? In Texas we don't really talk about New York models.

[Laughter.]

Tom, you should know that.

Mr. Kowalski. Sorry, Congressman.

Vice Chairman Brady. I would first like to ask permission to submit for the record from Congressman John Campbell, a member of the Committee, the statement by the California Health Care Institute related to innovation and job growth, if I may.

Chairman Casey. It will be submitted for the record.

[The statement by the California Health Care Institute, submitted by Representative John Campbell, appears in the Submissions for the Record on page 48.]

Vice Chairman Brady. Several of you have made the point that America is at risk of losing its leadership position in this very important industry.

Dr. Sands, in your written testimony you said many countries in Western Europe are implementing biotech-friendly tax incentives, including lowering the corporate tax rate for innovative industries as a means to grow their 21st Century economies.

Tom Kowalski said, over the last decade, America's leadership eroded. We can adjust our tax policies and remain the leader, or watch industry move overseas.

As we explore and move toward a lower tax rate with fewer exceptions, deductions, and complexity, knowing that is ultimately the goal, what tax changes can we make? What are the highest priorities in tax law to make today to ensure that private capital flows to the United States, so that this is the best tax climate in order to make these investments, and that encourages the life sciences innovation to both grow here and remain here as well?

Dr. Sands, and Mr. Kowalski, I will start with ya'all.

Dr. Sands. Go ahead. You can start.

Mr. Kowalski. Well we can take a look at state models. I think the tax credits that are allowed a company in the life science structure, particularly in the biotech arena, because many of these companies are so small, it goes to the bottom line. And you can see what the states are currently doing.

Right now—and this is according to the Battelle Report that has been produced by BIO—38 states are offering R&D tax credits. Twenty states are offering tax credits to angel investors who invest in technology companies. Twelve states are reported providing tax credits to individuals who invest in early stage venture funds.

One of the things that we have been advocating in Texas—and by the way, we do not have an R&D tax credit in the State of Texas; we're one of 12—and what we are advocating right now is a sales tax exemption on the purchase of equipment that would also be utilized in the R&D process, as well as the manufacturing process.

And to many of our companies, this is bottom line. It goes beyond that, as well. It is an economic development driver. So our chambers, our economic development corporations, are also advocating for this as well because the money that is saved is then reinvested back into the R&D process and utilized in the manufacturing process.

Vice Chairman Brady. Is that a higher priority than making, expanding, simplifying, and making the R&D tax credit permanent at the federal level?

Mr. Kowalski. I think making it permanent is—should be a priority, because it leaves the industry guessing. And so, yes, I would say it should be a priority.

Vice Chairman Brady. Well it seems like today we are buying the R&D car on installment payments, but we are not allowed to drive it as far and as fast as it can go by not making it permanent.

Dr. Sands.

Dr. Sands. Well I would echo what Tom just mentioned. But I would say conceptually anything that would reinforce long-term thinking and long-term investment.

I think one of the problems we have that I see in this country, and even from the investor side, is very short-term thinking. And the R&D process in our industry is extremely long, probably one of the longest.

The repatriation of capital for the large corporation. I know we are focused a lot on the small companies, but we do deals with big companies. And if their capital is locked overseas, there's less to do—less for us to do deals with. And we have actually seen that.

I find that whole concept just bizarre to me. I am not a tax expert, but if that capital could come back to the major American corporations, I believe they would be another source of funding for R&D for the small companies.

Vice Chairman Brady. Right. Thank you, Doctor. Mr. Heesen.

Mr. Heesen. I think a venture capitalist looks at things from the eyes of the entrepreneur. If the entrepreneur is happy, the venture capitalist is going to be happy. You have to look at and talk about the long-term dedication that entrepreneur has.

Is that entrepreneur going to leave AmGen or Medtronic and go up and create his or her own company? They're going to do that if they see a long-term tax potential. And that means a capital gains differential that gets that person up every day and says, not only am I going to try to help cure cancer, but I am also going to see an economic benefit at the end of the day.

And so making sure that there continues to be a distinction between ordinary income and capital gains is critically important.

And then also making sure that capital gains, we believe after seven years, you should not be paying capital gain, even. If you are going to lock up your money and your time that long in trying to create a drug, or a device that is going to benefit millions of Americans, that is something that should be—if you are risking your time and your money and venture capitalist money, at seven-plus years you should be looking at that very differently than a hedge fund person doing day trading.

Vice Chairman Brady. I should have warned you. In Washington you are really not supposed to talk about the profit motive, really. It's a nervous thing around here.

Dr. Tang.

Dr. Tang. Right. I certainly agree with the comments made by the fellow witnesses. I go back to what Mark just mentioned. I think risk taking has to be rewarded for the long term. That is very, very key.

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For start-up companies, in terms of policy, net operating losses have to be monetized. And the states compete on that level, but foreign municipalities put some very attractive offers on the table. So I think we need to acknowledge that entities outside the U.S. are making it very attractive for U.S. companies to do business there.

How are we going to catch up? And the Life Science Investment Job Act I think accounts for that. Repatriating foreign profits back into the U.S. But the piece that is the most helpful about that potential legislation is that it will enable investment in research infrastructure and the startup companies that Mark and his members fund, as well as all of the organizations that we have represented today.

So you essentially renew the ecosystem in the U.S. for innovation by repatriating these profits.

Vice Chairman Brady. Thank you very much. I appreciate it.

Chairman Casey. Congressman Cummings.

Representative Cummings. Thank you very much, Mr. Chairman.

You know, when I participate in these hearings I am always wondering how it plays back home. In other words, if my constituents are looking at this, I am trying to figure out what they are thinking. Okay?

And, you know, Dr. Kowalski and Dr. Tang, you are both deeply familiar with the significant role that—and I guess all of you are—that university research and public investments play in scientific breakthroughs and discoveries. Yet, given how long—and just to pick up where we left off—and complex the scientific process is, I believe a lot of people—you know, my constituents and people looking at this—regular citizens are unaware of the connection between the life sciences industry and the average citizen's daily life.

Therefore, they wonder why we need to invest federal dollars in what can be an abstract and elusive field. They just, sometimes people do not see it.

And so can you both cite real-world examples of the value of university research and federal R&D investment in people's everyday lives and whether it be past discoveries, or discoveries that may be right on the horizon? And be brief, because I have some other things I want to get to.

Dr. Tang. Certainly. It is a great question. And I will go back. The Mayor of the City of Philadelphia, Michael Nutter, says the life science industry has to reach not only Ph.D.s but GEDs. So we need to do a better job of making this industry more approachable for the average citizen. Granted.

Now, to your question of how has it impacted daily life? I could go on for hours. New therapeutics, new devices, new diagnostics, better ways to treat diseases early are all part of the basic research that has been funded at the federal level and then translated by venture capital and by state funding and other means into products.

So from the perspective of the Science Center, companies like Centocor with their product Remicade, which was a treatment for rheumatoid arthritis and was initially funded by federal dollars. Now it is the top-selling product in Johnson & Johnson to treat rheumatoid arthritis.

So just about every malady that is being treated today with advanced technology started with federally funded research.

Representative Cummings. Wonderful.

Mr. Kowalski. M.D. Anderson Cancer Center in Houston, Texas. It is a global destination for the treatment of cancer, but the amount of research that is going on at M.D. Anderson today. And it is the full package. It is not only the research, but there is also a commercialization center attached to it to where they are grabbing the latest ideas on the treatment of cancer and commercializing those ideas.

And just in a closing note, the university structure right now, particularly our health science centers, they are being hammered all across the state with this Recession. And the funding mechanism now is so important, particularly with the repatriation and the ability to be able to invest in those university components.

Representative Cummings. You know, I was listening to Arnie Duncan on CNN about how we've got 2 million jobs that we cannot even—we do not have the folks trained to do these jobs because they are highly technical. And I would guess that this is the stuff we are talking about—he is saying that basically there are vacancies. Two million jobs in America.

And I worry about our pipeline and the STEM program and making sure we are preparing our children to take these opportunities. I believe that you can have all the options you want, but if you are not prepared to take them you might as well not have them.

So I just want you to talk about that whole idea of STEM programs and things to prepare our people right here in America to take some of these jobs.

Mr. Kowalski. You know, one of our crown jewels that we do not mention often is the role that our community colleges play. Our community college in the life science field, it not only takes the Ph.D., it not only takes the CEO or the COO, but it also takes a front-line lab worker that knows the mechanisms and knows the equipment and how to utilize that equipment. And those are hourly jobs, high-paying hourly jobs, $18 to $22 an hour.

Our community colleges today I think are able to step into the challenge to be able to develop training curriculum. And they are already in place to be able to train those hourly workers that would be highly skilled and place them in well-paying jobs.

And so it works hand in hand, as we are going through this paradigm of the Recession and our academic components are getting hit, do not forget the role that this curriculum plays in our community colleges.

Representative Cummings. Well I am speaking at a community college graduation on Saturday morning and I am going to quote you on that.

Mr. Kowalski. I would be happy to send you some information.

Representative Cummings. Please do.

Mr. Kowalski. Yes, sir.

Representative Cummings. I see my time has run out, Mr. Chairman. Thank you.

Chairman Casey. Thank you, Congressman. Good questions on the jobs issue.

Next, by order of appearance, Congressman Mulvaney.

Representative Mulvaney. Thank you, Mr. Chairman, and gentlemen, for your time today.

I'd like to talk about an issue that I think is relevant in sort of a different way. This is Small Business Week in Washington, D.C. And, Mr. Heesen, I especially appreciated your thoughts on the SBIR program, something we have been working on, and I wish we could get some permanent resolution to.

I had always assumed before I came up here that this was an industry that was driven by some of the names that I heard earlier, the Genentechs, the Medtronics, the Eli Lillys. I am getting the impression that is not necessarily the case. And I am wondering, Mr. Heesen, if you could at least maybe help educate me a little bit, or perhaps all of you, on the role that small business plays in this particular industry.

Mr. Heesen. Well what happens very often today is that your larger pharmaceuticals, your larger medical device companies, are not doing R&D in-house. The way they grow today is by buying smaller venture-backed companies.

It is part of the DNA of many of these large corporations to basically look at what is happening at these smaller companies and cherry-pick and say, you know, we think that this company has potential and we will bring it in-house.

So the small businesses play an absolutely central role today, as more and more large corporations forego doing in-house R&D and go, frankly, shopping around and look at acquisitions of venture-backed companies and/or licensing agreements, which is becoming more and more prevalent as well.

So without these smaller companies, your larger companies are not going to be successful over the long term.

Representative Mulvaney. Let me press you on that. I do not mean to cut you off, but you mentioned before something that caught my attention. Which is, that an R&D tax credit really does not have immediate value to a small company that does not have any tax obligation.

Mr. Heesen. If you do not have a tax obligation, you are not—yes.

Representative Mulvaney. So if the small companies are doing all of the R&D, then how is a tax credit for R&D helping spur research and development?

Mr. Heesen. That is a good question. I think that the smaller companies that try to go public—and there are certainly those who will forego an acquisition because they really want to become a public company, which is a very important public policy goal—those companies eventually are going to get, if they continue to grow and go public, they are eventually going to get to the point where they are tax paying entities and are going to be able to take advantage of that R&D tax credit.

But that is a long time after the venture capitalist has gotten out of line.

Representative Mulvaney. Dr. Sands.

