BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

April 1, 2011

John Connor
Office of the Chief Economist
U.S. Department of Commerce
1401 Constitution Ave. NW
HCHB Rm. 4842
Washington DC 20230

Re: Request for Comments on the Strategy for American Innovation
Subject: Innovation Strategy RFI
Email: competitiveness@doc.gov

Dear Mr. Connor:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to respond to this Request for Comment issued by the Department of Commerce. BIO is a trade association representing more than 1,100 companies, academic centers and research institutions involved in the research and development of innovative biotechnology products and services. Our members are primarily small- and medium-sized enterprises working to develop and commercialize cutting-edge products in the areas of healthcare, agriculture, energy, and the environment.

Since its inception roughly 30 years ago, the biotechnology industry has spurred the creation of 7.5 million direct and indirect jobs in the United States and hundreds of innovative products that are helping to heal, feed, and fuel the world. In the healthcare sector alone, the industry has developed and commercialized more than 300 biotechnology therapies, cures, vaccines, and diagnostics that are helping more than 325 million people worldwide who are suffering from cancer, HIV/AIDS, and numerous other serious diseases and conditions; another 400 or so biotechnology medicines are in the pipeline. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide damage to the environment, conserving natural resources of land water and nutrients, and increasing farm income. Biotechnology companies are also leading the way in creating alternative fuels from renewable sources without compromising the environment.

But we have yet to scratch the surface of the tremendous innovative potential that exists within the industry. By its very nature, and because it has sprung from early-stage/hypothesis-driven research laboratories, the biotechnology industry is highly innovative – and thus very risky. Biotechnology researchers work every day to identify the causes and treatments for some of the world's most intractable diseases, such as cancer, Alzheimer's, Parkinson's, diabetes, and HIV/AIDS, and to address some of the most pressing agricultural and environmental challenges facing our society over the short and long term. Developing biotechnology discoveries into products for the public is, even under the best of circumstances, a time-, risk-, and capital-

intensive endeavor. However, today's economic and investment climate has only served to exacerbate this difficult process. It is precisely for this reason that our members are keenly interested in this Request for Information, which we hope will provide you with the input necessary to help create an environment conducive to risk-taking and one that will unleash the tremendous potential of biotechnology.

What follows provides BIO's general view regarding the questions set forth by the Request for Comment on the Administration's initiatives for revitalizing American innovation.

We appreciate the opportunity to provide our views on this important topic. Please do not hesitate to contact me or Lila Feisee, BIO's vice president for global intellectual property policy, at 202-962-9200, for additional information.

Sincerely,

James C. Greenwood
President and CEO

INTRODUCTION

The Biotechnology Industry Organization (BIO) appreciates the opportunity to respond to the Request for Comments issued by the Department of Commerce seeking input on the Administration's policy initiatives that aim to improve our national innovation system. Biotechnology is one of today's most innovative and research-intensive industries. To compete with their peers, biotechnology companies strive every day to increase their innovative capacity. As such BIO and its members are well positioned to provide comments on elements of the Administration's initiatives that will spur innovation in the biotechnology sector.

To fully appreciate the biotechnology perspective, it is necessary to clearly understand the nature of the biotechnology enterprise. Biotechnology research and development is extremely risky and capital intensive. It is generally acknowledged that it takes more than a decade and costs on average $1.2 billion[1] to bring a biotechnology therapy to market. The industry is replete with anecdotes of meticulous, lengthy and expensive experiments that have failed. It is estimated that for every successful medicine, 9,999 experimental compounds never make it to market.[2]

Furthermore, biotechnology R&D largely relies on a series of complex relationships among actors within the life sciences community, including venture capital. It is often in university laboratories that exciting discoveries are initially made. Researchers might, for example, identify the correlation of a particular DNA or protein with a particular disease state. They then work through their university technology transfer offices to patent their discoveries, and to find an appropriate partner or partners to develop and commercialize the numerous potential products or technologies that could be built off these initial discoveries. Most of these discoveries are early stage and require lengthy additional research and development, as noted above, which in turn requires a massive infusion of private capital. These partners often are small start-ups, backed by venture capital.

