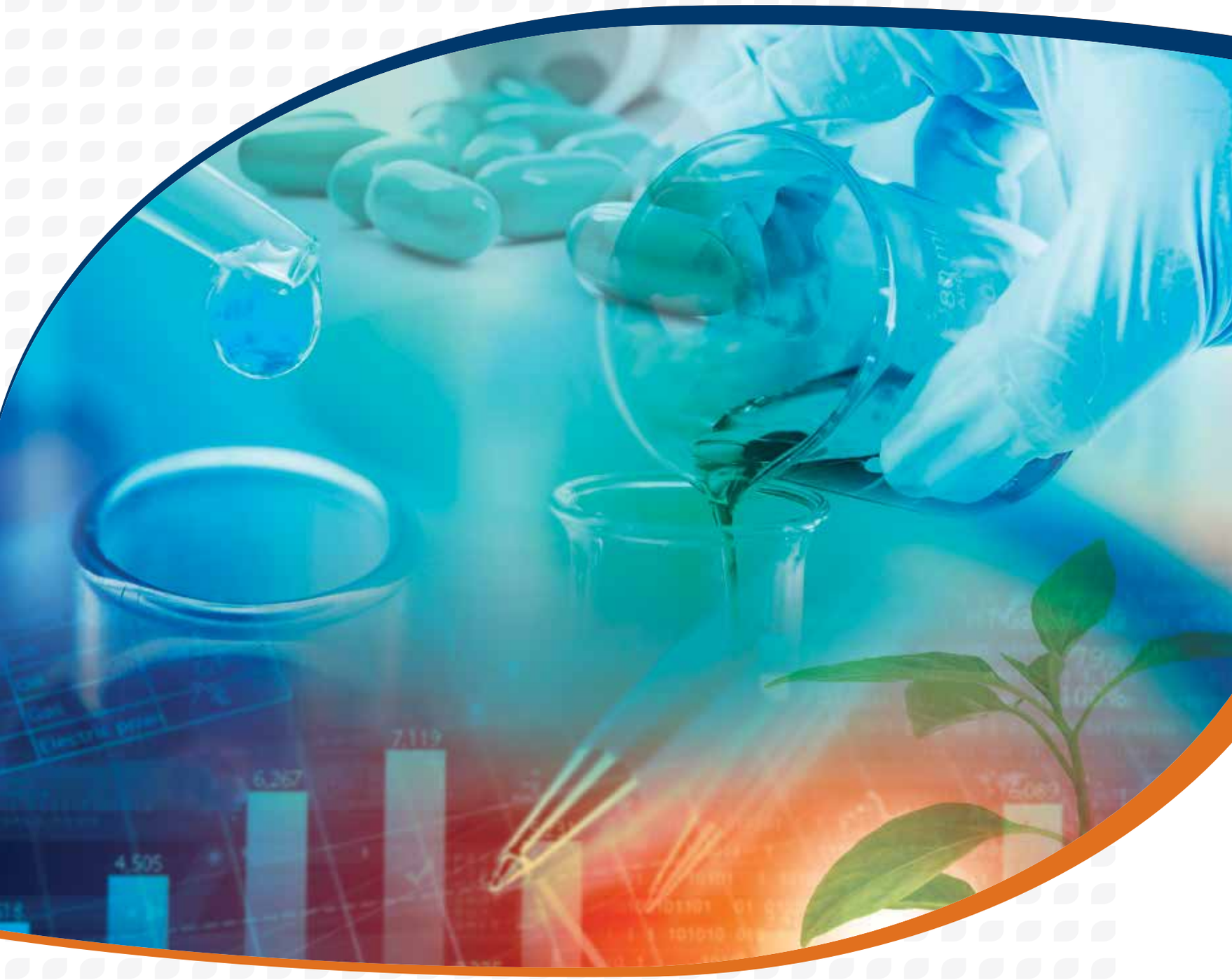
Biotechnology Innovation Organization

Fly-In

LEGISLATIVE DAY

BIOTECHNOLOGY INNOVATION ORGANIZATION



APRIL 12-13, 2016

Bio Fly-In CONTENTS

HEALTH

A Holistic Approach to Strengthening the Healthcare System

BACKGROUND

BIO member companies are committed to investing in, developing, and delivering innovative biopharmaceuticals that are transforming how we treat and cure patients with once-devastating diseases – giving them hope, extending survival, and saving millions of lives. The value that these innovative medicines offer to patients and their caregivers, the healthcare system, and society at large is truly a game-changer.[1]

To further this mission, in February 2016, BIO released *Principles of the Value of Biopharmaceuticals*. These *Principles* represent the first-ever systemic, industry-endorsed set of commitments by research-based biopharmaceutical companies to support comprehensive and sustainable solutions to improve patient access to and affordability of innovative medicines.

BIO Principles on the Value of Biopharmaceuticals:

BIO and its members commit to:

1. **Invest** in developing and delivering innovative biopharmaceuticals that offer value to patients and to society;
2. **Help patients obtain access** to the most appropriate therapies for them when the insurance industry fails to provide such access;
3. **Work collaboratively** with payors, providers, and policymakers to realize the full potential of 21st century medicines to maximize patient benefit and drive smarter overall healthcare spending;
4. **Engage all stakeholders**, including patients, on the ongoing, iterative discussion of the meaning of value; and
5. **Remove current legal barriers** that can limit the full potential of these commitments (including with respect to value-based communications and contracting arrangements).

Discussion Points:

- Innovative, life-enhancing medicines provide benefits far beyond their costs.
  - New medicines to treat HIV/AIDS resulted in a 23% decline in hospitalization rates between 2002 and 2007.
  - Because of innovative medicines, the Hepatitis C cure rate is 90%, saving patients—and the healthcare system—from years of less-effective maintenance therapy and liver transplants.
  - The U.S. would save $367 billion on health services by 2050 if we develop a new medicine that delays the onset of Alzheimer's disease by just five years.
- Gains in cancer survival are worth nearly $2 trillion, with the vast majority of that savings going to patients, families, and our economy as a whole.[2] Reducing cancer death rates by 10% would save current and future generations approximately $4.4 trillion dollars.[3]
- For every additional dollar spent on prescription drugs, Medicare spending is reduced by $2.06.[4]

- The value of an innovative therapy must be assessed holistically, including with regard to its full range of benefits and cost offsets over time. Proposed policies that focus on only one element of value—for example, short-term cost—risk undervaluing treatments and cures that benefit patients over years or even decades by mitigating disease symptoms or curing a disease altogether. In turn, undervaluing innovation can result in delaying or effectively denying patients access to new therapies.