Dr. Sands. Yes.

Representative Mulvaney. You all are, what, seven years into it? Is that what you said before?

Dr. Sands. Fifteen.

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Representative Mulvaney. Fifteen.

Mr. Heesen. Which is typical.

Dr. Sands. Seven drugs in development.

Representative Mulvaney. There it is, right.

Dr. Sands. But I do think the tax credit benefitting large companies is also important for small companies. You mentioned Genentech. We did a deal with Genentech. If they have more R&D dollars, they do deals with small companies. They do not just acquire them.

We studied 500 genes with Genentech. We knocked down and studied the functions of 500 novel genes. It was a core part of their research program and ours. In total, we've studied 5,000 genes. And this is all a product of the Human Genome Project, which was started of course and led by the United States.

But now all that information is out there in the rest of the world, and they are using it. But I do believe benefitting large companies is important, too, and will be important indirectly to us, because we seek deals with the large companies.

Representative Mulvaney. Yes, sir.

Mr. Kowalski. We had also built in, in Texas, at the time we did have an R&D tax credit, because the companies would take such a long time, we had built in a very healthy carry-forward. It was a 25-year carry-forward. So in the event, when they were profitable, there was an opportunity to begin to use those credits.

Representative Mulvaney. Got 'cha. Let me ask you a different question, because we have heard some discussion here today about the issues about repatriation and so forth. I guess I am trying to get a fairly simple question here, because I have only got 50 seconds left, which is:

What is preferable? I mean, in the overall scheme of things, what would you gentlemen rather see? A world where you have to come here every couple of years and ask for an R&D tax credit extension? Or a simplified tax system where the corporate tax rate is 25 percent; we have a territorial income tax system across the board?

Mr. Heesen. Simplification. And, more important, stability is most important, I think, to a long range planning of an entrepreneur.

Representative Mulvaney. Does anybody disagree with that? Dr. Tang.

Dr. Tang. I only disagree to the extent that the rest of the world has a different motive and a different method. If "simplify" does not make us globally competitive, then we cannot simplify for the sake of simplifying.

And to an earlier point, I think the R&D tax credit is important but it needs to catch up with the model of how R&D is being done in the life science industry. It needs to recognize that more R&D is being done off balance sheet from the large corporations, and that needs to be accounted for and encouraged.

Because the smaller companies unequivocally are the ones that are generating the jobs today. The larger companies are all consolidating and cutting jobs. So we have got to catch up with the model that actually exists in the world today.

Representative Mulvaney. Thank you, gentlemen. Thank you, Mr. Chairman.

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Chairman Casey. Thank you very much. Senator Lee.

Senator Lee. Thank you, Mr. Chairman.

I would like to follow up on the point made by Congressman Mulvaney. We have talked a lot about R&D tax credits today, and I understand the allure that those credits hold for this industry. And there is no one who wants more to incentivize and encourage research and development, particularly in this area, than I do.

And at the same time, I share many of the concerns that I think were underlying Congressman Mulvaney's questions in that I wonder whether we could not benefit from an effort to simplify our tax system. Even if, as Dr. Tang points out, it is not the way the rest of the world does it, it seems to me to be one way in which we could offer some value-added to would-be investors to invest in the United States.

So, Dr. Sands, I was noticing you pointed out that investment in this area really requires foresight not just of a few years but of several decades.

Dr. Sands. Yes.

Senator Lee. With an R&D tax credit, with a tax credit of any sort, even if you build into the law the ability to carry forward the benefit of that 25 years or so, that further complicates an already extraordinarily complicated tax code; one which, when considered together with all of its implementing regulations, occupies tens of thousands of pages.

Nobody has ever read the whole thing. If they did, they would promptly die.

[Laughter.]

Just like, as I am told, the guy who ran the first marathon collapsed and died right after. Very sad. I ran a marathon once; I did not die, but I felt like I was going to.

[Laughter.]

So, anyway, Dr. Sands, my question is: In light of your comment about how this requires foresight of many decades, don't you think we could benefit from moving toward a simpler tax code? One that tries to flatten out rate structures? It seems to me that regulatory and tax simplification could perhaps give the greatest degree of assurance of certainty that you would need in your industry.

Dr. Sands. Yes. I mean, unquestionably. The simpler, the better. But I have no idea how to accomplish that. I have never seen that done before. But if you guys can do it, I think you should.

[Laughter.]

Now I can say from the industry perspective, whatever can help not only the small companies but also the large companies, view research as a long-term investment worth doing, those incentives, if it is worth having something special, I think this industry is unique in that the basic unit of time is the decade. And that is a different way of thinking than most industries.

And given that it is at the core of health costs and other things, it may be worth some special attention. But, you know, I cannot tell you how that could be done.

Senator Lee. Okay. Thank you. Another area that I am always looking into, I always try to look at areas within government where we could simplify and roll back things that government does that make things more complicated, I like government solutions that do

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not cost us money in order to implement but that will yield the benefit to you.

In this industry, and this question is open to any of you who have an opinion on it, is the current patent structure that we have in place for pharmaceutical products sufficiently long to enable you to recover what you need to recover for the products that you are now developing?

Dr. Sands. No, it is not.

Senator Lee. What would, in your opinion, be a better solution? One that would still take into account the goal of not holding drug patents open perpetually, but would be more suitable toward allowing you to recover your investment?

Dr. Sands. Well I understand the difficulties in extending patent life from a statutory standpoint, but I think data exclusivity time periods, regulatory exclusivity, perhaps would be more manageable. And I know people have tackled that with regard to biologics.

I think it should apply to small molecules, because the extended regulatory hurdles that we have to overcome—for example, in diabetes trials—eats into the patent life, eats into our time frame to actually get a return on the investment. And as I said earlier, these numbers are very real.

Our Phase III trial alone is $200 to $300 million in Type II diabetes. And if——

Senator Lee. And the entire time the clock is ticking.

Dr. Sands. You are burning, yes, not only the dollars, but you are talking about a three- to four-year just Phase III period. And we file patents seven years previous to starting that. So you have burned up 10 years of your patent life before you even get on the market, at least.

So this concept of a 20-year patent is pure fiction. It really does not help you during the vast majority of your time there.

The other thing you mentioned about saving money and simplification. If you can cure diabetes, you will save the Federal Government billions and billions of dollars in terms of health care. You are talking about 35 million Americans with diabetes right now, going up to 50.

Senator Lee. Are you talking about Type I or Type II?

Dr. Sands. I am talking about Type II, adult onset diabetes. And the drug we are working on, by the way, should work in both.

Senator Lee. Great. Happy to hear that. I see my time has expired, so thank you.

Chairman Casey. Thanks, Senator. Congresswoman Maloney.

Representative Maloney. Thank you, Mr. Chairman. We in Congress get an opportunity to take all these ideas and translate it into legislation, and we do have a bill that one of you, several of you referenced during the hearing. But I would like you to comment on how it would help incentivize your numbers, and also to follow up on Dr. Tang's statement, catch up with models that exist already internationally.

Specifically, I talk about the bill—I would ask you to comment on the bill designed to provide companies with a choice between an increased R&D tax credit for the first 150 million of research in the life sciences, or the ability to return up to 150 million in foreign

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earnings to the U.S. free of tax, provided the earnings are used in life sciences.

The legislation also provided that 100 percent of qualified life sciences research done through nonprofit research areas or centers, or schools, would be eligible for the credit. And I must note that many of our universities have spoken to others about the support for research that is done in the United States. So I would like all of you to comment, or give us your insight on this legislation. Or if you think it should be changed in any way, or modified, or adjusted to what is happening internationally. Your comments, and just go down the line.

Dr. Tang.

Dr. Tang. Thank you, Congresswoman.

If I may begin, I believe it is a very well-crafted bill. I think it accounts for two things. The first is that R&D has become more expensive, more risky, and takes much more time, and is more expensive than we have ever imagined. And so the increase in encouraging more R&D on the one hand is important.

The other phenomenon is recognizing that countries outside the U.S. are making it very attractive for U.S. life science companies to do business in their countries. The only way we are going to gain from that is if we can repatriate some of the profits that are earned in those countries.

And so in effect what you have in this bill is a way of replenishing the ecosystem of life science ventures. Because the funds are directed towards improving and increasing the likelihood that small companies will thrive and exist who will probably be acquired at some point by these larger companies. And so it is sustainability, if you will, applied to the venture ecosystem in the life science industry.

Mr. Kowalski. Congresswoman Maloney, if you will think about this without repatriation, that money stays with our foreign competitors. And it is invested in their communities, in their university systems, training their researchers. I would rather have it here.

It is a great bill. We like it, and we support it. I particularly like the university component and allowing those universities to participate within it.

Thank you.

Dr. Sands. I think also it is an excellent bill. I think $150 million is not enough. I do not know why that number is what it is. It should be significantly more. And I think that then we would see our companies spending more on research.

Pfizer, for example, has been shutting down their research program. They are cutting, I think it is about 2- or 3,000 jobs. And that does not just hurt Pfizer; again, it hurts the little companies that seek to do business with the Pfizers of the world.

Mr. Heesen. Well most venture-backed companies will not be able to take part in this. It is still, as Dr. Sands says, very important that we have larger corporations out there who will have the ability to acquire us, or to enter into licensing agreements and other types of activities.

Most biotechnology companies will not have the ability to go public. And so they have to have another exit. And that exit is working with larger corporations. If they are healthy, we will be able to

work with them a lot longer and it will be a much healthier relationship at the end of the day.

Representative Maloney. Thank you. Some of you, or many of you have also mentioned the fact that we are now in a world economy, and we have to compete in a world economy. So could any of you, starting with you, Dr. Tang, talk about how the U.S. R&D tax credit fares when compared to other countries?

We used to lead the world. I understand that is not the case now, but where do we stand?

Dr. Tang. I think the statistic you mentioned before is we are now 24th. So we are clearly behind. Other countries with new sources of capital, the BRIC companies, Brazil, Russia, India, China, in particular, are out-maneuvering us. They are making it more attractive to do business and create innovation on their shores, not our shores. And I think it is a desperate situation, and it is one that I think threatens our economic development.

Mr. Kowalski. Our global competitors are reducing their costs that makes it attractive for our companies to go over there. I think the most exciting thing this week and this year has been hearing your comments, and your knowledge level in terms now of what it takes to build a successful American life science company.

Mr. Heesen. What you are seeing is an increasing amount of interest by U.S. venture capitalists in looking at companies that are not domiciled in the United States.

We follow the entrepreneur, not the other way around. And if the entrepreneur has a good idea and they can be funded in another country, that entrepreneur is going to get funded with U.S. venture capital.

If it is in Bangalore or in Birmingham, Alabama, we are going to make the decision based more on that entrepreneur and his idea than anything else. And so if they are located somewhere else, unfortunately we have to look at those opportunities overseas.

Representative Maloney. My time has expired. Thank you very much, Mr. Chairman.

Chairman Casey. Congresswoman, thank you very much. And I want to thank the other Members who are with us today.

I have just one question, and then both the Vice Chairman and I will wrap up.

First of all, Mr. Heesen, you mentioned the SBIR. You say in your testimony on page 11, "The ongoing lack of clarification regarding whether venture backed companies can apply for government grants (such as SBIR grants) to conduct early stage research has unquestionably hurt the innovation pipeline." And others have referred to it.