All of this activity takes place with no guarantees that these initial discoveries will ever lead to safe, effective, and commercially viable products that can secure regulatory approval. Accordingly, policies and programs that help reduce the risk companies must endure will help to stimulate investment and commercialization. In particular, policies that encourage full funding of basic research, predictability of and reliance on patents, flexible technology transfer, and early-stage funding opportunities and incentives will serve to stimulate biotechnology innovation.

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[1] Grabowski, Henry. "Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition" *Nature* 7 June 2008 Pg 482
http://www.nature.com/nrd/journal/v7/n6/full/nrd2532.html

[2] Ernst & Young report, Beyond Borders 2002

Government Research and Development

Continue supporting basic and translational research funding, maintain flexibilities that exist under the Bayh-Dole Act, and provide greater support for university technology transfer offices.

First and foremost, the United States should reaffirm and continue its commitment to basic research funding whether at government laboratories or universities. While biotechnology companies generally benefit most directly from initiatives more upstream on the research and development continuum, there is no doubt that some of the most important and fundamental questions in science are answered at the basic level. Without a robust basic research program, innovation in America would face a significant set-back over the long term.

Second, given that it is collaborations between the public and the private sectors that propel research toward a specific outcome and fill both the knowledge and funding void, it is critical to reduce and ideally remove barriers to such collaborations. BIO is pleased to work with the appropriate agencies and organizations to identify barriers that hinder collaborations, and to provide possible solutions.

University discoveries are a fair portion of technologies developed by biotechnology companies. Such discoveries can often open the door for creation of new companies leading not only to the development of product that benefit the public, but also jobs for the region. The Milken Institute, in a 2006 report entitled "Mind-to-Market: A Global Analysis of University Biotechnology Technology Transfer and Commercialization,"[3] identified five key factors that contribute to the successful commercialization of university biotechnology research: a consistent and transparent national innovation policy that recognizes intellectual property protection and promotes entrepreneurial capitalism; the availability of funding and venture capital; biotechnology clusters not restricted by geographic borders; robust university technology transfer mechanisms; and the availability of patents and flexible licensing arrangements.

A more recent study[4] showed that university research in conjunction with industry partnerships as facilitated by the Bayh-Dole Act has led to the development and approval of 153 new drugs, vaccines or in-vivo diagnostics, 36 of which were Orphan Drugs for rare diseases, and most of which were developed by small or start-up companies. Estimated U.S. sales of the resulting products are $39.6 billion and $100 billion worldwide. These facts stand in stark contrast to the situation prior to enactment of Bayh-Dole, when Congress could not uncover a single instance of federally-funded research leading to the development of a new therapy or cure.[5]

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[3] Mind to Market Study. http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=576&cat=ResRep

[4] Jonathan Jensen et al. "The Contribution of public Sector Research to the Discovery of New Drugs", presented at BIO Technology Transfer Symposium Oct 28, 2009.

[5] "The University and Small Business Patent Procedures Act" Report of the Committee on the Judiciary, U.S. Senate on S. 414 Dec. 12, 1979 Rep No. 96-480, p. 21.

Another recent report[6] about the economic impact of university licensing under Bayh-Dole, commissioned by BIO and evaluating only the period from 1996 to 2007, shows that these university/industry partnerships contributed as much as $186 billion to the Gross Domestic Product, added $457 billion to U.S. Industrial Output, and created more than 279,000 new jobs hroughout the United States. BIO also recently surveyed its membership about the importance of university technology transfer[7]. The findings are interesting:

- 50% of BIO companies were founded on in-licensed technologies
- 76% of BIO members in-license university inventions
- 58% of BIO companies *had fewer than 10 employees* before obtaining their first technology license. Two to five years later, 80% had more than 10 employees.
- Approximately 77% say it is "extremely important" or "very important" that they can obtain exclusive licenses for their commercial product development plans.

