

May 12, 2011

The Honorable Jack Kingston
House Appropriations Subcommittee
on Agriculture, Rural Development,
and Food and Drug Administration
2362-A Rayburn House Office Building
Washington, DC 20515

The Honorable Sam Farr
House Appropriations Subcommittee
on Agriculture, Rural Development,
and Food and Drug Administration
1016 Longworth House Office Bldg.
Washington, DC 20515

Dear Chairman Kingston and Ranking Member Farr:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to encourage your support of programs and initiatives of critical importance to our industry. Please support the following requests as you develop the Fiscal Year 2012 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act:

FOOD AND DRUG ADMINISTRATION (FDA)

For FY12, BIO respectfully supports the Administration's request for a total of \$2.744 billion in budget authority for the FDA. BIO recognizes the current constraints on government spending, and notes that the FDA recently received a budget increase while many federal agencies did not. We appreciate Congress's acknowledgement of FDA's unique role in supporting biomedical innovation and promoting the public health. The promise of the life sciences – economic expansion, jobs, and new therapies for unmet medical needs – requires an adequately funded FDA and a strong, reliable regulatory environment.

Human Drugs and Biologics Programs:

BIO supports a strong, fully-funded FDA with the resources necessary to keep pace with rapidly-evolving biomedical science and to make sound regulatory decisions in a timely and efficient manner. For FY12, BIO recommends \$497.5 million for the Human Drugs program and \$224.9 million for the Biologics program. For people with devastating diseases and disabilities, roadblocks to getting new cures developed and approved can be a matter of life or death. For patients who are still waiting for treatment options – such as a first-ever broadly-effective treatment for amyotrophic lateral sclerosis, a next generation treatment for multiple sclerosis, or the next miracle therapy for cancer – nothing is more important than seeing safe and efficacious products developed and approved as efficiently as possible without unnecessary impediments.

Adequate FDA funding is an economic imperative as well as a public health priority. FDA regulates approximately \$1 trillion in consumer products, or 25 cents of every U.S. consumer dollar spent, and it is critical to American economic health and competitiveness that FDA has the tools and resources necessary to effectively and efficiently preserve adequate standards for medical product quality. FDA support for medical innovation is also critical to tackling the nation's long-term fiscal health. Unmet medical needs for diseases such as Alzheimer's, cancers, diabetes, and Parkinson's will be significant drivers of our



PRINTED ON
RECYCLED PAPER



nation's entitlement spending as the Baby Boomer Generation continues reaching retirement age. Modern FDA regulatory approaches that promote the development of treatments that slow the advancement of Alzheimer's and other devastating diseases will have a profound impact on the nation's fiscal health, as well as public health.

- *Advance Regulatory Science:* BIO supports FDA's FY12 budget which places a renewed emphasis on Advancing Regulatory Science. The world of drug discovery and development has undergone revolutionary change in recent years adopting molecular and gene-based approaches, while FDA's evaluation methods have remained largely unchanged over the last several decades. Regulatory science is a unique and often neglected discipline aimed at developing and assessing modern tools, methods, and standards for evaluating the safety, efficacy and quality of FDA-regulated products. Through the application of modern regulatory tools and scientific approaches, safer, more effective, and more personalized medicines can be developed and reach patients without unnecessary delay. BIO supports \$48.7 million in appropriated funding for these activities in FY12.
- *Restore Funding for the Reagan-Udall Foundation:* Recognizing the urgency many patients face, Congress established the Reagan-Udall Foundation for the FDA in 2007 to advance regulatory science projects through private-public partnerships. Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress authorized FDA to transfer funding to the Foundation and also collect private funding. However, recent Appropriations bills have subsequently restricted FDA's ability to transfer federal funding to the Foundation. BIO believes that this promising partnership is best served by a balanced commitment of both private and public funding sources and urges Congress to lift the restriction.
- *Medical Countermeasures:* BIO supports the Administration's request for \$70 million for the Advancing Medical Countermeasure (MCM) Initiative, which will strengthen FDA's ability to support the development of MCMs to respond to chemical, biological, radiologic and nuclear threats, and to respond to naturally emerging diseases such as pandemic influenza.
- *FDA Transparency and Accountability:* Additionally, BIO fully supports increased transparency in how new appropriated monies are spent, and clear communications from FDA about the public health benefits that have been achieved with the new funding.

Food Safety

Center for Food Safety and Nutrition (CFSAN): For the Fiscal Year 2012, BIO respectfully requests \$955 million for CFSAN and Field Activities. BIO appreciates FDA's continuing commitment to ensuring the safety of the food supply through CFSAN. CFSAN provides important regulatory oversight of new plant biotech varieties intended for food use.