It has been stalled in the Senate. It has been a source of frustration for lots of us. Can you just speak to that again?

Mr. Heesen. Absolutely. I mean, the National Institutes of Health has stated that they are seeing the quality of their applications deteriorate because venture-backed companies, which are 50 percent or more owned by venture capitalists, those venture-backed medical device companies and biotechnology companies are precluded from taking part in the SBIR program.

And that simply means that the companies that have either voluntarily said that they don't want venture capital, or who have

gone through the venture capital process and frankly been rejected by venture capitalists, are the ones who have the ability to get these SBIR grants.

Our view is that you want the best companies to be able to get those grants at the end of the day, particularly in these budget-conscious days that we are in, and that means that we should be able to participate—our kinds of companies should be able to participate, just like any other biotechnology or medical device company.

It is an equal footing. It is not like we want preference. We just want to be viewed as the same. In many of these companies, there are five people working in a lab. If they are venture-backed, there are five people working in a lab. If they are not venture-backed there are still the same five people working in the lab. There is not a lot of difference there.

Chairman Casey. Thank you. And I know I have other questions and I will submit them for the record.

Chairman Casey. But I want everyone to know that Vice Chairman Brady and I did a scientific split here, the exact number of minutes, equivalent amounts for Texas and Pennsylvania were provided at this hearing.

[Laughter.]

We had a timer that was right up to the minute. So we are grateful for your testimony.

Vice Chairman Brady.

Vice Chairman Brady. Again, thank you, Mr. Chairman, for holding this hearing on this important issue. Senator Lee and I were noting the irony of the panel's response to his earlier line of questioning. Mapping the human genome? No problem. Simplifying the tax code? Hmmm, not so sure.

[Laughter.]

I appreciate, too, at this point being considered in Congress as we strive toward a lower, more competitive, simpler tax code, what can be done in the interim. Repatriation is an ability to lower that tax gate and allow that private capital to flow back, a no-cost stimulus at a critical time. This is one of the issues we are weighing very strongly.

But I wanted to finish with this, real quickly, to put all this in perspective. What is the latest data on the cost to bring a new drug to market in the U.S.? What range today are we looking at?

Dr. Sands. It is $1 billion to $2 billion. It is up, depending on the numbers. The common study, the Tufts study, is $800 million to $1.2 billion. That is about an eight-year-old study, or a ten-year-old study. So it is enormous.

And each trial period is expanding in time and cost. And this gets to the FDA regulatory burdens being lifted.

Vice Chairman Brady. Is there an average time, Doctor?

Dr. Sands. I would say eight years to bring a drug forward. And that does not count the discovery phase. That is just the clinical development phase, not the laboratory phase.

Vice Chairman Brady. Once you have made the breakthrough, that is the process to bring it to market?

Dr. Sands. Yes. Yes. And there are programs that are called "Fast Track" programs. Those can actually take longer, depending on——

[Laughter.]
The disease.
Vice Chairman Brady. Welcome to Washington.
[Laughter.]
Mr. Kowalski. Ten years ago, that cost was $800 million. So we have bumped it up over a decade a billion plus, and the time has lengthened as well, to bring a drug to the marketplace.
Mr. Heesen. And the important thing here is, once you bring it to market, you also have to get a price for that drug that makes that 15 years worth of work and effort worthwhile. And that is where CMS comes in, and the ability of the Federal Government to price a drug that is available to the public but at the same right rewards 15 years of long toil and investment on the other side.
And there are going to be investors who, at the end of the day, if that price is not set properly, are going to walk away and instead be doing frankly, unfortunately, work in the life science area that is not FDA regulated, or not CMS mandated. And so you are going to be looking at cosmetology types of deals. And is that really what you want this country to be looking at, as opposed to looking at these very important drugs and devices at the end of the day?
Vice Chairman Brady. Dr. Tang, any comment?
Dr. Tang. It is more expensive and more risky. I think that is the bottom line. And that needs to be rewarded in the overall process. And while I certainly appreciate the work that the FDA does, I do not think any business person in the life science industry will say that they are particularly easy to work with.
Vice Chairman Brady. We have got some work to do, especially if America is to continue its lead in this innovative area. So again, Mr. Chairman, thanks for holding this hearing.
Chairman Casey. Vice Chairman Brady, thank you.
Mr. Heesen, Dr. Sands, Mr. Kowalski, Dr. Tang, we want to thank you and your staff for making yourselves available for this remarkably good testimony, one of the best panels I have ever been a part of, or witnessed, I should say, at a hearing in the Senate. You have provided us a lot of perspective and a lot to think about. We will submit more questions for the record.
We should note for the record that the record will remain open for five business days for Members to submit both statements and questions for the record. And with that, we are all grateful for your testimony and the healing, the hope and the jobs that come from the investments that we want to incentivize in the life sciences. So thank you very much for your testimony. We are adjourned.
[Whereupon, at 11:16 a.m., Wednesday, May 25, 2011, the hearing was adjourned.]

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SUBMISSIONS FOR THE RECORD

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PREPARED STATEMENT OF REPRESENTATIVE KEVIN BRADY

Mr. Chairman, I would like to thank you for holding today's hearing on the life sciences industry. I would also like to welcome all of today's witnesses, especially my fellow Texans, Dr. Arthur Sands and Thomas Kowalski—both highly respected in their fields—and thank them for taking time out of their busy lives to testify today.

America's life sciences industry leads the world with innovations in biomedical science, biotechnology, agriculture, and medical devices. This industry's products help Americans live longer and healthier lives. It employs 1.4 million Americans and accounts for 1/3 of all research and development expenditures by private U.S. firms.

The Joint Economic Committee is holding this hearing today to discover what steps the U.S. government may take to help the life sciences industry prosper and strengthen its competitiveness both here and abroad.

Investment in research and development in life sciences creates good, high-paying jobs; keeps the United States on the cutting edge of global competitiveness; and enhances the quality of life not only for Americans, but for people everywhere.

Yet the upfront cost of investment in this industry is extremely high—companies spend years researching and testing, pouring millions and at times billions of dollars into the research, testing and trials of medical ideas that may never make it to market. Yes, the return can be high—but the investment is highly risky as well.

In this vital area of the economy, America is falling behind. Other countries are increasing their incentives for R&D in an aggressive effort to attract investment and the high-paying jobs that go with it. America's share of the world's research and development pie is shrinking as our global competitors are taking a page from our playbook and beating us at it. In 1981 America led the world as the first to create an R&D tax credit. By 2009 we ranked 24th out of 28 countries in the strength of our R&D incentives.

We need to rethink our approach to incentives. It's time we modernize the R&D tax credit; strengthen it to encourage companies to make even more substantial investments in research and hiring; and make it permanent so businesses and investors have the confidence to make long-term decisions.

At the same time, we should reform the way our overall tax structure operates by lowering the rate and simplifying the code. At 35 percent, the United States has one of the highest corporate tax rates in the world. Our complicated tax structure puts Americans at a disadvantage when competing at home and abroad. More than $1 trillion in capital earned by American companies and workers is stranded overseas because our tax code strangely penalizes companies for bringing profits home.

As an interim step, we have an opportunity today to temporarily lower tax barriers to incentivize companies to bring those profits back home for investment. The right form of repatriation measure would lower the tax gate and allow private capital to flow back to the United States to be used to create jobs, to expand businesses, and to invest in research.

Additionally, we should examine ways we can help boost incentives even more for the life sciences industry given its unique structure and the benefits it adds to our health and way of life. This could include further strengthening the R&D tax credit, and allowing life sciences companies to claim research expenses paid to universities.

However, we should not limit our considerations of tax provisions only to those benefiting the life sciences industry. The competitive challenges which federal policies pose to life sciences firms merely reflect the tax, trade, and regulatory impediments that all American companies face when competing in global markets.

To begin, we must look at fundamental reform of business taxation:

- We must lower the federal corporate income tax rate to a competitive level, so that both American and foreign firms will make new investments in the United States, creating more and better-paying jobs for American workers.
- We must also lower the after-tax cost of making new business investments by moving toward expensing new investments in equipment and software and significantly shortening the tax depreciation schedules for buildings and other structures.
- Finally, we must enact a permanent and generous tax credit for research and development.

Beyond business tax reform, we must continue to open new markets to American exports of goods and services. I call on President Obama to submit the pending free trade agreements with Colombia, Panama, and South Korea to Congress for approval. And we must ensure that intellectual property rights are fully respected by all countries.

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Finally, we must reform our regulatory structure to assure that the goals we all share for product safety and a clean environment are achieved in a cost-effective way that does not place undue burdens on American companies or their workers.

I look forward to hearing today's testimony.

PREPARED STATEMENT OF DR. STEPHEN S. TANG

Thank you, Senator Casey. I'm Steve Tang, President & CEO of the University City Science Center. It is an honor and a privilege to speak to this distinguished committee today.

Science and innovation are in my blood—and a part of my heritage. I'm the son of two Chinese-born scientists. I was born with high expectations from parents who sought—and largely achieved—the American dream.

My background is in both science and entrepreneurship. I have an undergraduate degree in chemistry from the College of William and Mary and a Ph.D in chemical engineering from Lehigh University—as well as an MBA from the University of Pennsylvania's Wharton School.

As a graduate student, I founded and ran my own technology assessment consulting firm, while at the same time pursuing my doctorate and managing Lehigh's biotechnology research center. After obtaining my MBA, I served as a management consultant at two international firms, focusing on projects in the chemical, environmental, health care and pharmaceutical industries. I then served as the CEO of a hydrogen and fuel cell company, guiding its growth as it moved beyond its start-up phase, completed a successful IPO, and attracted subsequent investment and financing. Next, I ran Olympus America's Life Science division, overseeing operations, finance, strategy, and product and business development.

Since 2008, I've had the privilege of leading the University City Science Center. I was motivated to take the position by my passion for science and technology—and their ability and potential to make the world a better place. And as a newly appointed member of the U.S. Commerce Department's Innovation Advisory Board, I welcome the opportunity to contribute to the national discussion on innovation and economic competitiveness, particularly as it relates to the life sciences.

The Science Center is a private, nonprofit research park and business incubator in Philadelphia. Located in the heart of the city's "meds and eds" community, we have existed at the intersection of innovation and economic development for close to 50 years. We are the nation's oldest and largest urban research park, with 15 buildings on 17 acres containing over 2.0 million square feet of lab and office space. More than 8,000 people come to work on our campus each day.

We are also home to innovative programs, such as the QED Proof-of-Concept Funding Program, which pulls technologies out of the lab and into the marketplace by pairing scientific researchers with experienced business advisors. At the Science Center, we firmly believe that our multi-institutional QED program is a unique and model "public-private partnership" that can be replicated across the nation to help promising ventures cross the "Valley of Death" in funding. I'm proud to report that QED achieved a funding milestone of its own last month when it received a two-year, $1 million grant from the U.S. Economic Development Administration. This federal funding is currently being leveraged with funding previously awarded to QED by the Commonwealth of Pennsylvania and the William Penn Foundation of Philadelphia, plus additional funding from the Science Center and the 19 institutions participating in the program.

The Science Center is owned by 32 of the leading colleges, universities, hospitals and nonprofit institutions throughout Pennsylvania, New Jersey, and Delaware, including the University of Pennsylvania, Drexel University, and The Children's Hospital of Philadelphia.