The U.S. system of commercializing scientific discoveries has made it the world leader in the area of biotechnology in large measure because it takes into account the factors identified by the Milken Report. However, this was not always the case. Indeed, rapid commercialization of scientific discovery did not fully come about until the enactment of the Bayh-Dole Act in 1980. Prior to enactment of this legislation, publicly-funded research was owned by the government and offered for licensing on a non-exclusive basis or simply dedicated to the public. As a result, there was little incentive for business to undertake the financial risk to take these inventions and develop them into commercial products. Prior to Bayh-Dole, only 4% of the patents that resulted from federally-funded research were commercialized (cite). Since Bayh-Dole, not only has the volume of invention resulting from federally-funded research increased enormously, but also the percentage of those inventions being commercialized has increased 10-fold to around 50%. For instance, in 2005, 17,382 inventions were disclosed, 10,270 new patent applications were filed (59%) and 4,932 licenses and options were granted (48% of new patent applications filed). The total pipeline of active licenses from all the years up to and including 2005 is more than 28,000.[8]

The U.S. system of transferring federally-funded research to private companies for research and development as set forth in the Bayh-Dole Act has been so successful that it has become a template for innovation and economic development for other enterprising countries such as South Africa, India and China. The Milken Report shows that, while universities in the United States have clearly set the standard in commercializing research, other countries, particularly in Europe and Asia, have recognized the role of universities in spurring the biotechnology industry. The study suggests that, in order for the U.S. to maintain its leadership in innovation, it must continue to fund research and university technology transfer offices, encourage the transfer of innovative research to the private sector, and ensure strong intellectual property protection. BIO

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[6] David Roessner et al. " The Economic Impact of Licensed Commercialized inventions Originating in University Research, 1996-2007, Sept. 3, 2009.
[7] BIO Member Licensing Survey--http://bio.org/ip/techtransfer/documents/Session2-Esham.pdf, Oct. 2009
[8] AUTM U.S. Licensing Survey, FY 2005; www.autm.net

agrees with this assessment, and would urge the Administration to focus on ways to strengthen technology transfer offices through increased funding, training, and information sharing.

Finally, the government and industry can both work together to identify initiatives for creating collaborations. For example, the newly created National Center for Advancing Translational Sciences (NCATS) is a program at the National Institutes of Health (NIH) intended to help fill the chasm between advances in scientific understanding of disease and the availability of venture financing. We hope that this program will provide additional opportunities for the NIH and companies to collaborate. Additional examples of collaborations include the biomarker consortium, efforts to repurpose failed compounds and the creation of disease specific consortia.

In this regard, BIO cautions that the government's efforts to help move discoveries along the research and development continuum should not come at the expense of basic science funding.

Entrepreneurship

Restore the eligibility of small, venture-backed biotech companies for the Federal SBIR program.

The government currently has the framework and elements of policies in place to help facilitate creation of successful new businesses. However, some of these existing policies are not in line with the needs of the biotechnology sector. In particular, the law governing small business status makes it impossible for small, venture backed biotech companies to be eligible for the Federal SBIR program.

Biotech firms typically have less than 50 employees, no product on the market, and rely heavily on a combination of angel investors and venture capital firms in order to raise the considerable funds necessary to make a new therapy or cure commercially available to patients. One of the greatest obstacles in the innovative process, especially in today's economic environment, is the ready availability of capital. Because biotechnology R&D is risky, investors are reluctant to invest significant funds into companies or research projects that are very early in the development phase. It is here that the Federal government can be of assistance in the biotechnology innovation process. The role of the Small Business Innovation Research (SBIR) program in bringing breakthrough therapies to the American people is a matter of record. In 2008, there were 252 FDA-approved biologics that were developed by 163 companies. Thirty-two percent of those companies have received at least one SBIR/STTR award. Despite its noble past, the ability of the SBIR program to provide critical funding for medical research projects will remain hampered unless the SBIR program is reauthorized in a way that restores eligibility for the vast majority of small U.S. biotechnology companies.

Congress created the SBIR program in the early 1980s because it recognized that promising, early-stage scientific research all too often failed to be funded through the markets because it was viewed as too high risk. This failure of the markets is often referred to as the "valley of death."