Oppose Additional Cuts To Physicians Who Administer Medicare Part B Drugs

BACKGROUND

Medicare Part B coverage of drugs provides an invaluable route of access for patients facing grievous illnesses such as multiple sclerosis, cancer, and rheumatoid arthritis. Part B provides an important pathway for patients to access a narrowly defined, limited number of provider-administered products (*e.g.*, those that are injected or infused under the direction of a physician).

BIO POSITION

BIO urges Congress to protect beneficiary access to important drug and biologic therapies by ensuring that physicians are appropriately reimbursed for these lifesaving therapies. BIO opposes any action that would result in further reimbursement cuts to Medicare Part B products through changes to the ASP system.

Discussion Points:

- BIO opposes CMS's recently proposed Part B Drug Payment Model, which: (1) threatens patient access to needed therapies—especially those treated in rural areas and/or by community-based providers—by proposing to slash drug reimbursement to effectively ASP+0%; (2) could result in higher overall health expenditures by accelerating provider/hospital consolidation, forcing patients to travel farther for care and receive care in a higher-cost setting; and (3) was developed without consideration of the potential impact on patients and without stakeholder input.
- The patients served under Part B are often the sickest and, therefore, most vulnerable. Disrupting how the care of these patients is delivered and paid for would disproportionately impact the sickest patients fighting devastating diseases.
- Medicare Part B drug reimbursement is based on a market-based reimbursement mechanism (Average Sales Price, or ASP, +6%) that reflects the actual prices paid by physicians and has driven down Medicare costs.[5]
- ASP is working. The non-partisan Medicare Payment Advisory Commission (MedPAC) noted, "As intended by the policy, payment rates for drugs were reduced to levels closer to provider purchase prices and payment rates for drug administration increased."[6]
- To protect small physician practices and doctors in rural areas that have less purchasing power, Congress set the reimbursement rate for most Part B drugs at ASP+6%. Even so, the same MedPAC report found that, for most physicians, the different between ASP+6% and their costs for drugs is "slim," and "there are some drugs [physicians] cannot purchase at the payment rate" as it stands.
- On April 1, 2013 sequestration was officially triggered for Medicare providers, whose reimbursement for Medicare Part B therapies was cut from the statutory payment rate of ASP+6% to approximately ASP+4%. Imposing additional cuts on top of that would further imperil patient access to Part B therapies.

Changing to the Part D Program May Have a Negative Impact on Patients

BACKGROUND & BIO POSITION

Moving forward with any of the recently-considered changes to the incentive structure of the Medicare Part D program would harm innovation and put patient access to innovative medical therapies at risk.

Discussion Points:

- Private competition is producing savings and preserving patient choice under the Part D Benefit.
  - Part D program costs are about 50% lower than originally projected when the program was passed into law in 2003.[7]
  - Average monthly premiums have relatively stable—between $31 and $34—for the last six years.[8]
  - Rebates from manufacturers reduce spending for brand-name drugs in Part D by 20 to 30%.[9]
  - Enrollees are overwhelmingly satisfied with their Part D coverage: 86% report being satisfied and 95% say their coverage works well. [10]
- According to the CBO, imposing mandatory rebates on Part D could: (1) contribute to an increase in seniors' premiums by as much as 20%;[11] reduce incentives to invest in R&D on new medicines;[12] and (3) result in price distortions in other programs (e.g., commercial insurance).[13]
- Government interference would reduce patient choice and restrict access to medically necessary medicines: Proponents of direct negotiations often laud the Veterans' Affairs (VA's) pharmacy benefit as a model that Part D should replicate. However, the VA program provides far less choice to patients: Part D plans cover, on average, 85% of the top 200 drugs, while the VA covers just 59%.[14]
- Striking the non-interference provision could harm the ecosystem of drug development, increasing the time-to-market for new medicines, and having an outsized effect on small companies, which depend on sustained investor capital over a number of years despite the low success rates of drug development (only about one in 10 products that enter clinical trials get approved).[15]

The 340B Drug Discount Program Requires Congressional Oversight

BACKGROUND

Congress created the 340B program in 1992 to help uninsured indigent patients gain better access to prescription medicines. Six types of hospitals and 10 types of clinics that receive certain federal grants are eligible by statute to participate in the program. A single participant is called a "covered entity." In 2005, there were 591 hospitals participating, a number while grew to 2,140 in 2014.[16] The 340B program requires manufacturers to provide substantial discounts to covered entities for prescription drugs.

BIO POSITION

The 340B Drug Discount Program is an important program designed to help uninsured indigent patients gain greater access to prescription medicines. However, exponential growth, significant rates of non-compliance revealed in audits, and a government report of lax oversight underscore the need to modernize this program to ensure it continues to serve patients in need.

Discussion Points:

- Congress should ensure 340B continues to operate as intended: to support patients in need.
  - The 340B program has departed significantly from its original intent of preserving access to outpatient medications for patients in need.
  - There are no requirements governing how hospitals utilize revenues produced by 340B discounts; revenue generation, not improved patient access, has become a key attraction of the program—not only to the covered entities enrolled, but to an emerging cottage industry of 340B services organizations.
- Comprehensive oversight is needed in the 340B Program.
  - Over the last 10 years, the GAO and the Department of Health and Human Services Office of Inspector General (HHS-OIG) have consistently called for more specific, formal guidance and improved oversight of 340B covered entities.[17]
  - HRSA's own audits of participating entities have revealed high rates of non-compliance with program requirements. [18]
  - Congressional Oversight Committees and the Health Resources and Services Administration (HRSA) have recently taken steps to improve oversight, and such efforts to ensure program integrity must continue and expand.

Building 21st Century Approaches to Cures/Drug Discovery, Development and Delivery

Entrepreneurial biotechnology companies are at the cutting edge of a new and revolutionary understanding of the genetic and biomolecular underpinnings of disease, and are committed to developing the next generation of medicines to transform patient care. However, this goal can only be realized in a public policy environment that sustains scientific discovery and biomedical innovation.

Last year, the House of Representatives passed the 21st Century Cures Act (H.R. 6). This bipartisan effort, led by Energy and Commerce Committee Chairman Fred Upton (R-MI) and Representative Diana DeGette (D-CO), aimed to accelerate biomedical innovation by ensuring that our nation's laws and regulations keep pace with the tremendous pace of scientific advancement.

This year, the Senate, Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamer Alexander (R-TN) and Ranking Member Patty Murray (D-WA) are continuing work on a complementary biomedical innovation initiative. Additionally, the biopharmaceutical industry and FDA have been engaged in technical negotiations that will result in a PDUFA Commitment Letter that is scheduled for reauthorization by Congress in October 2017.

These initiatives are collectively looking at the full arc of the biomedical innovation lifecycle to modernize the drug development and delivery process– from supporting discovery and basic science, to streamlining and modernizing the drug development and review processes, to empowering patient input and unleashing the power of data in pre and post-market settings.