More than 350 companies have passed through our doors since we were founded in 1963. The 93 that remain in the Greater Philadelphia region account for over $9 billion of sales and 15,000 current direct jobs. These jobs pay an average of $89,000 per year—a remarkable figure, especially in today's economy.

Our campus features two business incubators—collectively known as the Port—that are home to more than 30 start-up companies in life sciences, cleantech/greentech, and information technology.

These companies are at the cutting edge of scientific innovation. To give you an example, one of our start-up residents—Invisible Sentinel—is working on a fast, efficient way to detect food contamination. Another, BioNanomatrix, is using nanotechnology to decode the human genome. And a third, Enzybel International, a Belgian company, is dedicated to the production and commercialization of sustainable compounds derived from nature.

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In our 48 years of operation, we have helped to create the model for the modern research park and high-tech business incubator. Our graduates include Centocor, the maker of Remicade, global software giant Bentley Systems, and financial services powerhouse SEI Investments.

One of our latest incubator success stories, Avid Radiopharmaceuticals, exemplifies America's potential for innovation and entrepreneurship in the life sciences. Avid was founded by Dr. Dan Skovronsky, a neuropathologist at the University of Pennsylvania who had an idea for a technology that would revolutionize the ability to diagnose Alzheimer's and other diseases at an early stage.

In 2005, Dan moved his brand new company into the Science Center's incubator with one employee—himself. Over the next four years Avid refined its technology and added jobs. By 2009, the payroll had grown to 37 people. The company outgrew its space in our incubator and moved into custom-fitted, full-price office and lab space on our campus. Since then the company has grown to more than 50 employees.

Last fall, Avid was acquired by one of our nation's leading pharmaceutical companies, Eli Lilly, for $300 million in cash up front, plus another $500 million of additional payments over the next few years, based on the achievement of certain milestones. We were thrilled to learn that Avid currently plans to remain at the Science Center, continuing to bring new jobs and economic growth to Philadelphia and the region.

Avid represents a classic example of how research and development in the life sciences are essential to our nation's economic recovery.

Let's take a step back and look at the economic impact of the life sciences in the Science Center's home state of Pennsylvania.

As noted in the State Bioscience Initiative 2010 Report from Battelle and BIO, the biosciences sector in Pennsylvania employs 81,000 workers in the state at an average salary of $82,000—for a total of $6.7 billion in wages. With a multiplier effect of 4.38, the industry has a total employment impact of 354,000.

On a national level, according to the same report, total employment in the U.S. bioscience sector reached 1.42 million in 2008. When you figure in a multiplier effect of 5.8, the total employment impact of the bioscience sector is 8 million jobs nationwide.

Those are tough numbers to ignore. Yet, the life sciences industry does more than create well-paying jobs. Scientists and researchers are dramatically improving treatments, therapeutics, and ultimately patient care and quality of life.

Think back to our Port business incubator resident Invisible Sentinel. Their work in detecting food contamination may also have applications in the detection of pathogens associated with hospital-acquired infections, as well as in cancer detection and homeland security.

At the Science Center, we look forward to helping our residents advance science and technology and invent new products that will change the world—while creating new jobs and economic growth along the way.

I also would like to express my strong support for the proposed Life Sciences Jobs and Investment Act. This legislation will help strengthen the biotech sector's culture of innovation, discovery, education, and job creation across the nation.

The Life Sciences Jobs and Investment Act will offer tax incentives for small and midsized businesses to invest in life sciences research and development on a targeted basis. It will also ensure the availability of an educated, skilled workforce that will sustain our pipeline of bioscience innovations, companies, and jobs over the long term.

One out of every six jobs in the Greater Philadelphia region can be traced back to the life sciences. The Life Sciences Jobs and Investment Act is key to the long-term success of this crucial industry sector. This is the kind of proactive legislation that we need to maintain our competitive edge as we ensure that biotech in the region—and the entire country—continues to grow and thrive.

Thank you for your kind attention! I welcome your comments and questions.

PREPARED STATEMENT OF MR. THOMAS R. KOWALSKI

Thank you, Chairman Casey, Vice-Chairman Brady and the entire Joint Economic Committee for inviting me here today.

I'm Tom Kowalski, President of the Texas Healthcare and Bioscience Institute.

Our organization's mission is to research, develop, and advocate policies and legislation that promote biomedical science, biotechnology, agriculture, and medical device innovation in Texas.

The issue you are considering today—how targeted tax incentives can be used to enhance medical innovation, life sciences education, and job creation here in the United States—is of great interest to me and of vital concern to our industry.

The impact of the life sciences industry on the US economy is significant. It advances medical knowledge, develops products that keep our country at the cutting edge of global competitiveness, and supports millions of high-quality jobs.

As important as the direct benefits to our nation's economy, the innovations produced by these companies are also helping Americans live longer, healthier lives.

I would like to share with you the positive impact the life sciences industry has had in Texas both in improving the health of Texans, as well as in creating a robust job sector. Much of this development has occurred because of the very vital investment Texas has been willing to make into the life sciences.

Texas has a dynamic biotechnology marketplace with an estimated economic impact of 75 billion dollars. The state has many national top 10 rankings in biotechnology and is home to over 4,100 biotechnology, biomedical research, business and government consortia, medical manufacturing companies, and world-class universities and research facilities, employing over 104,400 at an average annual salary of over 67,300 dollars. A significant number of top global biotechnology and pharmaceutical companies have Texas locations, underscoring the state's vitality. Government support; a highly trained workforce, excellent educational, medical, and research institutions; a first-rate transportation and logistics infrastructure; and a top-ranked business climate all strengthen the state's status as a biotechnology leader.

There are significant factors pointing to the robust growth of the Texas Life Science Industry.

First—University research is the lifeblood of our state's innovation, medical treatments, and job creation. The Texas Health Science Centers are the crown jewels of our industry.

Secondly—There has been a significant investment from the State into the life science industry which has enabled research technology transfer and commercialization to successfully occur. Much of the state's investments require academic/private sector collaboration, and the Life Sciences Investment Act will compliment these efforts by the potential infusion of industry research dollars and future collaborations which extend to increase workforce and added clinical trials.

The Texas Emerging Technology Fund is one of those programs. The ETF, as it is known, has allocated more than 193.7 million dollars in funds to 131 early stage companies and nearly 173 million dollars in grant matching and research superiority funds to Texas Universities.

Investments by the TETF attract additional investment capital to emerging technology companies. Since the fund's inception, more than 407 million dollars in private capital has been invested in ETF-funded businesses—*more than double* the state's contribution.

Another key program in Texas has been the creation of the Cancer Prevention and Research Institute of Texas. It is known as CPRIT. The Texas Legislature and the Governor authorized the program, which the voters approved in 2007. The program has funded 256 grants totaling more than 382 million dollars for cancer research, commercialization, and prevention in 46 academic institutions, nonprofits, and private companies. More than 500 million dollars, including matching funds, have been invested in Texas extraordinary efforts to lead the nation in cancer research. CPRIT has become one of the largest cancer research grant-making organization in the nation. Our focus in Texas has been to create such a strong life science environment that we keep our companies in our state and attract additional companies to Texas. By these investments, we continue to fine tune our workforce and more importantly put our graduates to work in Texas companies.

The industry has enjoyed a strong growth rate of 14% from 2003 to 2008. These programs have added stability during the last two years to enable our companies to continue to raise capital and invest that capital into the R&D process.

While individual states can do much to support the growth of the life sciences industry, continued and increased support at the federal level is paramount.

The biotechnology industry directly provides hundreds of thousands of good-paying jobs for America's working families. However, over the last decade, America's leadership in the life sciences industry has begun to erode. To retain those jobs and to create new ones, the success and growth of the industry's basic research efforts, as well as innovations in effective treatments and associated technology advancements, must remain in the U.S., where they will contribute to our nation's future economic growth and international competitiveness.

Unfortunately, as the costs of developing new biotechnology products in the U.S. continue to rise, companies are under great pressure to find lower-cost locations to conduct their research and development.

We can adjust our tax policies and remain the international leader in biotechnology research, development, and manufacturing, or we can watch the industry move overseas, like so many before it.

Narrowly tailored tax incentives aimed at ensuring investment in domestic biomedical research and development will create a demand for highly skilled workers, promote higher education in the life sciences, encourage greater scientific collaboration, and improve our nation's overall economic well-being and health.

Thank you.

PREPARED STATEMENT OF DR. ARTHUR T. SANDS

Good morning Chairman Casey, Vice Chairman Brady, Ranking Member DeMint, Ranking Member Hinchey, Members of the Committee, ladies, and gentlemen. I am President and Chief Executive Officer of Lexicon Pharmaceuticals, Inc. I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO). BIO represents more than 1,200 companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.

I have been a part of the biomedical industry since the early 1990s, beginning with my work as an American Cancer Society postdoctoral fellow at the Baylor College of Medicine's Department of Human and Molecular Genetics. It was an extremely exciting time, as Baylor was one of the major genome sequencing centers of The Human Genome Project. In 1995, I co-founded Lexicon Pharmaceuticals and helped pioneer the development of large-scale gene knockout technology for use in drug discovery. Gene knockout technology allows us to turn off and/or modify any gene in order to study human disease. Since most drugs act by inhibiting the function of the products of genes, this technology enables us to genetically model what a drug would do in an animal before embarking on the arduous task of inventing such a drug. With the DNA sequence of all genes now available, Lexicon has focused on knocking out those gene products that are "druggable"—approximately 5,000 genes, or almost a quarter of the entire genome. In particular, Lexicon targets those genes that, when blocked, confer a favorable effect that could be used to create a new medicine to fight disease. This powerful approach to drug discovery has been the source of our drug pipeline now in development, including drug candidates with breakthrough potential in diabetes, cancer, rheumatoid arthritis, and gastrointestinal disease.

When I founded Lexicon, it was just a small, privately funded research stage company. Currently, there are thousands of similar companies throughout the United States, each one with molecules and drug candidates that could change the face of modern medicine. Biotechnology may hold the answers to the medical problems that America faces, from the devastation of cancer and HIV/AIDS to the personal losses of Alzheimer's and Parkinson's to the spiraling costs of health care associated with diseases of epic proportions, such as Type 2 diabetes. Of the 118 scientifically novel drugs approved from 1998 to 2007, 48% were discovered and/or developed by biotech companies. These revolutionary cures and treatments save lives and reduce healthcare spending. As Congress continues to look for ways to reduce our nation's deficit, it is important that we remember the impact that innovative therapies can have on increasing overall health, especially by combating costly chronic diseases. These advances will save taxpayers money by decreasing the outlays necessary to care for our aging population.

Additionally, the biotech industry is a thriving economic growth engine, directly employing 1.42 million Americans in high-quality jobs and indirectly supporting an additional 6.6 million workers. The average biotechnology employee makes $77,595 annually, far above the national average salary. President Obama has called for the United States to lead in the 21st century innovation economy, and biotechnology can be a key facet of our nation's economic growth.

Despite these windows of opportunity, biotechnology research and development is often a difficult process. Bringing groundbreaking therapeutics from bench to bedside is a long and arduous road, and small biotechnology companies are at the forefront of the effort. It takes an estimated 8 to 12 years for one of these breakthrough companies to bring a new therapy from discovery through Phase I, Phase II, and Phase III clinical trials and on to FDA approval of a product. The entire endeavor costs between $800 million and $1.2 billion. Due to this capital-intensive process, biotechnology companies lacking research and development funds turn to private-

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sector investors and collaborative agreements to finance the early stages of therapeutic development.