Advancing science through the valley of death has never been more important than it is right now, as numerous small biotechnology companies are being forced to shelve promising therapies as a result of the current economic crisis and restrictive capital market. The impact of the current economic crises on small biotechnology companies has been and continues to be severe. In fact, since 2008, at least 47 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV/AIDS, cervical cancer, multiple sclerosis, and diabetes. According to the latest data available, there was a 27 percent drop in venture funding between 2009 and 2010 ($2.75 billion vs. $2 billion). The numbers in 2010 fell below even the $2.3 billion raised in tumultuous 2008. The biggest drop was seen in initial venture rounds, with Series A deals bringing in $479 million for biotech in 2010 compared to $849 million in 2009.[9]

The "valley of death" issues facing small biotech companies have always been challenging, and will continue to be so. However, in one particular area, this was not always the case. For 20 years, small domestic biotechnology companies competed for and often won SBIR grants. In addition to providing funding, these grants were a powerful signal to the private sector that a company's research was compelling and possessed scientific and technical merit, fueling matching private resources. However, in 2003 the Small Business Administration's Office of Hearings and Appeals (OHA) ruled that a biotechnology company, Cognetix, did not meet SBIR eligibility requirements because multiple venture capital investors, in the aggregate, owned more than 50% of the company's stock. The ruling, which is not based on the SBIR statutory language but rather a narrow interpretation of agency regulations, has made the SBIR program off-limits to a wide swath of the biotech industry, and ignores the realities of the marketplace in which small biotechnology firms often must rely on multiple sources of venture capital funding to begin start-up operations.

In 2009, the National Research Council issued a report entitled "Venture Funding and the NIH SBIR Program." The report found that "…restricting access to SBIR funding for firms that benefit from venture investments would thus appear to disproportionately affect some of the most commercially promising small innovative firms…" and that the current SBA eligibility rules have "…the potential to diminish the positive impact of the nation's investments in research and development in the biomedical area." The report recommends that the SBA ruling be repealed or modified so that majority-venture funded companies with significant commercial potential can compete for SBIR funding.

BIO believes that restoring eligibility to hundreds of small biotechnology companies would have an immediate impact on stimulating biotechnology innovation and ultimately, job creation.

Intellectual Property

Preserve the strength and predictability of the patent system that fuels the innovative process.

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[9] *BioWorld Today*, January 26, 2011

The United States currently leads the world in biotechnology in large part because of the strength and breadth of its patent system. The biotechnology industry pinpoints its modern origin to two seminal events that occurred in 1980: The passage of the Bayh-Dole Act and the landmark Supreme Court decision of *Diamond v. Chakrabarty*. By allowing universities and research institutions to patent and retain title to their inventions, and allowing flexibility in licensing without excessive government intervention, the Bayh-Dole Act provided the necessary foundation for technology transfer, and provided the incentives for the private sector to further develop and ultimately commercialize the fruits of publicly-sponsored research. And the Supreme Court decision in *Chakrabarty* opened the door for the patenting of key biotechnology inventions, including those arising from biological materials and living organisms.

As a result of these two events, the United States has experienced an incredible wave of biotech innovation for the benefit of society, including, among other things, the commercialization of hundreds of innovative therapeutics, diagnostics and research tools, industrial processes, renewable fuels, and agricultural products, as well as the millions of new, high-paying American jobs resulting therefrom. Today, there are efforts to roll back and perhaps eliminate the very patents that helped to spur an entire new sector of the U.S. economy. Decisions such as that before the Court of Appeals for the Federal Circuit[10] invalidating so-called "gene patents" may call into question the very foundation of biotech patents, and in so doing may jeopardize the United States' leadership position and global competitive advantage. In an industry where it can take decades and hundreds of millions of dollars to move from invention to market, the very instrument for enticing risk-taking – a strong patent portfolio – may now become undermined, at the very time when other nations around the globe are striving to become the next biotech hub. BIO cautions against any effort that would weaken U.S. patent protections for biotech inventions. BIO urges Congress and the Administration to defend the broad eligibility parameters of current patent law, and to permit the Patent & Trademark Office (PTO) to raise – and keep – the fees necessary for the timely issuance of patents upon which our innovative society is built.

On a related note, BIO believes that the current patent laws which date back to the middle of the last century are in need of reform. While the United States still enjoys the most robust and inventor-friendly patent system in the world, there are some elements of the laws that can be improved to unleash innovative capacity. The Senate recently passed S. 23, the America Invents Act by a vote of 95-5. The House is also developing its own legislation.

BIO urges the Administration to work with the House of Representatives in order to introduce patent reform legislation similar to that passed by the U.S. Senate.

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[10] *Association for Molecular Pathology v. United States Patent and Trademark Office*, Southern District of New York, March 29, 2010.