Veterinary Medicine

Center for Veterinary Medicine (CVM) (Animal Drugs and Feed): BIO strongly supports appropriate funding for CVM, which oversees biotechnology-derived plant products used as, or in, animal feed as well as genetically-engineered animals and their products. However, additional resources are required for the animal biotechnology program to keep the momentum of the regulatory process for genetically-engineered animals focused toward product approvals, including premarket, postmarket, research, infrastructure, training, communications and field resources. Therefore, BIO recommends the

Committee provide \$155.5 million in FY 2012, of which \$10 million should be directed to the animal biotechnology program.

BIO respectfully requests the inclusion of the following specific language:

“The Committee directs \$10 million to the FDA, CVM Animal Drugs and Feed budget authority to be expended in the conduct of the animal biotechnology program including premarket, postmarket, research, infrastructure, training, communications and field resources aspects of the program for genetically engineered animals and their products leading toward additional approvals and to allow continued monitoring of the international scientific progress on livestock cloning.”

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

Office of General Counsel: BIO supports robust funding for the Office of General Counsel (OGC) and requests that the Committee provide at least \$46 million for this. BIO believes additional resources are needed at OGC to handle legal matters resulting from National Environmental Policy Act (NEPA) and Endangered Species Act (ESA) analyses by USDA’s Animal and Plant Health Inspection Service (APHIS). BIO has consistently supported a rigorous regulatory system that demonstrates the safety of biotech-derived crops, and continues to do so. However, timely, science-based authorizations are needed to allow farmers access to technologies that they badly need to meet the challenges of modern agriculture. The lack of a sufficient number of staff for legal reviews is significantly hampering the ability of USDA to issue decisions on an increasing number of new products that would be of use to agricultural producers.

Biotechnology Regulatory Services (BRS): Since its inception in June 2002, BRS operates a program that regulates the field testing, movement, and importation of crops and foods improved through biotechnology. This includes coordinating domestic regulation and policy regarding genetically-engineered organisms among U.S. agencies, particularly with USDA, FDA and EPA. As agricultural biotechnology continues to grow with an increasing number of new products, the workload at BRS is increasing substantially in this area. Further, in light of recent federal court rulings, additional staff to prepare National Environmental Policy Act (NEPA) and Endangered Species Act (ESA) analyses is needed to ensure regulatory decisions keep pace with the evolving technology. Agency resources are currently taxed to the point where it cannot meet its own regulatory timelines.

Biotechnology and Trade Activities: BIO believes that maintaining and expanding markets for agricultural biotechnology products is critical to the long-term health and prosperity of the U.S. agricultural sector. Rather than requesting funding for different offices within USDA for biotechnology-related activities, this account was created to provide critical funding for the various agencies involved to provide U.S. leadership globally on matters related to agricultural biotechnology. Additionally, when the FDA and EPA are involved, this account provides for the travel expenses for the representatives of these separate agencies helping to provide needed scientific expertise to countries around the globe. Increased resources should be used proactively to help key developing countries better understand and support a science-based regulatory approach for agricultural biotechnology, thereby promoting regulations that support innovation and agricultural producers to benefit from the technology. Therefore, BIO requests the Committee provide \$2.5 million for this account in the FY 2012 budget.

Biorefinery Assistance Program: Authorized in Section 9003 of the Food, Conservation, and Energy Act of 2008, the Biorefinery Assistance Program provides loan guarantees for the development, construction, and retrofitting of commercial-scale biorefineries and provides grants to help pay for the development and construction costs of demonstration-scale biorefineries. This program has become vital to unlocking private capital for next generation biorefinery construction. BIO strongly supports this

program, and encourages the Committee to provide the full authorized amount of \$150 million for FY 2012.

Biomass Crop Assistance Program: Authorized in Section 9001 of the Food, Conservation, and Energy Act of 2008, the Biomass Crop Assistance Program (BCAP) provides funding for establishment and maintenance of purpose-grown energy crops, and for the collection, harvest, storage and transportation (CHST) of biomass material to approved energy conversion facilities. BCAP is funded through the Commodity Credit Corporation at such sums as necessary through FY 2012. BIO strongly supports this program, and supports the President's request of \$201 million in funding for FY 2012.

Biobased Markets Program: The Farm Security and Rural Investment Act (FSRIA) of 2002 included a mandate for USDA to develop and implement a comprehensive program for designating biobased products. This program, known as the Biobased Markets Program, directs federal agencies to increase their purchase and use of biobased products. This program also establishes a labeling program for biobased products to accelerate commercialization. As the single largest consumer in the United States, purchasing roughly \$400 billion annually in goods and services, the federal government's preferred use of biobased resources will lessen our dependence on foreign-based petroleum sources. We ask that the Committee provide full mandatory funding of \$2 million for this program in FY 2012.