However, the current economic climate has made private investment dollars extremely elusive. In 2010, venture capital fundraising endured its fourth straight year of decline and its worst since 2003. Biotechnology received just $2 billion in venture funds, a 27 percent drop from its share in 2009. Even worse, the biggest fall was seen in initial venture rounds, which are the most critical for early stage companies. Series A deals last year brought in just over half of what they did in 2009. Decreasing upfront investment could mean cures and therapies being shelved in labs across the nation and ultimately not reaching patients.

In 2000, Lexicon completed one of the most successful initial public offerings (IPO) in biotech history, raising $220 million from a range of investors. By putting our company on the public market, we were able to provide our initial backers with a return on their original investment as well as open ourselves to myriad other sources of funding. IPOs like ours used to be the standard for the industry—after we showed proof of concept in our gene knockout technology, we knew a successful public offering was in the cards. However, companies today with science just as groundbreaking do not have the same support on the public market. From 2004 to 2007, the United States had an average of 34 IPOs in biotechnology per year. From 2008 to the first quarter of 2010, we had a total of 8. While the numbers have ticked up slightly this year, the weak demand for these offerings is restricting access to capital. This then hampers critical research and depresses valuations of later-stage venture rounds.

As U.S. biotech companies face financial uncertainty, other countries are increasing their investments and enacting intellectual property protections to encourage domestic biotech growth. We still hold our place as the leader in global biotechnology patents thanks to our large head start, but China and India rank first and second in biotech patent growth. These emerging powers are heavily investing in science, and particularly in biotechnology. Meanwhile, the U.S. has fallen to twentieth out of twenty-three countries in new biotech patent applications. Additionally, many countries in Western Europe are implementing biotech-friendly tax incentives, including lower corporate tax rates for innovative industries, as a means to grow their 21st century economies. This lag has put us at risk of losing our place at the forefront of this important and innovative economic driver.

THERAPEUTIC DISCOVERY PROJECT

There are certain steps that Congress has taken to maintain American leadership in the biotechnology space. Last March, Congress enacted the Therapeutic Discovery Project (TDP), an important tax credit program designed to stimulate investment in biotechnology research and development. Under this program, small biotech companies received a much-needed infusion of capital to advance their innovative therapeutic projects while creating and sustaining high-paying, high-quality American jobs.

In total, the Therapeutic Discovery Project awarded $1 billion in grants and tax credits to nearly 3,000 companies with fewer than 250 employees each. These small companies were eligible to be reimbursed for up to 50% of their qualified investment in activities like hiring researchers and conducting clinical trials. The impact of this funding was felt across the American biotech industry, as companies in 47 states received awards. The average company received just over $200,000, an important shot in the arm in these rough economic times. While Lexicon was not eligible for the program because we have 290 employees, my colleagues at other emerging companies in Texas greatly benefitted from this important investment. In fact, Texas was among the top ten states in total TDP funds awarded.

The infusion of capital for small biotech companies provided by the Therapeutic Discovery Project is an essential incentive for companies to keep their research and development, manufacturing, and operations here in the U.S. The critical funding will also accelerate the movement of cures to patients who need them. This program was a step in the right direction by Congress to invest in growing the U.S. biotech industry to keep pace with our global competitors. Given the imbalance between the extraordinarily high demand by small biotech companies and the limited pool of funds, I hope that Congress will extend and expand this oversubscribed program and assist more American companies in pursuing breakthrough medical discoveries and supporting American jobs.

R&D TAX CREDIT

As you know, Congress has also striven to aid the life sciences industry through the research and development (R&D) tax credit. Most biotechnology companies

working toward new cures and therapies are small, research-intensive companies that are not profitable because they do not yet have an FDA-approved product on the market. As companies like mine struggle to raise capital to finance their cutting-edge research, we rely on a stable and predictable R&D credit as part of our investment decisions.

Vice Chairman Brady recently introduced the American Research and Competitiveness Act, which would support and foster the creation of the high-wage jobs associated with R&D in the biotechnology industry by strengthening and making permanent the R&D tax credit. A permanent R&D credit would provide greater certainty and assist American biotechnology companies as they plan future research investments in the U.S. The legislation would also increase the Alternative Simplified Credit (ASC) rate to 20 percent, making U.S.-based R&D more attractive relative to the research incentives offered by many foreign governments seeking to foster their own biotechnology industries. I strongly believe that enacting this legislation would be a boon to our industry.

LIFE SCIENCES JOBS AND INVESTMENT ACT

I also believe that Chairman Casey's efforts to support job creation in the life sciences industry will be beneficial to biotech companies like mine. The Life Sciences Jobs and Investment Act, introduced by Chairman Casey, would incentivize research and investment in the life sciences industry on a very targeted basis. Under the bill, a taxpayer engaged in the life sciences could elect an increased R&D tax credit for their first $150 million spent on life sciences research. The taxpayer would also have the option to return up to $150 million of foreign earnings to the United States free of taxation in lieu of the increased R&D credit. The repatriated funds would be earmarked specifically for investment in new jobs, and would have to be kept in a special account or trust, to be disbursed only for permitted activities. Through this legislation, biotechnology companies would have the resources necessary to hire additional scientists and researchers, increase partnering with American universities, and invest in new research facilities, so I support its enactment.

MODIFICATIONS TO CURRENT TAX INCENTIVES IMPACTING INNOVATIVE BIOTECHS

Given the long R&D timeline and arduous road necessary to bring a therapy from bench to bedside, emerging biotechnology companies—which are not currently profitable—are unable to immediately benefit from various tax incentives in the current tax code. These incentives do not provide much-needed capital to small research-intensive companies because their lack of profits makes tax benefits unredeemable.

There are two specific areas of the Internal Revenue Code which provide opportunities for Congress to invest in America's future through biotechnology: with modifications, Section 1202, which covers reduced capital gains tax for the sale of qualified small business stock, and Section 382, which imposes limitations on the use of net operating losses, could encourage private investments into biotech.

Reduced Capital Gains Rate for Sale of Qualified Small Business Stock (IRC Section 1202)

Congress's original intent in enacting Section 1202 was to stimulate investment in small businesses. President Obama and the 111th Congress further emphasized the importance of small business investment by enacting a law temporarily allowing 100% of gains from the sale of qualified small business stock to be excluded from capital gains taxation. Thus, investors in qualified small businesses are eligible for a zero percent capital gains rate on their sale of certain stock through the end of 2011. However, despite Congress's support for stimulating investment in small and start-up businesses, Section 1202, which defines the qualified small business stock eligible for an exclusion from capital gains tax, is too limited and presents technical challenges which investors in small innovative companies are unable to overcome. Among other challenges, Section 1202 employs a test in which a corporation's gross assets must be less than $50 million immediately before and after the stock is issued in order to be eligible for preferred capital gains treatment. When IP is incorporated as an asset, small biotech companies are almost always over the $50 million limit. The high value of our IP belies the fact that our emerging companies are small businesses that need support if they are going to continue to work toward important medical breakthroughs. Given the emphasis placed on small business job growth through innovation by Congress and the President, it is important that Congress take a look at modifying the small business stock rules in Section 1202 to more accurately represent the state of innovative small businesses in America.

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Limitations on the Net Operating Losses (IRC Section 382)

As I have mentioned, many of these tax incentives are necessary because of the capital-intensive nature of the long development process in the biotechnology industry. During the early years of development, biotech companies are generally not profitable. As such, they may accumulate net operating losses (NOLs) for years before they ever have a product on the market. NOLs may be carried back two years and carried forward twenty years to offset positive income. Unfortunately, many biotech startups are not able to utilize their NOLs within this time period, and these tax assets expire unused. Additionally, Section 382 operates to further limit the utilization of NOLs by many biotech companies. Section 382 was designed to combat the very real problem of NOL trafficking, wherein profitable companies buy companies with losses in order to acquire their NOLs. The Section describes the many circumstances that can be classified as an ownership change and prohibits NOLs from flowing to the new controlling entity if an ownership change occurs. Unfortunately, the law as written captures the frequent biotech practice of raising equity in successive financing rounds, a practice essential to successfully negotiating the long product development and FDA approval process. Thus, these limitations have the effect of discouraging investment in biotechnology research, leaving the companies that would otherwise conduct that research in dire financial straits. Vice Chairman Brady proposed a bill in 2007 to ease Section 382 restrictions, and I believe that the passage of similar legislation by Congress would represent an important step forward in research financing in the biotechnology industry.

NEW TAX PROPOSALS ENCOURAGING PRIVATE BIOTECH INVESTMENT

While modifications to Sections 1202 and 382 would represent key improvements to the biotechnology investment environment, Congress has the opportunity to enact new tax incentives which would further encourage private investment in our industry. There are a number of new proposals, including partnership structures to support high-risk industries, incentives for industry collaborations, and angel investor tax credits, which could open up new sources of capital for biotech.

Partnership Structures

Congress' support for biotechnology is critical in this uncertain economic climate. Historically, Congress has provided tax incentives to high-risk industries as a means of encouraging investment in new endeavors which it deems important. For example, the oil and gas industry often invests significant amounts of capital to determine whether a particular well will be successful. When Congress wanted to spur oil and gas exploration, it included provisions in the Code allowing investors to take advantage of tax benefits accumulated by high-risk drilling and exploration companies. This encouraged investment despite the uncertain nature of the oil and gas business.

Similarly, research and development in the biotechnology industry is a high-risk undertaking with substantial start-up costs, a lengthy R&D period, and the possibility that the technology will not be commercially viable. The challenges that smaller oil and gas corporations face in finding and developing new resources and diversifying risk are analogous to the hurdles that small biotech companies must overcome. These companies expend substantial financial resources on research and development before successful FDA approval.

As Congress looks to continue America's leadership in the 21st century innovation economy, it should look to tax incentives available to the oil and gas industry that would be equally beneficial to the biotechnology industry. These incentives, when combined with the research and development tax partnership structure, would encourage investment in the biotechnology sector. For example, allowing biotech companies to drop their R&D projects into joint ventures with investors to provide tax benefits to those investors would create a powerful incentive structure for private investment in this high-risk industry.

Incentives for Collaborations, Liquidity, and Initial Public Offerings

While most investment in the biotechnology industry comes from private sources, companies within the industry often collaborate with one another to pursue their research and development objectives. Collaborative arrangements provide an opportunity for specialization—small companies can focus on innovation while larger companies utilize their greater expertise in downstream clinical trial management. Each company uses its strength in order to bring cures to patients faster. These agreements involve upfront, milestone, and reimbursement payments for research and development undertaken by the small biotech. Given that these agreements have been pervasive throughout the industry and are critical to its success, I would suggest encouraging this important financing mechanism through tax incentives. A greater

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proliferation of these types of collaborations would provide substantial capital for small biotechs and would leverage the "know how" found in the larger companies in the industry to speed medical breakthroughs to patients.

Separately, as I have mentioned, there has been a dearth of initial public offerings for biotech companies. This is problematic for two key reasons: first, it means that the early investors, generally angels or venture investors, cannot sell their shares. That means that they cannot return their initial capital or any return to their limited partners, who are primarily large institutions such as public pension funds or endowments. Second, it means that companies are unable to access the considerable resources available in the public markets.