Incentives to Innovate

Support, expand, or create tax credits/grants/investor incentives for development of early-stage research; reduce regulatory burden; and fully fund networks and programs to help bridge the "valley of death" in product development.

Experience has shown that a commercially relevant early stage technology takes a minimum of five to seven years of further research and development by industry before it is ready for the market. As mentioned above, developing a new drug can take twice that long and hundreds of millions of dollars, with many years of financial losses and no guarantee of commercial success. Federal policies can and do have a profound impact on the research and development ecosystem. The recently enacted, first-of-its-kind, Therapeutic Discovery Project Tax Credit is an excellent example of a federal policy that will help small biotechnology companies survive the recent economic downturn and foster the progression of their innovative pipeline projects.

This credit – which can be cashed in for an actual grant for those companies that do not have tax liability – is available to defray up to 50% of pre-clinical and clinical development expenses incurred in 2009 and 2010 by small biopharmaceutical companies working to develop novel products for patients. The R&D tax credit is another current program that fosters innovation in America's research and development companies. This tax credit program should be strengthened and made permanent – by doing so, the United States will be more competitive with incentives provided by other countries vying for research investment dollars.

There are other policies in varying stages of development on Capitol Hill that would also serve to bolster America's innovation industry. In 2009, the House passed H.R. 3854, which contained the Small Business Early-Stage Investment Program. This new Small Business Administration program would provide matching funds for venture capital investors who specialize in investing in small high-technology companies (including but not limited to biotechnology companies). Such a program, if enacted, would help encourage venture capital investment in small high-tech companies that are working on the products of tomorrow, while providing a much needed stimuli to regional venture capital funds that were especially impacted by the economic downturn. Lastly, tax incentives for angel investors and other private sector investors would serve to bolster the much-needed infusion of dollars required to develop early-stage research into products that can benefit the American public.

Given the significant risk and expense associated with the development of a biotechnology product, in order to attract and retain capital for the duration of the discovery to development to market cycle, capital risk must be reduced. Moreover, in the biotech model, the cost of R&D is fairly consistent throughout the development process as opposed to other industry sectors where capital is invested in significant amounts in the front end of development. Policies that can help de-risk investments in the biotech enterprise and allow for more consistent investment throughout the R&D process would encourage innovation in the biotechnology sector. Policies worth exploring include tax policies that recognize the capital intensive biotechnology model, an evergreen fund model that recognizes the lengthy investment period of biotechnology product development, and innovation bonds among others.

Due to significant regulatory requirements that biotechnology products face and the often delayed marketing approval, policies that extend market exclusivity or streamline the regulatory review process can incentivize established companies to innovate. Such incentives include lengthening the period of data exclusivity for drugs that meet criteria for unmet public health needs, creating a tradable voucher program, and modernizing and streamlining regulations and regulatory processes for the approval of biotechnology products at the various regulatory agencies.

To commercialize agricultural biotechnology products, researchers potentially have three federal regulatory agencies that need to authorize the products. Indeed, even during research and development, the recordkeeping on plants grown out of doors is extensive and can create a disincentive to researchers who may not be familiar with the protocols, regulations, paperwork, and necessary data collection needs of the agencies. Some of these regulatory requirements exceed the level of risk. BIO encourages the Administration, through the government's Coordinated Framework, to work towards reducing the regulatory burden to be commensurate with the risk of genetically-engineered products. In addition, services or programs could be developed within the U.S. government to help guide potential researchers and developers through the regulatory maze.

For early stage companies BIO is open to creative means of stimulating innovation, albeit in a flexible manner. The biotechnology enterprise, across all of its sectors, is more amenable to the availability of a well-capitalized fund similar to the recently-enacted Cures Acceleration Network (CAN), or a model based on the successful In-Q-Tel program that has proven successful in the development of strategic technologies in other fields, both of which will be discussed later in this document.

The Cures Acceleration Network is a new statutorily-authorized program at the NIH designed to help bridge the "valley of death" in the drug development process. Timely and adequately resourced implementation of CAN, whose passage BIO strongly supported, will help researchers in academia, foundations, and biotech companies bridge the precarious gap between basic research and the eventual development of new cures and treatments for suffering patients. The legislation authorizes grants for public and private entities to further research on discoveries that have shown promise at the laboratory level, but have not been able to advance enough to attract sufficient private investment. If fully funded, CAN has great potential to significantly increase the ability of biotech companies and their partners in academia and disease research foundations to move promising research down the development path to innovative products. In addition to accelerating the development of therapies and cures, funding for CAN will also provide the economy with a much-needed boost – creating more high-wage jobs in the growing life sciences sector. BIO urges that $500 million be provided by Congress to fund CAN in the upcoming budget year.