BIO is excited to continue to work with Chairman Upton, Representative DeGette, Chairman Alexander, Ranking Member Murray, other Members of Congress and the FDA as they seek ways to ensure our nation maintains and enhances its position as the biomedical innovation capital of the world.

BIO POSITION

BIO has identified the following proposals developed to enhance the drug development process as priority issues for consideration by FDA and Congress: integrating patient perspectives in drug development; advancing the ability to develop and utilize modern drug development tools and approaches to clinical development; aligning market forces to spur biomedical innovation; and ensuring FDA has the resources and expertise it needs to fulfill its mission. BIO looks forward to working with policymakers to enact these proposals.

Discussion Points:

BIO's proposals are based on several simple, yet powerful themes that promise to transform the healthcare system:

- **Embracing Precision Medicine and Genomics through Regulatory Science:** Industrial-scale biomarker qualification and whole genome sequencing will help to better understand the molecular basis of disease and develop targeted, precision therapies individualized to the unique genetic makeup of each patient's specific disease.
- **Patient-Centric Approaches to Drug Development:** Essential to innovation is the incorporation of the patient voice into the drug development cycle. The future of the drug development process will require active collaboration and cooperation between FDA, Sponsors, and, most importantly, patients. Placing patients at the center of the drug development process will spur the development of therapies for the conditions that matter most to patients and their caregivers.
- **A Shared National Research Commitment to Chronic Disease:** In light of current demographics, the extraordinary toll of chronic disease will overwhelm the U.S. healthcare system in a relatively short time. Our hope for better treatments and cures hinges on understanding how to intervene to prevent the onset or halt the progress of disease. A shared national commitment to a large-scale research program on Alzheimer's disease and other chronic conditions could identify precursors and early signs of disease risk and unlock the root causes of these devastating conditions that threaten both ordinary Americans and our nation's fiscal health.
- **Harnessing New Information Technologies and Data Analytics:** Modern technology and cutting-edge analytical methods must be embraced by FDA. Sophisticated approaches to harnessing sources of existing data and emerging health information technologies will help to improve the efficiency of clinical trials and transform the drug development process by learning from the real-world performance of treatments.
- **Combating Infectious Disease in a Globalized World:** Next-generation vaccines and antibiotics to prevent and treat endemic, emerging, or drug-resistant infectious diseases represent one of our best lines of defense against deadly pathogens. Creating a robust environment of collaboration with U.S. government partners is critical to continuing the development of lifesaving vaccines and ensuring access to critical immunizations for all Americans across their lifespan.
- **Promoting a Science-Driven Regulatory Environment:** In order to realize a vision of a modern regulatory environment, it is critical to enhance FDA's scientific capacity and infrastructure. The size and complexity of the FDA, its increasing statutory responsibilities, and globalization of FDA-regulated industries have placed significant demands on the Agency and may hamper its ability to pursue forward-looking management strategies to prepare for the future of biomedical science. We must promote and empower a strong and flexible FDA with world-class scientists ready to meet the complexities of modern scientific discovery, and encourage robust, science-driven communication regarding available medicines and appropriate patient care.

- **Align Market Forces to Spur Biomedical Research:** Over the past several decades, the time and cost to develop new therapies have dramatically increased. To remain competitive in a globalized world, we must build upon current research and development incentives—such as regulatory and patent-related protections—and ensure a sustainable reimbursement environment that continues to encourage innovation.
- **Improving Patient Access, Sustaining Incentives for Innovations, and Building an Efficient, Learning Healthcare System:** Ensure that: (1) patients have access to the therapies they need by preserving the patient/provider decision-making process, and ensuring that access to health insurance translates into meaningful access to high-quality healthcare; (2) 21st century medicines are met by a 21st century healthcare system that values innovation; and (3) stakeholders across the healthcare system collaborate to overcome existing regulatory hurdles to maximizing the efficiency and effectiveness of the delivery of care, including through the increased use of real-world data to make evidence-based decisions.

The urgency of finding and developing 21st century approaches to cures, drug discovery and delivery cannot be overstated. Devastating diseases such as Alzheimer's, cancer, Parkinson's, diabetes, or rare genetic conditions affect millions of Americans and their families. Biotechnology holds the greatest promise for finding the solutions to so many unmet medical needs. We must act now for the patients and their families who are counting on us.

FUNDING

Support for the National Institutes of Health (NIH) is Critical

BACKGROUND

The tradition of public investment in the NIH has helped establish the United States as a global leader in medical research and innovation. This commitment has laid the foundation for the development of many breakthrough drugs and therapies that have extended and improved the lives of countless patients and their families in the United States. This investment also serves to drive the innovation pipeline that is critical to ensuring that the medical research and biopharmaceutical industry, which provides high-paying jobs and makes significant contributions to the U.S. economy, continues to grow in the United States.

The NIH is the nation's premier research agency for the study of human health conditions, diagnostics, and treatments. The United States has historically been the foremost leader in the world for biomedical research and development. Breakthroughs in biomedicine and health over the past 50 years are largely due to the research and development that occurs within the biotechnology and pharmaceutical industries, as well as the publicly- funded biomedical research enterprise centered at the NIH. At a time when global completion has intensified from China and the European Union, the United States should not abdicate its role as global leader or diminish its competitive edge.

Since the doubling of the NIH budget between 1998 and 2003, funding levels for the NIH have consistently remained flat over the past decade, and sustained cuts as a result of sequestration in 2013. When NIH funding is measured against the rising cost of conducting medical research (known as the biomedical research and development price index, or BRDPI), NIH funding has decreased by 22% between 2003 and 2013. The FY 2016 budget provided a much needed 5% increase in biomedical research funding, reflecting the strong bipartisan recognition that maintaining the United States position as the global leader in medical innovation is a priority for Americans. The discoveries that result from NIH research are critical to the ability of the biopharmaceutical industry to deliver the next generation of medicines and provide new solutions to address our nation's most pressing health care needs.

In addition to the NIH's role of supporting medical research, it also provides critical early-stage funding opportunities to small U.S. biotechnology companies developing innovative medicines through the Small Business Innovation Research and Small Business Technology Transfer programs. NIH's Cures Acceleration Network also offers collaboration and funding opportunities for public-private partnerships to advance the development of high-need cures and reduce significant barriers between research and clinical trials. The National Center for Advancing Translational Sciences is doing important work to facilitate medical innovation and enable partnerships between government and industry to transform the translational science process in order to better enable industry to develop and deliver treatments and cures to patients faster. Finally, the President's Precision Medicine Initiative Cohort, the Vice President's National Cancer Moonshoot

initiative and the White House Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative all have the potential to advance biomedical science and potentially improve the drug development process, thus improving the ability of the biopharmaceutical industry to develop and provide modern medicines to the patients who need them.