Accordingly, Congress should consider a set of incentive structures, perhaps through capital gains rate advantages or otherwise, that increase opportunities for liquidity for investors and expand public appetite for public offerings.

Angel Investor Tax Credits

Congress can also look to the states for examples of how to spur biotech innovation. Over 20 states have implemented angel investor tax credit programs, in which high-net-worth individuals are incentivized to invest in small innovative businesses like mine. Angel investors play a valuable role during the seed stage of therapeutic development. They are the main source of capital for about 50,000 companies each year, but that number could decrease significantly unless action is taken to promote investment and minimize risk. The states have recognized the importance of angel investors and implemented tax credit programs reimbursing angels for 25% to 50% of their qualified investments in biotechnology and other small businesses. This investment by the states makes clear the important impact that innovation can have on the national level. It is imperative that Congress look at measures the federal government could take that would spur seed investing vital to the beginning of the research and development process.

CLOSING REMARKS

The U.S. biotechnology industry is a thriving growth engine for the American economy, creating high-quality jobs in every state. Additionally, the medical breakthroughs happening in labs across the country could unlock the secrets to curing the devastating diseases that affect all of our families. Congress has taken admirable steps toward supporting this valuable industry. However, if the United States is to hold its place at the forefront of the 21st century innovation economy, further investment is needed. Congress has the opportunity to make that investment, both by improving current programs and incentives and by creating new ones which recognize the vital part that biotechnology will play in America's future.

PREPARED STATEMENT OF MR. MARK G. HEESEN

INTRODUCTION

Chairman Casey, Vice Chairman Brady, and members of the Committee, my name is Mark Heesen, and I am president of the National Venture Capital Association (NVCA) based in Arlington, VA. The NVCA is the only national trade group representing venture capitalists. Our 400+ member firms invest in start-up companies across the country as well as globally in high-tech industries such as life sciences, information technology, and the clean technology sectors. We estimate that our membership comprises more than 90 percent of the venture capital under management in the U.S.

It is my privilege to be here today to share with you the role of venture capital investment in start-up companies—and how that role contributes to economic growth and innovation in the United States, particularly in the areas of life sciences. We appreciate the opportunity to offer a transparent view into our world and answer any questions the Committee might have.

THE FUNDAMENTALS OF VENTURE CAPITAL INVESTING

Venture capital funds typically are organized as private partnerships with a significant percentage of capital provided by qualified institutional investors such as public and private pension funds, universities and endowments, private foundations, and to a lesser extent, high-net-worth individuals. These investors, referred to as the limited partners (LPs), have benefited greatly from the high-risk/high-reward exposure afforded by venture capital as a relatively small component of their diversified investment portfolio. The venture capitalists that seek out start-ups for in-

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vestment are the general partners (GPs), and they also supply capital for the fund from their own personal assets.

A venture fund is typically structured with a fixed term of at least 10 years, sometimes extending to 12 or more years. At the outset, a limited partner commits a fixed dollar amount to the fund. As the GPs identify a new idea or company for investment, they make "capital calls" from their LPs, essentially collecting a portion of the capital commitments to make the investment. Further capital calls are made as each portfolio company becomes ready for a new tranche of investment by meeting milestones or growth trajectories. When a portfolio company has reached either stand-alone stability and sustainability, or when it needs to access the deeper resources of the public capital markets, the GPs "exit," through an initial public offering (an IPO) or an acquisition by a larger company, and the liquidity from these "exits" is distributed back to the limited partners. Limited partners may not otherwise withdraw capital during the life of the venture fund.

After the venture fund is formed, the GP's job is to find the most promising, innovative ideas, entrepreneurs, and companies that have the potential to grow exponentially with the application of the venture capital expertise and investment. Often these companies are formed from research that spins out of university and government laboratories. Because the venture industry has historically focused on high-technology areas such as information technology, life sciences, and clean technology, we rely a great deal on these labs to feed our pipeline.

Once a promising opportunity has been identified, venture capitalists vet the entrepreneur and his or her management team and conduct due diligence research on the market, the financial projections, and other areas. For those opportunities that clear this investigation, VCs make an investment in exchange for equity ownership in the business. Venture capitalists also generally take a seat on the company's board of directors and work side by side with the company founders to grow the business. In many cases, particularly in the area of life sciences, the company founders are scientists with limited business experience. Therefore, the venture capitalists can play a crucial and complimentary role by helping to recruit talent, secure customers, implement budgets, and develop long-term strategic plans. In other words, venture capitalists are not passive investors. In fact, many are scientists and technologists by trade and are therefore able to apply their technical and business experiences directly to the growth of the company.

Venture capitalists expect to hold a typical investment for 5–10 years, often longer in the area of life sciences, and rarely much less. During that time, VCs continue to invest additional capital into those companies that are performing well and cease follow-on investments into companies that do not reach their agreed-upon milestones.

The ultimate goal is described above—an exit—which is when the company is strong enough to either go public on a stock market exchange or become acquired by a strategic buyer at a price that ideally exceeds the investment. At that juncture, the venture capitalist "exits" the investment, though the business continues to grow. In recent years, the venture-backed acquisitions market has far exceeded the IPO market in terms of volume. This is especially true in the life sciences industry where larger corporate pharmaceutical companies have come to rely on the purchase of smaller venture-backed companies to support their R& D efforts.

Because at least one-third of venture-backed companies ultimately fail, and those that succeed usually take 5–15 years to do so, there have historically been no other asset classes that have the long-term patience and fortitude to withstand the high-risk nature of providing capital to these businesses. Commercial banks lack the appetite to invest in companies that have little or no collateral and such a high failure rate. Hedge funds and buyout shops typically balk at the long-term nature of our investments and the required level of engagement in the company's operations. Friends and family and angel groups have become more active in recent years—mostly in the technology sector, less in life sciences—but they do not have the capital necessary to take their companies all the way to a public offering or acquisition. Because of these dynamics, the venture industry has been the only source of capital for many of these companies as they move through their life cycles.

It is important to recognize that, despite the growing value created by venture capital, we remain a small industry that is actually shrinking still. In 2010, the venture industry invested just $22 billion—representing less than 0.15 percent of GDP. We currently have approximately $177 billion under management as an industry, compared to the buyout or private equity industry which manages approximately $800 billion and the hedge fund industry which manages an estimated $2 trillion. We estimate that there are about 790 venture capital firms in the U.S. of which 58 percent are actively making new investments. Our small investment goes a long, long way.

CONTRIBUTION OF VENTURE CAPITAL TO THE U.S. ECONOMY

For the last four decades, the venture capital community has served as a founder and builder of companies, a creator of jobs, and a catalyst for innovation in the United States. This contribution has been achieved through high-risk, long-term investment of considerable time and dollars into small, emerging growth companies across the country and across industry sectors. According to a 2011 study conducted by econometrics firm Global Insight, companies that were started with venture capital since 1970 accounted for 12 million jobs and $3.1 trillion in revenues in the United States in 2010. In doing so, our industry has collectively earned above average returns for our country's pre-eminent institutional investors and their beneficiaries, including public pension funds, university scholarship endowments, and charitable foundations.

Venture capital has been behind such technology innovations as computer chips (Intel), search engines (Google), operating systems and routers (Microsoft and Cisco), hardware (Apple), online social media (Facebook and Twitter), and online retail and auctions (Amazon and eBay). We have also supported business model innovations such as superstores (Home Depot and Staples), quality food chains (Whole Foods), and coffee houses (Starbucks).

Within the last five years, the venture capital industry has committed itself to investing in the clean technology space, specifically renewable energy, sustainable materials, and environmental innovations. Since 2006, the industry has invested nearly $14 billion dollars in companies innovating in the areas of solar and wind power, electric cars, advanced battery technology, efficient energy grids, and water purification. I can say with confidence that the clean tech economy of the future will be powered by venture capital.

Nowhere has the power of venture-backed innovation been felt more than in the life sciences sector. Approximately one-third of all venture investment is directed into biotechnology and medical device start-up companies each year. After funding companies such as Genentech, Amgen, and Medtronic, the venture capital industry has helped bring life-saving medical innovations to market over the last four decades. The results have been astounding. In 2010 alone, venture capitalists invested nearly $6 billion into biotechnology and medical device start-ups. We estimate that more than 100 million Americans have been positively impacted by a venture-backed medical innovation. Without venture capital, companies that have brought to patients medical devices such as the pacemaker, ultrasound, MRI, angioplasty, and blood glucose monitoring and drugs such as Integrillin, ENBREL, and Epogen would likely have never come into existence. At one time, these lifesaving innovations were simply ideas put forth by scientists who had little experience in growing a business. The infusion of venture capital dollars and expertise moved their products to market and, in doing so, these companies created new markets that have made our lives healthier and more productive.

Despite popular belief that our industry only resides in Silicon Valley, venture capital is a national phenomenon with investment going to all 50 states. While certain regions of the country—such as Northern California and New England—have successfully established thriving venture-backed communities, other areas such as Pennsylvania, New York, Colorado, Virginia and Minnesota continue to successfully support their own start-up ecosystems.

Political leaders in these states and others are seeking to do for their states what venture-backed companies such as Dell have done for Austin or Medtronic for Minneapolis. The positive economic impact of a successful venture-backed company headquartered in a region can be measured not only in jobs and revenues of that particular company but also by the spinouts of companies that inevitably emerge. A culture of entrepreneurship feeds on itself and can organically grow if the environment is properly nurtured.

Despite the value and economic strength created by venture capital investment, we are still a small and fragile industry. Our investing dynamics are highly susceptible to changes in our ecosystem. The one commonality for innovation and entrepreneurship to succeed is a consistent alignment of critical investment drivers including robust capital markets, access to talent, and a regulatory and tax environment that supports risk-taking and long-term investment. Over the last several years, we have faced challenges—both market and policy driven—but with these challenges comes opportunity to mitigate the uncertainty and continue to encourage long-term investment in America's start-up companies.

PROTECTING THE AMERICAN START-UP ECONOMY AND INNOVATION

Public policy plays a significant role in the health of the venture capital industry and in the companies in which the industry invests. Given the dynamic and evolu-

tionary nature of our ecosystem, we need policies and programs that promote certainty, supporting and encouraging the formation and growth of companies that are innovating in a meaningful way. The following represents some of the most important ways that policymakers can help ensure our start-up ecosystem continues to prosper.

Encouraging Long-Term Investment Through Tax Policy—NVCA has long advocated for a tax structure that fosters capital formation and rewards long-term, measured risk taking. We believe that the returns earned by venture capitalists and entrepreneurs as a result of building successful companies that are out-innovating others over the long term should be taxed at the capital gains rate. In recent years, this tax rate has been threatened by those who do not understand the importance of encouraging venture investment. It is critical that the capital gains tax rate is globally competitive and preserves a meaningful differential from the ordinary income rate so that proper incentives remain for investors who are often dedicating more than a decade of capital and time to each of their companies. We appreciate the support of many members of Congress, including Chairman Casey and Vice Chairman Brady, in recognizing this dynamic.