There is no question that the United States expends a significant portion of its budget to fund basic research. This investment spans multiple agencies, supporting our unparalleled university and federal laboratory research system. Yet experience shows that laboratory discoveries are on average five to seven years away from becoming actual products. Life science discoveries

require twice this incubation period and are vastly more expensive to develop. As such, many of these discoveries often never make it through the "valley of death" because they are too early-stage to attract industry or venture funding.

When facing a similar problem finding the technologies needed to meet its mission, the U.S. intelligence community developed a program known as "In-Q-Tel." The program comprehensively nurtures the development of early-stage technologies with important potential applications. In-Q-Tel provides a variety of services ranging from technology acceleration, capabilities building, forums for discussing next stage innovation, and most important, a strategic investment fund managed by commercialization experts.

These are the missing ingredients in the development of many nascent life science discoveries arising from our university and federal laboratory research base. BIO believes that a holistic approach for nurturing potentially important discoveries in the life sciences would go a long way towards incentivizing commercialization, and by extension, innovation, economic growth, and job creation.

The creation of a program based on the successful In-Q-Tel model could be an imaginative response to the life science "valley of death" problem – one that could reap significant benefits for the nation and the world.

Finally, the Federal government should look to the States, where there are many examples of ways that job creation is being stimulated through commercialization of life sciences research. A 2008 report conducted by Battelle[11] has many examples of successful models that can be further supported through sound policies and funding. This report will be updated in May 2010. A preview of some examples includes the Ben Franklin Partnership at http://benfranklin.org/ , San Diego CONNECT at www.connect.org, Colorado Advancement of New Bioscience Discoveries Initiative, and the Kansas Bioscience Initiative, http://www.kansasbio.org/news/events/07presskit/kansasbioscienceiniativesheet.pdf. Each of these initiatives touches on areas where the life sciences sector needs support in order to further innovation, such as assisting small biotech companies in finding investment and partnership opportunities.

CONCLUSION

We applaud the Administration for looking into ways to further stimulate innovation in America. The innovation infrastructure of the United States has worked well in the life sciences over the past 30 years. Substantial federal funding of basic research, combined with intellectual property incentives and flexible technology transfer policies and practices have propelled this nation to new heights in therapeutic development, agricultural efficiency, and environmental products. BIO believes that Congress and the Administration should continue to support this world-class innovation infrastructure by providing additional funding and support for basic research,

[11] Battelle/BIO State Bioscience Initiatives, June 2010. http://www.bio.org/local/battelle2010/Battelle_Report_2010.pdf

university technology transfer offices, and the PTO. BIO further urges full funding and timely implementation of new programs such as the Cures Acceleration Network and NCATS, extension and expansion of projects such as Therapeutic Discovery Project Tax Credit, and reforms to existing programs such as SBIR. These programs can help to bridge the valley of death that many promising technologies face on the long and risky path to commercialization, and are particularly critical in the current economic environment. BIO also believes that much can still be done to reduce barriers to collaboration and regulatory approval and that the tax code is ripe for reforms that take into consideration the capital and research intensive biotechnology model.

Fostering innovation in biotechnology benefits not only the healthcare sector stakeholders, but also stakeholders in the agricultural and environmental space. For all of these segments of biotechnology streamlined and science-based regulation can stimulate commercialization and thereby innovation. Accordingly, we caution against adopting policies that would, weaken market incentives by undermining protections for innovations, or through excessive government regulation of technology transfer or overburden innovators unnecessarily. We also caution against whole-sale adoption of innovation policies across industry sectors. Not all sectors are the same. Policies such as open innovation, modularity, and multidisciplinary innovation may work in some sectors but not others. Successful innovation policies include sufficient flexibility to enable each industry sector to derive the most benefit from engaging in the innovative process.

We urge the Administration to continue its far-sighted approach to innovation as it continues its efforts in this very important area.