BIO POSITION

For Fiscal Year (FY) 2017, BIO supports a budget of at least $34.5 billion for the NIH and opposes any cuts to the current NIH budget.

Discussion Points:

- Sufficient NIH funding is necessary to capitalize on new and unprecedented scientific opportunities in an era of genomic health and personalized medicine.
  - Research conducted and supported by the NIH has led to advances in genomics, proteomics, and new biomedical technologies and tools that have the potential to bring us into an era of personalized, predictive, and preemptive medicine.
  - Funding the NIH at $34.5 billion would provide the minimum level of funding needed to reflect the rising costs associated with biomedical research and ensure that the United States is able to continue to advance biomedical research and enable the biopharmaceutical industry to discover and develop the next generation of medicines.
  - This funding will also serve to advance new initiatives such as the President's Precision Medicine Initiative Cohort, the Vice President's National Cancer Moonshoot initiative, and the White House BRAIN Initiative that have the potential to advance drug discovery and improve the drug development process.
- Biomedical research is the key to improving the quality of life for patients and their families. Advancing medical science has and can provide medical solutions that decrease hospitalizations, help patients live a higher quality of life, and prolong the ability to live independently.
- Maintaining a strong, publicly-funded NIH is important to America's scientific competiveness. As a result of our historic public commitment to biomedical research, America has always been the global leader in biomedical technology. However, as global competition increases and U.S. funding decreases, this position of leadership is in jeopardy. In an era where we are working to build and support 21st Century jobs, we must support funding opportunities for the next generation of doctors and scientists that are the backbone and future of America's life sciences industry.

Robust Funding for Federal Biodefense and Pandemic Influenza Programs

BACKGROUND

After the 2001 terrorist attacks, the Congress mandated a dedicated effort to develop and stockpile drugs and vaccines needed to protect the American people from chemical, biological, radiological, and nuclear (CBRN) and pandemic threats. Because medical countermeasures (MCMs) to protect against threats like anthrax, Ebola, and plague have little or no commercial market, in 2004, Congress passed the Project BioShield Act which created the Special Reserve Fund (SRF). Subsequently in 2006, Congress created the Biomedical Advanced Research and Development Authority (BARDA), which has additional responsibilities for MCM development and pandemic influenza funding.

BARDA and the Assistant Secretary for Preparedness and Response (ASPR) are charged with the prioritization and development, through partnerships with industry, of vaccines, treatments, and diagnostics for CBRN and pandemic influenza threats for use during a man-made, natural, or accidental emergency. The funding for these vital national security products comes, in large part, from the Project BioShield SRF and pandemic influenza budgets.

The SRF was originally funded through an advanced appropriation of $5.6 billion over 10 years, which successfully created a "guaranteed market" to incentivize biopharmaceutical companies to develop and produce civilian MCMs for which there is a limited or no commercial market. This funding expired at the end of Fiscal Year (FY) 2013 and since FY 2014, the SRF has been funded through the annual appropriations process, receiving $255 million both FY 2014 and 2015 and $510 million in the FY 2016 Omnibus. While BIO was pleased with the increased funding in FY 2016, we were concerned by the President's request of $350 million for the SRF in FY 2017.

New funding must be appropriated at a level consistent with past appropriations for Project BioShield and the level authorized in the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013 (P.L. 113-5) – $2.8 billion over five years – to support procurement priorities identified by the government. The current funding trajectory risks a shortfall of 600 million to $1 billion below the authorization.

BARDA, which oversees advanced research and development efforts, also requires an annual appropriation to support its advanced development pipeline, which currently includes approximately 200 candidate MCMs. In 2014, BARDA's scope was expanded to include work on antimicrobial resistance (AMR) public health threats. Funding for BARDA should take into account both BARDA's advanced research and development and antimicrobials work.

Past appropriations for multi-agency pandemic influenza response have been previously funded through supplemental measures. Despite the depletion of these supplementals, pandemic influenza has been woefully underfunded the last few years. Unlike many emerging infectious diseases, pandemic influenza is a known threat that is very challenging given its versatile and persistent nature. It is imperative that our pandemic preparedness include advanced development of vaccines, antivirals and diagnostics, rapid response capability building, and the replenishment of vaccine and antiviral stockpiles. With these funds depleted, without continued robust funding, some companies may not have sufficient time to respond to pandemic influenza threats due, in part, to delays in federal funding commitments to the manufacturing of seasonal influenza products and pandemic flu threats such as H7N9.

BIO POSITION

BIO requests that Congress appropriate $2.8 billion for the SRF over five years (FY 2014-18) for the procurement of MCMs, including $560 million in FY 2017, which is one-fifth of the authorized five-year total. Additionally, for FY 2017, BIO encourages Congress to appropriate $607 million to BARDA, $575 million for the Strategic National Stockpile (SNS), and $250 million for pandemic influenza preparedness.

Discussion Points:

- **Funding to support HHS efforts to prepare for, and respond to, a pandemic influenza outbreak by developing vaccines, antivirals, and rapid diagnostic tests is critical:** These activities were previously funded using unobligated supplemental pandemic influenza balances. The $72 million obligated in the FY 2014 2016 appropriations omnibus reflects the minimum amount needed for pandemic influenza MCM development and acquisition by ASPR and BARDA. Past appropriations for multi-agency H5N1 and H1N1 preparedness and response activities, including MCM development and acquisition, were as high as $6.23 billion in FY 2006 and $8.23 billion in FY 2009. Robust funding is necessary for regular testing and evaluation of preparedness and rapid response capabilities for known and new pandemic threats, maintenance of adequate vaccine stockpiles, and support for the advanced development of improved influenza products.
- **Project BioShield has improved our nation's ability to protect against security threats:** The Department of Homeland Security has identified 13 chemical, biological, radiological, and nuclear (CBRN) agents as material threats

to our nation. BARDA reports that 12 vaccines and drugs against anthrax, smallpox, botulinum toxin, and radiological agents were procured during that 10-year authorization period. There are over 200 MCMs in the pipeline and BARDA expects to procure another 12 MCMs by 2018.

- **Project BioShield has facilitated investments in novel technologies that will help solve both preparedness and public health problems:** The accomplishments of Project BioShield go beyond the quantities of CBRN MCMs stockpiled or the number of advanced development contracts awarded. The program has fueled innovation in vaccine development, diagnostics, and medical devices. Many companies are currently researching and developing products or platforms that could function as both MCMs and commercial products, such as broad-spectrum antibiotics.
- **Without the certainty of a guaranteed MCM market, companies may be forced to redirect their priorities to other markets:** The SRF and BARDA pandemic influenza funding are the cornerstone of the the U.S. Government's commitment to create a guaranteed market for MCMs. Without adequate funding for the SRF and pandemic flu, companies will face tremendous uncertainty related to the timing, size, and/or speed of funding, making it even more difficult to attract private investor funding and operate.

