



HEARING TESTIMONY

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ON BEHALF OF THE

BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE UNITED STATES CONGRESS JOINT ECONOMIC COMMITTEE

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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 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 Biotech

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.

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's 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 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.