To encourage truly long-term investment, serious discussion regarding the holding period required to qualify for a long-term capital gain should be made part of any upcoming debate on tax reform. The NVCA has been supportive of increasing the holding period generally for capital gains and also developing a tiered capital gains rate so that the longer an investment is held, the lower the tax rate on the ultimate gain. One area where a longer holding period would be helpful is in the capital markets where many investors are buying and selling shares of our venture-backed companies quickly. Offering capital gains tax incentives for investors to buy and hold public stock of small cap companies for longer periods of time will help encourage investment in our companies once they go public, increasing the appeal of an IPO.

Ironically, although the R&D tax credit is important to many midsize and large corporations—many of whom are venture "graduates"—it is not a critical component of tax policy for start-ups that are still in the venture fold. Companies receiving current venture support generally are losing money—which is why banks and other traditional sources of finance find them too risky—and thus cannot use a tax credit that is structured for companies that are profitable. As lawmakers consider broad-scale tax reform to create a simpler, fairer tax code, the NVCA urges both Congress and the Administration to build a system that supports small companies and their investors as well as those that address the concerns of large, multinational corporations.

Protecting Sources of Future Capital—As previously stated, venture capitalists receive more than 90 percent of their money from institutional investors who commit a small percentage of their portfolio to alternative assets of which VC is but one. These investors typically enjoy above-average returns in exchange for the risk factors associated with venture investing. We estimate that public and private pension funds represent approximately 40 percent of the institutional investor base for venture capital, making this investor group the largest overall for the venture industry. The share is significant to the future of our industry as we are beginning to see a movement from defined benefit to defined contribution pension plans, particularly at the state and local level. If this shift continues in a meaningful way, the venture industry will be at risk for losing a critical source of capital as there is currently no viable means by which a defined contribution plan can invest in our asset class.

In 1978 Congress and the Department of Labor worked with the then fledging venture community to develop rules which permitted defined benefit pension plans to take part in venture capital. The result was the beginning of the American venture capital process we know today. Not since that time has the issue of institutional investor pools been more important to the future of the venture industry, and we hope to work together to develop some viable solutions to this looming concern over the next several years.

Encouraging More Small Cap IPOs—Studies show that more than 90 percent of job creation occurs after a venture-backed company goes public. In the last decade, however, the market for venture-backed initial public offerings (IPOs) has suffered due to unfavorable market conditions and ramifications from one-size-fits-all regulations. From Sarbanes Oxley (SOX) to the Global Settlement to Reg FD, regulations intended for larger multinational corporations have raised burdensome obstacles and compliance costs for start-ups trying to enter the public markets. From 2008–2010, only 62 venture-backed companies have gone public compared to the same time period one decade ago when 583 companies had IPOs. At the same time, venture-backed acquisitions have been taking place in record numbers. While venture capitalists can return money from an acquisition, the IPO is the exit which translates into job creation for the U.S. Imagine if, instead of going public, Genentech

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was acquired by Johnson & Johnson. While one would hope that the innovation would prevail, the job creation that would have inevitably been quashed in the consolidation is almost unimaginable. The IPO dearth must be addressed or we face serious economic risks for our country.

The NVCA is actively engaging with Congress, the Administration, and regulators on ways in which we can make the path to an IPO once again smoother, particularly for small cap companies. We feel there is an appetite for regulatory right-sizing so that our capital markets can once again be a viable—and preferred—exit for venture-backed companies.

Implementing Health Reform that Promotes Innovation—Improving the quality of care and fostering the advancement of innovation that improves the efficiency and cost-effectiveness of healthcare delivery are critical pieces to venture capital investment and our health care system. While not the focus of today's hearing, we do have concerns regarding the medical device excise tax as well as the Medicare capital gains tax and the potential impact of those measures on our portfolio companies and our industry. As the law is implemented, we hope that all Members of Congress will remain open to hearing from our industry on those issues.

Other elements of the health care reform law, such as the increased emphasis on comparative effectiveness (CER), have the potential to improve patient outcomes and increase the efficiency with which our system delivers them. However, it is essential that CER be undertaken with the proper focus and context, to ensure that CER does not create undue hurdles for innovative new drugs and technologies.

Similarly, we are concerned that the Independent Payment Advisory Board (IPAB) has the potential to be an unbalanced regulatory authority that could stifle advances in medical innovation and hobble free market competition. NVCA believes that, to be effective, entities such as the IPAB and the CER must include persons with deep expertise in medical technology innovation. These members would serve as needed advocates for innovation, ensuring that attempts to cut costs are balanced by an understanding of both the benefits of innovation and the potential impact that certain reforms may have on the future of medical innovation in our country. This will ensure a proper balance between saving money, continuing to invent life-saving treatments for the future, and continuing to allow patient access to innovative technologies and therapies.

Supporting Broad-Based FDA Reform—Just as one-size-fits-all regulation has impacted the public stock markets, so too has it impacted medical innovation. The Food and Drug Administration (FDA) is one of the most influential government agencies in the United States, regulating 25% of the products in the domestic economy and impacting millions of patients each year. In recent years, when evaluating new drugs and medical technologies, the FDA has become increasingly reticent to balance the benefits against the risks of new therapies and technologies for seriously ill patients. In many cases, the evidence demanded to support approval has become unnecessarily extensive and cumbersome, deterring investment in innovative therapies and technologies for serious diseases. This is particularly troubling in areas where there are unmet medical needs and is resulting in less and later access to life-saving products when compared to other countries. Moreover, the regulatory burden is having a negative impact on job creation and is threatening our country's leadership in life sciences innovation.

Within the last year, our organization has formed the Medical Innovation and Competitiveness Coalition (MedIC) which comprises both venture capital firms and companies operating in the life sciences arena. The mission of the coalition is to advocate for policies that improve certainty and transparency within the FDA approval process which will, in turn, encourage investment in life sciences companies. Specifically, we are calling for FDA reform that returns the balance to the review and approval process, ensuring seriously ill patients access to breakthrough therapies and technologies in a timely fashion. The regulatory assessment of benefit and risk should reflect the importance that patients and healthcare providers place on access to new products in the United States.

NVCA MedIC will be asking Congress to enact a set of focused and targeted policies that would restore the balance of patient benefits and risks in FDA decision-making, reform the regulation of innovative technologies, hold the Agency more accountable to patients, healthcare providers, and sponsors, and strengthen the FDA's role in the innovation economy to restore U.S. competitiveness. A copy of our priorities in this regard is attached as addendum A.

Also, it should be stated for the record that the NVCA understands that these reform measures require an FDA that is adequately funded. While the 2011 fiscal budget largely spared the FDA from significant cuts, we have concerns regarding future cuts in the 2012 budget. While all agencies should root out waste and duplication, untempered resource reduction at the FDA will result in a reduction in inno-

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vation being delivered to the American people. We ask that Congress be mindful of the trade-off here.

Filling the R&D Pipeline—Maintaining America's global innovation advantage requires continued federal funding for basic research and development. Discoveries in federal labs and universities remain the germination points for the breakthrough ideas that can be commercialized by entrepreneurs and venture investors and transformed into the promising new companies that will drive job creation and economic growth. This unique public-private partnership has delivered countless innovations to the American public and a decisive competitive advantage to the U.S. economy for decades. Yet, recently, fiscal realties have threatened the funding levels for basic research grants in such areas as life sciences and energy. We understand the need for fiscal responsibility, but drastically reducing the funding those types of companies that can participate will be devastating long term to our global economic leadership. As Congress reviews ways to cut spending and balance the budget, we urge lawmakers to take a longer-term approach and protect those areas that are innovating for the future.

Further, we remain extremely disappointed regarding the once again stalled SBIR Reauthorization bill. The ongoing lack of clarification regarding whether venture-backed companies can apply for government grants (such as SBIR grants) to conduct early stage research has unquestionably hurt the innovation pipeline. We hope that another year does not go by in which the most promising, innovative projects are not eligible to receive SBIR grants and subsequently die on the vine.

Embarking Upon Legal Immigration Reform—The U.S. must continue to attract and retain the world's best and brightest minds if it wants to maintain its global economic leadership. However, a number of factors have hindered our ability to keep foreign-born entrepreneurs here in the U.S. The first is that developing countries such as India and China have been hard at work over the last decade growing their own start-up ecosystems that today rival the U.S. market. In many cases, they are offering tax and other incentives for entrepreneurs to form their companies on their shores. Foreign-born entrepreneurs now have a number of good choices in terms of where they start their businesses. Second, and more importantly, it has been increasingly difficult for these foreign-born entrepreneurs to come to the U.S. and build their companies here due to our immigration policies. Even students who have studied at the best American universities are finding it difficult to remain and innovate here. We estimate that 25 percent of the largest venture-backed companies that today are thriving public entities were founded by one or more foreign-born nationals. Unless our government is able to reform our legal immigration policies, we remain at high risk for losing these innovators to other countries.

For this reason, NVCA supports policies that allow foreign-born entrepreneurs to come to America to build their companies and create U.S. jobs. Proposals such as the Start-Up Visa Act will allow enterprising professionals to come here to develop their ideas and then remain here to build their companies, as opposed to innovating and creating economic value overseas. Further, the NVCA supports a streamlining of the pathway to "green cards" for foreign-born graduate students who wish to remain in the United States upon completion of their studies.

Protecting Small Innovators and Inventers with Patent Reform—We continue to have significant concerns regarding the patent reform legislation that has passed the Senate and which is currently being taken up in the House. While we strongly support the provisions that would end the diversion of fees from the patent office, giving examiners critical resources, we remain concerned that other sections of the bill may not adequately protect small innovators. Small venture-backed companies use every dollar for research, product development, and scaling their enterprise. They do not have the deep reserves necessary to protect themselves from large companies that infringe on their patents or that may use some of the new procedures in the legislation, such as postgrant review, as a harassment tool. We will continue to work with Congress to amend the current bill to help these small companies as the implications for investment in this sector are significant.

CONCLUSION

In many ways, America is at a cross roads when it comes to enacting policies that support start-ups' job growth and innovation across all industry sectors, including the life sciences industry. Market forces have challenged the U.S. venture capital industry over the last several years while foreign countries have grown their own ecosystems at a rapid pace. At the same time, the regulatory restrictions placed upon those companies that are innovating in meaningful ways have weighed down the growth trajectory these start-ups once enjoyed. Our global leadership in innova-

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tion can no longer be taken for granted; in fact we are at risk for losing it in certain areas if we do not address the challenges that we face.

The opportunity remains to encourage long-term investment in start-up companies through smart and fiscally sound tax policy. The regulatory environment can be right-sized and adjusted to ensure that the best companies are able to bring their most innovative products to market and thrive in our country's capital markets system. And policies can be enacted so that the best and brightest minds can build their businesses in the U.S., and the best and brightest breakthroughs can be funded in their earliest stages. If we take the proper paths here, there is no doubt that innovation will prevail. We appreciate your willingness to better understand our industry and its key drivers so the path towards growth and protecting innovation will indeed be taken.

The venture capital industry remains committed to long-term investment in our country's future. We look forward to working with Congress to ensure that our companies continue to grow and create significant economic value for years to come.