Legislation Advancing Medical Countermeasure R&D and the Partnership with Industry

BACKGROUND

Medical countermeasures (MCMs) for material threats such as anthrax, Ebola, or plague, have only one purchaser – the U.S. government. In 2004, recognizing the role of the federal government in the development and procurement of these critical products, Congress created the Project BioShield Special Reserve Fund, which created a guaranteed market for MCMs through the establishment of a $5.6 billion advance appropriation over ten years. *(The Biodefense Funding issue brief has more information on this topic.)*

When this advanced appropriation authorized under the Pandemic and All-Hazards Preparedness Act (PAHPA) expired in FY 2013, Congress began funding the SRF through annual appropriations. Pharmaceutical and biotechnology companies that had been attracted to the biodefense space lost the guarantee of a market for their products. Though the PAHPA reauthorization legislation authorized $2.8 billion over five years (FY 2014-2018), Congress has failed to provide sufficient appropriations through the annual appropriations process only $1.02 billion has been appropriated in the first three years of the authorization. This risks a $600 million to $1 billion shortfall under the authorized level.

Additionally, companies in this space have reported experiencing delays in the contracting process due to BARDA's contracts being managed at the HHS Acquisitions Management, Contracts, and Grants (AMCG) office and a requirement of contract review by the Office of Management and Budget (OMB). Streamlining contracting is key to ensuring that there are not excessive delays in the implementation of vital research.

Additional incentives are needed to continue to attract companies to medical countermeasure research and development, demonstrate the federal government's commitment to biodefense, and enhance the public-private partnership.

In order to strengthen the public-private partnership and institute novel incentives for MCM R&D, Representatives Susan Brooks and Anna Eshoo have introduced H.R. 3299, the Strengthening Public Health Emergency Response Act of 2015, and Senators Richard Burr and Robert Casey have introduced S. 2055, the Medical Countermeasures Innovation Act of 2015.

H.R. 3299 and S. 2055 help to create stability and certainty by:

- Streamlining the federal contracting process by moving contracting authority from AMCG office to BARDA.
- Extending the Food and Drug Administration's (FDA's) Priority Review Voucher (PRV) program for neglected tropical diseases to biological agents included on the material threat list.
- Prioritizing finalization of the FDA's Animal Rule Guidance.
- Requiring BARDA and the Centers for Disease Control and Prevention (CDC) to coordinate on stockpiling plans for the Strategic National Stockpile (SNS).
- Setting requirements for the annual Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Five-Year Budget Plan, including the addition of pandemic influenza funding to the budget plan.

BIO POSITION

BIO urges all Members of Congress to cosponsor H.R. 3299 and S. 2055, and calls upon Congress to act swiftly to pass these bills.

Discussion Points

- The public-private partnership between biotech companies and the federal government is essential in the biodefense space, as there often is no commercial market for these products.
- The guaranteed market created by the Project BioShield Special Reserve Fund was successful in stimulating investment in MCMS: there are now more than 200 MCM candidates in the development pipeline, 12 products have been procured since 2004 and 12 more procurements are anticipated by 2018, and anthrax and smallpox products have been developed and procured. But funding has not been consistent with the level needed to sustain these activities.
- The Biomedical Advanced Research and Development Authority (BARDA) reports that now there are more than 200 product candidates in the pipeline. But the current funding trajectory chances alienating companies who are partnering with the government on these products at risk, and puts our ability to respond to a potential CBRN incident in jeopardy.
- In light of reduced funding, additional incentives are needed to attract and retain companies to invest in this field. H.R. 3299 and S. 2055 demonstrate Congress' and the federal government's commitment to improving the public-private partnership and investing in MCM and pandemic influenza product development.

Appropriations for the Combating Antibiotic-Resistant Bacteria (CARB) Initiative

Antimicrobial resistance (AMR) is an urgent global public health issue; in 2013, the Centeres for Disease Control and Prevention (CDC) estimated that each year in the U.S. alone more than two million people contract an antibiotic-resistant infection and about 23,000 people will die from their infection. Resistant pathogens threaten to reverse the progress we have made in modern medicine, both in our ability to treat infections and our ability to perform common surgical procedures and treatments.

In September 2014, the White House announced a number of federal activities related to the issue of AMR, including an Executive Order, the report of the President's Council of Advisors on Science and Technology (PCAST), and a National Strategy for Combating Antibiotic-Resistant Bacteria. A federal interagency task force then developed a National Action Plan for Combating Antibiotic-Resistant Bacteria, which was released in March 2015. These documents outline the federal government's plans for stewardship, surveillance, and innovation going forward.

While novel antibiotics are critically needed to fight resistant bacteria, we believe antibiotics are *one* part of a broader infectious disease strategy that also leverages vaccines, diagnostics, and other novel products. All of these products should be available to clinicians so that infections can be effectively prevented, diagnosed, and treated in patients.

Because AMR is a growing public health and national security threat and there is a significant unmet medical need in this area, significant federal investments are needed to spur the discovery and development of new products. The President's FY 2017 Budget includes such funding as part of the Administration's CARB Initiative.

As it relates to the CARB Initiative, BIO Supports:

1. **$607 million for the Biomedical Advanced Research & Development Authority (BARDA).**
   - In 2014, BARDA's mission was expanded to include work on antimicrobial-resistant public health pathogens in addition to biothreats. A funding level of $607 million will provide full funding for antimicrobial R&D ($192 million) while maintaining the authorized level of funding for medical countermeasure advanced research and development ($415 million).
2. **$251 million for the CDC.**
   - $200 million for the Antibiotic Resistance Solutions Initiative, which establishes state prevention programs, supports a new Detect Network of regional labs to improve outbreak response, and creates a new bank of current resistant threats which helps companies developing new products and tests. This is an increase above the FY 2016 funding level of $160 million.
   - $21 million for the National Healthcare Safety Network (NHSN). This allows CDC to expand the NHSN to more than 17,000 facilities and work with partners to implement AMR prevention strategies.
   - $30 million for the Advanced Molecular Detection (AMD) Initiative, which strengthens epidemiologic and laboratory expertise to effectively guide public health action. This program also received $30 million in FY 2016.
3. **$41.6 million for the Food & Drug Administration (FDA).**
   - This funding, the same amount as FY 2016, supports the evaluation of new antimicrobial drugs, streamlining of clinical trials, and development of a system for monitoring antimicrobial drug use in food-producing animals.
4. **$413 million for the National Institute of Allergy and Infectious Diseases (NIAID).**
   - This funding will help spur R&D for new rapid diagnostics, develop a national database of genome sequence data of all reported human infections with antimicrobial-resistant microorganisms, launch a large-scale effort to better understand drug resistance, and create a rapid-response clinical trial network to test new antibiotics on individuals infected with highly resistant strains.
5. **$61 million for the Department of Agriculture (USDA).**
   - Proposed funding allows the USDA to support research on the relationships among microbes and livestock, the environment, and human health.

