U.S. Senate Committee on Appropriations
FY15 Hearing: Driving Innovation through Federal Investments
Testimony: Biotechnology Industry Organization
Tuesday, April 29th, 2:30 pm

Chairperson Mikulski, Ranking Member Shelby, Members of the Committee, thank you for the opportunity to provide you with written testimony on the extremely important topic of driving innovation through federal investments.

BIO is the world's largest trade association representing biotech companies, academic institutions, state biotech centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. The biotech industry is working toward groundbreaking cures and treatments for devastating diseases, developing technologies for advanced biofuels and renewable chemicals, and developing innovations for a safe and clean supply of healthy food. This testimony will focus on key funding areas (NIH, FDA, BARDA, ASPR, USDA and DOE programs) where the federal government plays a vital role in supporting this growing sector.

Importance of Investing in Biotechnology Innovation

Building an Innovation-Driven Economy: Biotechnology R&D provides high-wage jobs at public research institutions and the biotech companies that typically locate near centers of academic research. The indirect effects of increased research funding on these regional economies are significant. The nation's 1.42 million bioscience jobs support an additional 6.6 million jobs, resulting in a total employment impact of more than eight million jobs in the biomedical sector (Battelle). In particular, federal funding for research and commercialization of renewable fuels and chemicals produced through industrial biotechnology has helped the U.S. become the global leader in this sector, employing more than 400,000 Americans today, with an additional 800,000 jobs expected by 2022 (Bio Economic Research Associates).

The biotechnology industry remains committed to improving the lives of all Americans, developing a healthier American economy, and creating high-quality jobs in every state. To accomplish these goals, the U.S. must maintain its leadership in biotechnology research and commercialization. However, we are facing unprecedented competition from around the globe that is challenging that leadership. For example, in 2011, the Chinese government named biotech one of seven industries that will receive $1.7 trillion in government funding over the next five years. The European Union's Innovative Medicines Initiative is pumping over $2 billion into Europe's biopharma industry. While America has developed more cures, breakthrough medicines, and innovative industrial biotech products than any other country and is home to over 2,500 biotech companies, this is not a position that will be sustained without continued investment and policies focused on supporting and incentivizing the next generation of biomedical and industrial biotech discoveries.

Improving Public Health: Medical innovation has improved the longevity and quality of lives for patients. Breakthrough scientific discoveries in labs across the country are unlocking the secrets to preventing, treating, and curing many devastating diseases that affect all of our families. It is critical that even in an environment of budgetary constraint we do not lose the next

generation of discoveries that offer solutions to one of the nation's leading health cost drivers – chronic and debilitating diseases. Almost 80 cents of every health care dollar is spent for the care of individuals with a chronic disease (Robert Wood Johnson Foundation). The national imperative could not be clearer: we must find new treatments and cures for chronic diseases. This can only be achieved with continued federal investment in biomedical research and policies incentivizing innovation.

NIH: A Driver of the Innovation Pipeline

It is imperative that we continue to invest in scientific discovery. NIH-supported biomedical research builds the foundation of scientific and clinical knowledge that is widely communicated and used to improve the treatment of patients and underpin the development of new diagnostics, treatments, vaccines, and cures.

Increased investment in NIH-supported research will significantly enhance our ability to make new scientific discoveries that will advance the ability to prevent, diagnose, and treat diseases most effectively. Unfortunately, after nearly a decade of budgets below biomedical inflation, NIH's inflation-adjusted funding is close to 22 percent lower today than in FY 2003 (FASEB).

In addition to supporting medical research, NIH also provides critical early-stage funding opportunities through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs for small biotechnology companies developing innovative medicines. These small business programs at the NIH play a critical role in the ability of small businesses to advance early-stage research programs.

Sustained commitment to investment in NIH drives the innovation pipeline that is critical to ensuring a robust medical research infrastructure and a thriving biopharmaceutical industry. BIO requests that Congress appropriate at least $32 billion for the NIH for FY 2015.

FDA: Critical to Turning Medical Discoveries into Benefits for Patients

Bringing a new drug, biologic, or diagnostic to market requires extensive research, including clinical trials, that requires a decade or more to complete. This risky, long-term investment by biotechnology firms and venture capitalists is predicated on working within an FDA regulatory framework that is predictable, consistent, and well-resourced, and that has the scientific capability necessary to evaluate the benefits and risks of novel products in a timely manner. It is imperative that FDA oversee the development and approval of innovative diagnostics, treatments, vaccines, and cures efficiently.

Nearly 25 cents of every consumer dollar spent in the United States—$1 trillion—is on a product or process regulated by the FDA, and it is critical to American economic health and competitiveness that the agency has the resources necessary to carry out its mission effectively and efficiently. An effective and efficient FDA is critical for encouraging biomedical innovation to deliver treatments and cures.

BIO respectfully requests a total of $2.784 billion in Budget Authority for the FDA. This funding would ensure that FDA programs and initiatives such as Advancing Regulatory Science, Oversight of Pharmacy Compounding, Supply Chain Traceability, and the Medical Countermeasures Initiative can keep pace with today's science and better promote and protect public health. Lastly, for FY 2015, BIO recommends an investment of an additional $100

million in FDA's medical products programs, including a total of $528 million for the Human Drugs Program and the $231 million for the Biologics Program. In addition, BIO strongly supports legislation that would prevent user fees from being sequestered in future years, as this would threaten the FDA's ability to ensure patients get new treatments and cures at the earliest possible time.