PREPARED STATEMENT OF THE CALIFORNIA HEALTHCARE INSTITUTE, SUBMITTED BY REPRESENTATIVE JOHN CAMPBELL

INTRODUCTION

CHI is the statewide public policy organization representing California's innovative biomedical sector, including the state's premier research universities and institutes, venture capital firms, and medical device, diagnostics, and biotechnology companies. Our mission is to identify and advocate for policies that encourage life sciences research, investment, and innovation. We are grateful for the opportunity to provide comment on innovation and job growth within the life sciences sector and to address the importance of certain federal policies to the continued vibrancy of the sector, especially given broader macroeconomic factors and conditions as the financial markets crisis and increased global competition.

BACKGROUND

California's biomedical industry is responsible for breakthrough treatments, therapies, and technologies that are improving and extending the lives of millions in the United States and around the world. It is also a key component of our state and national economy. As reported in our CHI/PricewaterhouseCoopers/BayBio 2011 California Biomedical Industry Report, California is home to over 2,200 biomedical companies, employing 268,000 people, making it one of the top high-tech employers in the state. The sector is responsible for over $114 billion in annual revenues, $15.4 billion in exports, and $19.4 billion in wages and salaries. Last year, California's biomedical innovators also attracted $3.2 billion in National Institutes of Health (NIH) research funding and $2.6 billion in venture capital (VC) investment.

Over the past generation, California has developed a remarkably rich and diverse ecosystem that has fostered the growth of vibrant biopharmaceutical and medical technology industries. This ecosystem is shaped and influenced by many factors that can bolster or weaken it. At the federal level, these factors include policies set by Congress and government agencies in areas such as science funding, tax policy, and regulation by the U.S. Food and Drug Administration (FDA). It is also shaped by other external economic factors. Below is an overview of each of these themes.

Federal Biomedical Research Funding has historically served as the fuel priming the pump of biomedical innovation. In fact, the biotechnology industry was born in California with the founding of companies like Amgen and Genentech based upon biomedical research at institutes such as Stanford and the University of California. Today, one-third of our state's biotechnology firms were founded by University of California scientists.

California has averaged 15 percent of NIH-awarded funding over the past decade. In 2009, NIH grants, excluding R&D contracts as well as stimulus bill-funded projects, totaled $21.483 billion. That year, 7,082 California applicants were selected for funding that totaled $3.2 billion. As NIH funding helped make California and the United States the global leader in biopharmaceutical innovation, the future of the industry will likewise be tied to the commitment of Congress to continue its support for such funding, even in such fiscally challenging times as today. Moving forward, CHI is hopeful that Congress will better recognize the value of NIH funding as an investment into the innovations, jobs, and medicines of the future and commit to a more thoughtful approach to strengthen and sustain support for the nation's biomedical research infrastructure.

Numerous Federal Tax Policies exist to encourage increased investment into the research that enables companies to develop new treatments, technologies, and therapies for patients here at home and around the world, while also creating quality jobs that fuel economic growth in California and across the nation. This includes, of course, the *federal Research and Development (R&D) tax credit*. As important as this policy is, the requirement of annual extensions instead of long-term or permanent extension results in uncertainty and makes long-term investment planning difficult. R&D uncertainty drives capital away as companies seek out other markets or apply the credit less when making assessments about whether to invest in new, costly projects. According to the Information Technology and Innovation Foundation, the United States ranks No. 17 in R&D tax incentives out of the top 30 Organizations for Economic Co-Operation and Development (OECD) countries. The United States ranked No. 1 as recently as the 1990s.

Two more recent tax policies enacted as part of the new healthcare reform law demonstrate seemingly contradictory goals. In the case of the *Therapeutic Discovery Project Credit*, Congress created grants and credits, limited to companies with less than 250 employees, to purposely encourage investment into new therapies. Specifically, the program allotted $1 billion over FY2009 and FY2010 for investments that demonstrated potential to result in new therapies to treat areas of unmet medical needs or to prevent, detect, or treat acute conditions, reduce long-term health costs in the United States, or significantly advance the goal of curing cancer within 30 years, and advance U.S. competitiveness and create and sustain high-quality, high-paying jobs in the country. The provision was hugely successful. California-based firms alone were awarded with over $280 million in grants and credits for projects targeting conditions and diseases such as cancer, spinal cord injury, tuberculosis, Parkinson's, hepatitis, diabetes, and heart disease.

Unfortunately, the same law enacted a *$20 billion excise tax on the medical device industry*, which will, without a doubt, negatively impact R&D and job creation to some, likely considerable, extent. There are over 8,000 medical device firms throughout the nation employing over 400,000 people. California is home to over 1,200 of these firms—more than any other state in the nation—and the more than 107,000 medical device jobs in California represent roughly one-quarter of the total U.S. medical technology workforce. Given our still uncertain economy, it is especially important that we do everything we can to encourage, not hamper, investment, entrepreneurship, and innovation. Again, for most companies, the device tax would threaten payroll reductions and slash R&D investments—anything but foster innovation. This is especially the case for small firms, which make up the bulk of the sector in California and across the country. It is difficult to quantify the precise number of jobs or lost R&D the tax would pose to California companies, however, it is reasonable to worry that as home to the largest segment of the nation's medical technology industry, our state will be disproportionately impacted by the device tax.

FDA Regulatory Consistency, Predictability, Transparency, and Efficiency helped the United States become the global leader in life sciences innovation. Indeed, history shows that a strong, science-based FDA and well-articulated, predictable, and consistent regulatory process are essential to biopharmaceutical and medical technology investment, innovation, and patient care. And, until recently, FDA policies and organizational structure have served as models for regulators around the globe.

Beginning in approximately 2007, however, evidence clearly confirms that FDA biopharmaceutical and medical device regulation has become increasingly slow and unpredictable.

As documented by the FDA's own data in our recent CHI report, "Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry," comparing the latest data with the 2003–2007 period:

- Drug and biologics review times have increased by 28 percent
- 510(k) device clearances have slowed by 43 percent
- PMA device approval times have lengthened by 75 percent

No single factor explains this decline. Clearly, part of the problem lies beyond the direct control of the FDA and its leadership. In recent years, for example, Congress has enlarged the Agency's scope into new fields (e.g., tobacco) and added to its responsibilities and authority. Yet federal appropriations have largely failed to keep up with new mandates, forcing greater reliance on industry-funded user fees. Similarly, expanded and tightened responsibilities under the FDA Amendments Act of 2007 (FDAAA), such as intensified conflict of interest rules on advisory committees, have constrained the Agency's capacity.

Perhaps the most important factor in the Agency's recent history, though, has been a change in its culture. Faced with accusations from the press, consumer

groups, and some in Congress that its reviews were too lax and failed to protect the public from safety problems with drugs and devices, the FDA has shifted emphasis in product reviews from the benefits of new products to an increasing weight on their possible risks. When broken down, industry anecdotes about Agency uncertainty, unpredictability, "moving goalposts," and the like all seemingly revolve around ever-increasing demands that are not justified by science or by any increased risk profile of the medicines or devices to which those demands are associated. From the perspective of an FDA device reviewer, this is understandable. After all, an individual reviewer has nothing to gain by approving a product but much to lose by approving a product that has a problem in the future.

In a larger sense, a serious problem for device and drug innovation alike is that there is no shared understanding of the benefit-risk calculus. Most medical advances carry some risks. And a basic principle of medicine is that the risk of any intervention—a procedure, a drug, a device—should be commensurate with the seriousness of the patient's disorder. Accordingly, for example, patients with advanced coronary artery disease are typically willing to accept risks for new minimally invasive procedures and technologies that have a chance to not only treat the condition but result in faster recovery times and shorter hospital stays. What has happened within the FDA, though, is that more and more attention has been focused on the potential direct risks of new medicines and technologies without sufficient appreciation of potential benefits.

But just as important to consider are indirect risks—distortions in the regulatory process, for example. How do we calculate and consider the public health loss to patients if investors and companies avoid entire diseases and conditions because the FDA's demands for clinical data are so extensive and its standards for approving new products so uncertain?

With this in mind, CHI believes that it is critical that Congress, the FDA, industry, patient groups, and other stakeholders come together with the will and ideas to restore Agency performance—to rejuvenate, support and sustain a strong, science-based FDA and efficient, consistent, and predictable review processes to ensure safe and innovative therapies, treatments, and technologies for patients in need.

In addition to these federal policies, a number of important **External Macroeconomic Factors** have combined to worsen the environment for the life sciences industry.

Beginning in 2008, the Great Recession devastated investment portfolios, including the pension funds and institutional endowments that historically have been the main source of life sciences venture capital. Meanwhile, VC firms themselves also sought to reduce risk, trending away from early stage investments—ones that combine the greatest innovation with the greatest risk. To make matters worse, the initial public offering (IPO) market for biotechnology and medical device companies all but vanished. After the collapse of iconic firms such as Lehman Brothers, Wall Street had little interest in offerings from young companies with no operating revenues that would need continuing infusions of capital over many years.

Smaller companies were forced to adapt by redesigning the biomedical business model—receive regulatory approval, demonstrate adoption by physicians and patients, and present to potential acquirers as a lower-risk investment. From the perspective of company and investor alike, winning approval sooner in any market became far more valuable than gaining FDA approval later.

Levels of regulatory uncertainty—delays, missed timelines, doubts about eventual approval—that had been uncomfortable in good economic times became intolerable after the economic downturn. Especially, as investors and executives came to realize, there are practical, more efficient routes to market outside the U.S.

Overseas regulators have recognized that regulatory efficiency can bolster biomedical innovation, investment, and job creation without undermining patient safety. The European Medicines Agency (EMA) has been especially forthcoming about its ambitions to encourage and facilitate biomedical investment and innovation in the EU. For example, in its strategic document, "Road Map to 2010: Preparing the Ground for the Future," the EMA stated that "its role in enabling the pharmaceutical industry to achieve the objective of industrial competitiveness is crucial." They have begun to succeed. Today, complex medical devices approved via the PMA process in the United States are approved in Europe on average nearly four years ahead of the United States, up from just over a year earlier this decade. And where new medicines were approved first in the U.S. by an average on nearly seven months between 2004 and 2006, recent years show products approved on average two-and-a-half months earlier in the EU, a shift of nine months. Of course, in either case, the result is that European patients benefit from U.S. innovations before

Americans do. And no evidence exists to suggest that these faster approval times in Europe have led to systemic patient safety-related problems.

These elements—macroeconomic factors and increased global competition—emphasize the important consideration that must be given, including through constructive congressional hearings such as today, to the costs of regulation. As this Committee and the Congress seek paths to create new jobs and promote innovation, the costs of the regulatory system should be carefully weighed. As the global economy grows ever more connected, American leadership in the life sciences sector faces intense competition: for capital, for markets, for talent and for jobs. As these competitive forces gather momentum, investors, managers, and policymakers ignore them at their peril. If FDA regulation, for example, is just one factor among several, it nonetheless can be pivotal.

CONCLUSION

California's life science sector is a critically important element of our state and nation's continued vitality in the increasingly competitive 21st century global economy. It is also, just as important, critical to improving patient care and public health here in the United States and around the world. However, the biomedical innovation ecosystem in California and nationwide is under tremendous stress. And in today's still uncertain economic environment, it is especially important that policymakers thoughtfully weigh the full consequence of decisions and trends in areas such as NIH funding, tax policy, and the FDA in the context of broader macroeconomic factors and the global economic competitiveness framework in order to help foster and stimulate the environment to encourage job creation, attract investment, and promote continued life sciences innovation.

Again, we thank you for the opportunity to have our remarks be a part of the record.