INTELLECTUAL PROPERTY

Target Abuses of the U.S. Patent System without Weakening Innovation and Economic Growth

Intellectual property is the lifeblood of the biotechnology industry. Strong patents, and an efficient, predictable, and objective patent system, are critical to ensuring a steady stream of capital to biotechnology companies developing innovative medicines, alternative energy sources, insect- and drought-resistant crops, and a wide range of other innovative biotechnologies that are helping to feed, fuel, and heal our planet. This quintessentially-American industry leads the world in innovation, providing the United States with a global competitive advantage and spurring economic growth and the creation of high-paying jobs here at home.

BIO'S POSITION

Currently-pending patent litigation reform legislation is highly relevant to the biotech business model. Any legislation passed by this Congress must not impair the ability of the vast majority of patent owners to enforce their legitimate patents in a legitimate way. The injection of additional systemic uncertainty by, for example, making the enforceability of patents against infringers more costly, lengthy and risky can negatively affect which new cures and treatments may become available a decade from now, or whether the next generation of renewable energy ever makes it to market. BIO urges Congress to proceed cautiously in this complex area, and to focus on those reforms that would clearly target abusive behavior without undermining the ability of small, investment-intensive businesses to be able to protect and enforce their key assets – their patents – in a timely and efficient manner.

Despite their well-intentioned efforts to curb abuses, proponents of patent litigation reform are pressing for sweeping ideas to remake the patent litigation system in fundamental and untested ways, based on questionable data and without sufficient consideration of the impact of those changes on the vast majority of patent owners and licensees who engage in legitimate and good faith patent licensing, partnering, and enforcement activities. Instead of surgically targeting abusive practices, they support general, far-reaching patent litigation changes, such as:

- Vastly increased amounts of detailed information would be required in order to file a patent infringement suit; insufficiencies could lead to dismissal right away;
- Patent infringement lawsuits would be prevented from getting underway if the accused infringer files certain motions, potentially creating long, business-crippling delays;
- Infringing manufacturers and sellers of patent-infringing products could inappropriately deflect patent lawsuits away from themselves towards their suppliers; and

- Patent infringers could threaten the patentee's business partners – investors, licensors, development partners and others with a financial interest in the patentee's business – by adding them to the litigation as unwilling co-plaintiffs to pay the other side's costs under a new "losers pay" approach;

Many of these provisions would depart greatly from the normal civil litigation rules that apply to other commercial litigation under the U.S. system. Congress should pause before singling out patent litigation for such special rules found in no other area of civil litigation. It is true that most of these litigation reform provisions were improved after long negotiations, particularly in the Senate bill – but they remain one-sided and impose new burdens only on patent owners of all stripes, not on patent infringers. In an effort to erect barriers against patent-asserting entities, or so-called "patent trolls," these provisions would systematically raise the cost and risk of patent enforcement for all patentees, with disproportionately greater negative impact on smaller, poorly-funded patent holders. This is particularly true with respect to H.R. 9, the House version of this bill, which BIO strongly opposes.

Both bills do, however, contain some positives, specifically in the way they would change the Patent Office's so-called Inter Partes Review (IPR) system. Under this system, anyone can currently file an administrative challenge to an existing patent. Unfortunately, IPR unfairly stacks the deck against patent owners in many ways, leading to patent invalidation rates nearly twice those seen in district court patent litigation. Not surprisingly, these types of statistics are inviting all sorts of unintended abuses and predatory practices by those seeking to attack patents for their own profit – what BIO calls "reverse patent trolls." For example:

- Hedge funds are taking "short" positions in the stock of biopharmaceutical companies and then filing IPR challenges against one or more patents protecting key products in an effort to profit from driving down the companies' stock prices.
- Other questionable entities are using the IPR system as a way to get into the extortion racket – threatening to file IPRs against a biotech company's key patents unless a substantial "payment" is made.
- Generic drug companies are using the IPR system to skirt the long-established and carefully balanced rules governing brand-generic patent dispute resolution enshrined in the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (BPCIA).

The biotechnology industry is particularly susceptible to such abusive practices because these companies tend to have few products on the market and just a handful of very valuable patents protecting those products. Threatening just one or two key patents with IPR can demonstrably scare away investors and impair a company's ability to raise capital for research and development.

Both the House and Senate patent reform bills would begin to fix these problems by making IPR more fair: patent claims would be given the same scope as in district court (by elimination of the PTO's "broadest reasonable interpretation" (BRI) claim construction); by offering patent owners more opportunities to present evidence in defense of their patents; and by other incremental changes. The Senate bill would also ensure that patent owners have meaningful opportunities to correct flaws in challenged patents, so that patent rights can be preserved in clearer, narrower form instead of being struck down indiscriminately.

However, neither bill addresses the biotech industry's major concerns with IPR – the lower evidentiary standards for patent invalidation; opportunities for repetitive, abusive petitions; its use by financial speculators or extortionists; and the lack of any exemption from IPR for patents that are subject to the detailed dispute resolution schemes created by Congress in Hatch-Waxman and BPCIA.

CONCLUSION

The United States leads the world in biotechnology innovation and product development due in large part to the strength and predictability of the U.S. patent system. Proposals that would routinely and indiscriminately complicate, delay, and make more risky and expensive the efforts of all patent owners and licensees to protect and enforce their patents would do serious harm to the life sciences ecosystem in particular. BIO urges Congress to focus on those reforms that would clearly target abusive behavior – both by patent owners and against patent owners – without undermining the ability of small, investment-intensive businesses to be able to protect and enforce their key assets – their patents – in a timely and efficient manner. It is critical that Congress "do no harm" in its enthusiasm to reform a system that has made the United States the innovation engine of the world. Accordingly, BIO strongly opposes the current House bill, H.R. 9, and does not support the Senate version in its current form.

TAX

Start-up Jobs & Innovation Act/PARTNER Act

BACKGROUND

The Start-up Jobs & Innovation Act and the Partnerships to Advance Revolutionary Technology and Novel Entrepreneurial Research (PARTNER) Act would allow small, R&D-focused companies to partner with their investors on research projects. These collaborations, called R&D Partnership Structures, would allow the investors to recognize the tax losses and credits generated by the R&D in a project. These bills would encourage early-stage investment in innovative research.