BARDA, SRF, Pandemic Influenza Preparedness: Protecting the American Public
Federal investments in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) have driven innovation in the field of biodefense over the past decade. Since Congress established the Project BioShield Special Reserve Fund (SRF) as a guaranteed market incentive, approximately 50 companies have engaged in the development of novel vaccines, therapeutics, and diagnostics to address naturally occurring and man-made threats to our nation's public health and security. Additionally, multi-billion dollar supplemental appropriations for pandemic influenza preparedness have resulted in the development of novel influenza vaccine technologies, and the nation was able to mount an effective response to the H1N1 pandemic of 2009-2010. To continue this progress and ensure companies do not redirect their talents to other markets, a strong federal funding commitment is needed. BIO requests $415 million for the Biomedical Advanced Research and Development Authority (BARDA), $636 million for the SRF, and $300 million for pandemic influenza preparedness activities in the Office of the Assistant Secretary of Preparedness and Response (ASPR) in FY 2015.

Securing our Energy and Manufacturing Future while Protecting the Environment: Industrial biotechnology innovation is enabling a whole new generation of fuels and chemicals produced from renewable, sustainable sources such as forestry and agricultural residues, municipal solid waste, novel purpose-grown energy crops, and even industrial waste gases. These technologies hold great potential for economic, environmental, and energy security gains.

USDA Energy Title Programs: Paving the Road to Commercialization
Title IX of the Agriculture Act of 2014 (Public Law 113-79, signed into law on February 7, 2014) reauthorizes and provides mandatory funding for a suite of programs vital to helping the next generation of renewable fuels and chemicals to market. BIO urges the committee to provide the full mandatory and discretionary funding for the Biorefinery Assistance Program, Biomass Crop Assistance Program, Biobased Markets Program, and Biomass Research and Development Program, each of which contributes substantially to rural economic prosperity by growing a 21st Century bio-based economy. BIO also urges the Committee to support the Administration's commitment to advanced biofuel use in the U.S. military as established in the 2011 Memorandum of Understanding signed by USDA, DOE, and the Navy.

DOE: Supporting Ongoing Innovation and Technology Demonstration
Department of Energy programs in research, development, demonstration and deployment of industrial biotechnology are working to drive new innovation and attract private investment in this important sector. BIO requests the Committee support the Administration's proposed funding levels for the Bioenergy Technologies Office, Advanced Manufacturing Office, Advanced Research Projects Agency-Energy (ARPA-E), and the Biological and Environmental Research Programs and Basic Energy Science programs of the Office of Science.

EPA: Adequate Resources Needed to Review New Fuel Pathways

The Environmental Protection Agency is the key federal agency regulating the biofuels industry. As the industry has grown exponentially since the enactment of the enhanced Renewable Fuel Standard (RFS) under the Energy Independence and Security Act of 2007, implementation of the program has been increasingly strained by the burden of annual rulemaking, legal challenges, and approval of a growing list of fuel pathways applications. Under the RFS, all new feedstocks and fuel technologies must be approved as new fuel pathways by EPA before they may be used to make biofuels that qualify under the program. Inadequate staffing at EPA for this purpose is contributing to lengthy delays in pathway approval, which is significantly impeding commercialization and the potential of new fuel pathways to help achieve the ambitious gallon requirements under the RFS. Approval of these new fuel pathways will allow for continued growth in the renewable fuel sector which has spurred billions of dollars of investment in rural economies and created more than 400,000 jobs across the United States. BIO requests EPA be provided sufficient funding to quickly review the growing backlog of new fuel pathways.

USDA: Turning Public Investment into Food Productivity

By 2050, the global food supply needs to double in order to feed more than nine billion people worldwide. Agriculture innovation and, in particular, agricultural biotechnology will be necessary to increase food productivity in order to meet global population growth projections. Public R&D funding plays a critical role in agricultural productivity, however since the 1980s, funding for public agricultural research has stagnated and agricultural productivity has not kept pace with global needs. The United Nations Food and Agriculture Organization estimated that technology innovations must provide 70 percent of the increase in food production. Money invested in agriculture R&D is wisely spent as the funding returns $20 to the economy for every $1 spent. Furthermore, the President's Council of Advisors on Science and Technology (PCAST) recommends a rate of three percent of GDP to be spent on R&D, but currently the U.S. only spends 1.9 percent. BIO requests increases in funding to research at USDA, which is needed to spur private sector funding and provide the needed increases in productivity to feed a growing population.

Conclusion

With more than 4,286 innovative research and discovery projects in the pipeline, the biotechnology industry can facilitate job growth, provide the next generation of medicines that will improve the lives of patients and their families, and create new solutions to the public's health care needs. In order to prepare for population growth, farmers will need the tools that biotechnology can provide to keep up with food demands. With continued strong investment in industrial biotechnology, the U.S. can also build on its global leadership position and ensure continued job growth, environmental protection, and energy security from the development of next generation renewable fuels and chemicals.

Driving innovation through federal investments can play a vital role in solving the most pressing challenges facing our society. We appreciate the opportunity to provide our perspective on these critical issues.

Should you have any questions or comments, please feel free to contact Tracey LaTurner, Director of Federal Government Relations BIO at (202) 962-6696.