The early growth of the biotech industry was fueled in part by the ability of growing companies to use R&D Limited Partnerships, in which individual investors would finance R&D projects and then utilize the operating losses and tax credits generated during the research process. These structures gave investors a tax incentive to support biotech research at its earliest stages. During the late 1980s, the ability to pass losses and credits through to investors was eliminated, but the Start-up Jobs & Innovation Act and the PARTNER Act would make a targeted change to the passive activity loss (PAL) rules to incentivize vital research.

BIO POSITION

BIO strongly supports enactment of the Start-up Jobs & Innovation Act (S. 341) and the PARTNER Act (H.R. 2179). The R&D Partnership Structures allowed by this legislation will lead to long-term investment strategies, which are critical to the success of innovative research.

Discussion Points:

- The R&D Partnership Structures proposal in the Start-up Jobs & Innovation Act and the PARTNER Act would stimulate $10.3 billion in investment per year and create 156,000 jobs.
- Many small innovative companies do not yet have product revenue because they are still conducting research. Consequently, they depend on private investment to fund their work. The Start-up Jobs & Innovation Act and the PARTNER Act reform partnership rules to encourage the long-term investment required for innovative businesses to be successful.
- Only emerging companies dedicated to R&D would be eligible for these partnerships, so investors would be incentivized to invest at an earlier stage, when the capital is most needed.
- Policies designed to stimulate private investment in cutting-edge R&D will speed the development process and create high-quality research jobs. Emerging pre-revenue innovators are vital to supporting America's 21st century economy.

The Start-up Jobs & Innovation Act would also allow investors in emerging companies to benefit from a decreased capital gains tax rate under Section 1202. Currently, only investors in companies with aggregate gross assets below $50 million are eligible for this provision, but this legislation would increase the gross assets limit to $150 million, incentivizing investment in a wider pool of innovators.

Promoting Innovation Through the Tax Code

BACKGROUND

BIO believes it is vital for the United States to have a tax code that allows it to be competitive on the global stage. Currently, the U.S. corporate tax rate is the highest among countries in the OECD. High tax rates can impede growth, and this is particularly true in the biotechnology industry, where it can take more than a decade and cost more than $1 billion to develop a single breakthrough technology.

BIO supports efforts to streamline the tax code in order to facilitate lower rates and international competitiveness. At the same time, there are provisions in the current code that stimulate biotech R&D and early-stage commercialization, and these provisions are vitally important to the scientific progress of BIO members. These provisions, including the Orphan Drug Tax Credit and the Second Generation Biofuel Producer Tax Credit, should be retained in any reformed tax code. In combination with lower overall rates, these incentives will support breakthrough research and foster commercialization to bolster the economy.

Additionally, Congress has the opportunity to take new steps to inspire innovative research, development, and commercialization. Many biotech companies operate without product revenue to fund their scientific progress, which means they have little or no taxable income in early years, so provisions in the current code designed to incentivize research actually function as a potential future benefit rather than providing immediate support for R&D. Congress should bear in mind the needs of these pre-revenue innovators, which depend almost entirely on external capital to fund the typical decade-long, billion-dollar biotech development program.

BIO POSITION

BIO supports a U.S. tax code that recognizes innovation as a crucial part of the 21st Century American economy and helps the United States compete more effectively on the world stage. BIO supports changes to the tax code to lower corporate tax rates while moving to a territorial system of taxation and maintaining vital provisions like the Orphan Drug Tax Credit and the Second Generation Biofuel Producer Tax Credit.

In addition to lowering the corporate tax rate and maintaining important provisions from the current code, Congress should enact targeted provisions that support innovative companies early in their life cycle. Specifically, policymakers should promote the world-leading U.S. innovation ecosystem by incentivizing companies, individuals, and funds to invest in pre-revenue companies and support their cutting-edge research.

Discussion Points:

- The high U.S. corporate tax rate has led many multinational corporations to locate their operations overseas. Other countries lead the world in incentives for innovation and have less burdensome tax systems.
- Moving to a territorial system is a critical step towards creating a competitive tax code. Freeing up over one trillion dollars that is currently trapped overseas due to the inefficiencies of the U.S. tax code will boost economic growth and capital investment.
- BIO supports maintaining the Orphan Drug Tax Credit. By reducing the costs of developing drugs for smaller patient populations, the Orphan Drug Tax Credit has allowed companies to develop hundreds of new therapies that would otherwise not have been commercially feasible.
- BIO supports targeted tax incentives to spur research by and investment in small, pre-revenue innovators. Incentives in the current tax code do not reduce current operating or capital costs for emerging companies. Congress should go further and enact targeted provisions that support innovative companies early in their life cycle.
- Congress should make every effort to establish a permanent, stable, and predictable tax system that allows America to better compete with its global challengers.

CAPITAL MARKETS

Fostering Innovation Act

BACKGROUND

Emerging growth companies (EGCs) are given a temporary exemption from Sarbanes-Oxley (SOX) Section 404(b) by the Jumpstart Our Business Startups (JOBS) Act. A company remains an EGC for 5 years after its IPO, unless it exceeds either $700 million in public float, $1 billion in annual revenues, or $1 billion in non-controvertible debt. Assuming it does not trip one of these tests, it retains its SOX 404(b) exemption for its entire five-year life as an EGC.

Most biotechs remain pre-revenue long after their EGC status expires – so they will see a damaging diversion of capital from science to compliance in the form of expiring JOBS Act exemptions at the dawn of year six on the market. In order to address this issue, the Fostering Innovation Act would extend the SOX 404(b) exemption in the JOBS Act's IPO On-Ramp to a certain subset of low-revenue/low-public float former EGCs in years six through 10 after their IPO.

A company's EGC status would expire after five years, but its SOX 404(b) exemption would be extended for years six to 10 if it maintained a public float below $700 million and average annual revenues below $50 million.

BIO POSITION

BIO strongly supports enactment of H.R. 4139, the Fostering Innovation Act. This bill will institute a commonsense regulatory burden for growing companies and stop the damaging diversion of capital from science to compliance.

Discussion Points:

- More than 185 emerging biotech companies have gone public under the JOBS Act. Supporting their growth on the public market will ensure a strong IPO market and a robust capital formation ecosystem.
- Groundbreaking research can be delayed when government compliance burdens siphon off innovation capital. Early-stage biotech innovators operate almost entirely without product revenue, so costly regulations like SOX Section 404(b) force companies to spend dollars on reporting rather than research.
- BIO believes that extending the JOBS Act EGC exemption from SOX Section 404(b) would more accurately reflect the business model and long development timelines of emerging, pre-revenue businesses. Further, an additional five years without the cost burden of SOX 404(b) compliance would allow biotech companies to focus their capital on groundbreaking R&D, stimulating job creation and the search for the next generation of medical breakthroughs.

Small Company Disclosure Simplification Act

BACKGROUND

Public companies are required to provide their financial statements in an interactive data format using eXtensible Business Reporting Language (XBRL). XBRL "tags" certain data points in issuers' reports and exports them in a standardized format. XBRL is reported in a unique computing language – one that requires specific expertise outside the bounds of traditional financial or accounting training.

Companies need experts in the XBRL language to properly file the appropriate reports, so small issuers turn to external contractors to complete their XBRL filings. The cost of an external XBRL contractor is significant for an emerging company, reducing the capital available for more vital functions like research and development. Furthermore, XBRL has yet to prove its worth as an effective, reliable tool for investors or regulators.

The Small Company Disclosure Simplification Act would build on the success of the JOBS Act by providing an XBRL exemption for emerging growth companies. It would also institute a temporary exemption for small businesses with annual revenues below $250 million while requiring the SEC to make recommendations on how to improve the compliance mechanism.

BIO POSITION

BIO supports enactment of H.R. 1965, the Small Company Disclosure Simplification Act. A targeted XBRL exemption for emerging innovators would free growing companies from a costly regulatory burden that does more harm than good.

Discussion Points:

- Without product revenue, biotech companies on the public market are forced to ask investors to pay for XBRL reporting rather than scientific research. The cost burden of this requirement, and therefore the amount of capital diverted from R&D, is significant.
- The information included in an XBRL report is often not indicative of the health of a smaller issuer. Because XBRL reporting does not provide much insight for potential investors in small companies, the high cost of compliance far outweighs its benefits.

FOOD AND AGRICULTURE

The Congress must pass national GMO food labeling uniformity legislation without any delay.

BACKGROUND

"Genetically modified organisms," or GMOs, are plants and animals developed with precision breeding to exhibit specific useful traits – traits valuable to farmers, like insect and herbicide tolerant crops, and to consumers, like non-browning apples and potatoes. The scientific community stands strongly behind GMOs. They are widely used by farmers in the U.S. and around the world. In our country, more than 90% of corn, cotton, soybeans, canola, and sugarbeets contain at least one GMO trait. Despite their valuable benefits and a proven safety record, GMOs remain a major topic of discussion today. Much of the public conversation on GMOs centers on whether the government should mandate a special label for foods produced with ingredients derived from GMO crops.

BIO SUPPORTS FEDERAL GMO LABELING UNIFORMITY LEGISLATION

Last year, the House of Representatives overwhelmingly approved H.R. 1599, bipartisan labeling uniformity legislation sponsored by Representative Mike Pompeo (R-KS) and Representative G. K. Butterfield (D-NC). The House vote was 275 to 150, with 45 House Democrats voting yes. This year, the Senate is considering similar legislation to establish uniformity and provide consumers with more consistent information about GMO food.

Ask us anything about GMOs at www.GMOAnswers.com

The biotechnology industry supports greater public education and engagement about GMOs and is committed to a transparent dialogue with the public about how our food is grown, particularly the application of genetic engineering to the production of agricultural crops and food ("GMOs"). BIO supports an initiative generated by the Council for Biotechnology Information known as **GMO Answers** (**www.gmoanswers.com**), which is directly engaging consumers online, across social media and in-person. GMO Answers provides information directly to consumers, so they can make up their own minds about GMOs with facts in hand. We hope you will visit the website to obtain information or ask questions you might have about GMOs.

BIO POSITION

BIO strongly endorses a federal legislative solution that provides consistency regarding the labeling of bioengineered food and moves the country beyond state-by-state labeling challenges that are needlessly undermining consumer confidence in the safety of the U.S. food supply and threatening to harm state economies and businesses. The Congress must pass bipartisan legislation quickly and send it to the President for his signature. Without a federal law to stop Vermont and other states from establishing a patchwork of different GMO food labeling requirements, American consumers, farmers, and small businesses will pay a significant price.

INDUSTRIAL AND ENVIRONMENTAL

Get the Renewable Fuel Standard back on track; Restore Support for Industrial Biotechnology in the Tax Code; and Maintain Mandatory Funding for Farm Bill Energy Title Programs

BACKGROUND:

To grow America's 21st Century bio-based economy, BIO supports stable government policies that drive private sector investment and commercial scale production within the U.S. industrial biotechnology sector. BIO members use biotechnology to produce better performing and higher yielding feedstocks and to convert those feedstocks into advanced biofuels, renewable chemicals and biobased products. Economic data shows that these applications of biotechnology create high quality jobs, ignite domestic manufacturing of renewable materials, and improve energy security.

Discussion Points:

RFS: The EPA must implement the RFS as intended by Congress. By establishing a market for emerging advanced and cellulosic biofuels, the RFS provides the policy foundation for private investment in these technologies. Thanks to the RFS, billions of dollars in private capital were invested to commercialize advanced biofuels and U.S. transportation-related carbon emissions were reduced by 589.33 million metric tons. Unfortunately, just as many companies were beginning to build first of a kind biorefineries, EPA reversed course in its implementation of the policy. This policy instability caused a $13.7 billion shortfall in investment for advanced biofuels. The RFS spurred growth for advanced biofuels. Those opportunities still exist and getting the RFS back on track will revive investment in those technologies.

Tax: Congress should extend second-generation biofuel tax incentives beyond 2016 without delay to provide stable policy incentives for advanced biofuels. Comprehensive tax reform must contain long-term incentives for advanced biofuels, renewable chemicals, and biobased products to stimulate investment and promote domestic production of industrial biotech innovation.

Farm Bill: The 2014 Farm Bill includes vital mandatory funding and key policy improvements that will spur further growth in the industrial biotechnology sector, including language that opens biorefinery loan guarantees to producers of renewable chemicals and biobased products, maintains incentives for farmers who choose to grow purpose-grown energy crops, prioritizes research and development on crop insurance programs for those crops and continues an important federal procurement program for biobased products. It is crucial that Congress provides the funding to foster innovation in feedstocks, advanced biofuels, and renewable chemicals.

BIO POSITION

- BIO supports the Renewable Fuel Standard, or RFS. It provides the policy foundation for private investment in the advanced and cellulosic biofuels industry. The U.S. Environmental Protection Agency's (EPA) recent implementation of the RFS puts this policy at risk. BIO is committed to get the policy back on track and opposes any legislative attempts to weaken or eliminate the RFS.
- BIO asks that Congress extend important advanced biofuels tax credits beyond 2016 and move quickly to establish stable, long-term tax policy that supports not just biofuels, but innovative renewable chemicals and biobased products.
- BIO urges Congress to maintain mandatory funding for Farm Bill energy programs which creates new opportunities for renewable chemicals manufacturing and promising new purpose-grown energy crops.

Endnotes

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