Animal and Plant Health Inspection Service (APHIS)

Animal Care (AC): The Animal Care Program determines and promotes standards of humane care and treatment of animals through inspections and educational efforts. Many BIO members are regulated by the USDA under the authority defined in the Animal Welfare Act. In FY 2010 Congress appropriated \$25 million to enforce the Animal Welfare Act. BIO supported this increase then, and encourages the Congress to provide \$29 million in FY 2012.

Veterinary Services, Center for Veterinary Biologics (CVB): CVB plays a vital role in regulating products that diagnose, prevent or treat animal diseases. Every year the U. S. animal health companies produce 83 billion doses of animal vaccines, many which are biotech-derived. These vaccines are critical to protecting the health of America's livestock and pets from domestic and foreign animal diseases. Despite the significant role that CVB plays in global human and animal health, for the past three Fiscal Years, CVB's funding has not met cost of living increases, so no progress has been made in filling vacant positions. The lack of funding at CVB is dire, and threatens the innovation and availability of animal health products. BIO supports the mission for CVB and requests \$24.5 million for FY 2012

Foreign Agricultural Service:

One of USDA's strategic goals is to expand global markets and enhance international competitiveness. In recent years, unjustified sanitary and phytosanitary (SPS) trade barriers have been adopted by foreign governments at an alarming rate, including for agricultural biotechnology. While countries may maintain measures to ensure that food is safe for consumers and to prevent the spread of pests or diseases among animals and plants, the measures must be science-based. BIO requests at least \$2.5 million in FY 2012 for the Foreign Agricultural Service.

Food Safety Inspection Service:

Codex Office: To protect the health of consumers, to enhance U.S. trade interests, and to ensure that international standards are based on science, the U.S. Codex Office requires a reliable and adequate

budget commitment that is proportional to other developed nations. We respectfully ask for the inclusion of the following language:

“The Committee provides \$4.5 million for the activities of the U.S. Codex office, including international outreach and education. The Codex Alimentarius Commission is critical for the protection of consumer health globally and for facilitating trade.”

Agricultural Research Service (ARS):

BIO believes that public funding for agricultural biotechnology research conducted through intramural programs of the ARS is critical to the discovery of new biotech solutions toward production of improved, healthful and safe foods that will feed the global population of the future. BIO is concerned that ARS funding has not kept pace with inflation and urges Congress to sustain and enhance ARS funding. In particular, BIO supports research to advance agricultural genomics research in several areas, including livestock and crop production and biofuels development to provide new technologies that can increase competitiveness and improve agricultural performance and efficiency. For FY 2012, BIO requests Congress provide \$1.25 billion to meet these goals.

Regional Biofuels Feedstock Research and Demonstration Centers: BIO supports the President’s request for \$6 million for Regional Biofuels Feedstock Research and Demonstration Centers. These Centers will coordinate efforts for research conducted by other agencies and departments to accelerate the development and deployment of energy feedstocks and sustainable feedstock production systems for advanced biofuels. They will seek out those suited for best participation within different regions across the U.S. by adopted feedstocks.

National Institute of Food and Agriculture:

BIO supports an appropriation of \$350 million for the Agriculture and Food Research Initiative (AFRI). Congress should appropriate a substantial boost in AFRI funding to even reach the halfway mark of its authorized level of \$700 million in the last year of the current Food, Conservation, and Energy Act. This funding is needed to make up for the loss in research money with the defunding of specific Congressionally-directed research projects. AFRI is the premiere USDA competitive grants program that takes research and innovation beyond the development phase, into implementation through contemporary education and extension programs in areas that include plant health and production, animal health and production, and renewable energy.

Natural Resources Conservation Service:

Biomass Research and Development: Section 9008 of the Food, Conservation, and Energy Act of 2008 is a program that was originally authorized in the 2002 Farm Bill (P.L. 107-171) and is administered jointly by USDA and DOE. It supports research on and development and demonstration of biofuels and biobased products, and the methods, practices, and technologies for their production. The 2008 Farm Bill provides mandatory funding of \$40 million for FY2012. BIO requests the Committee provide the full mandatory funding level in FY 2012.

Thank you for your consideration of these requests. Should you have any questions or comments, please feel free to contact Tracey LaTurner, Director of Federal Government Relations at (202) 962-6696. We look forward to working with you throughout the appropriations process.

Regards,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is written in a cursive style with a large, looping initial "J" and a distinct "d" at the end.

James C. Greenwood
President and CEO
Biotechnology Industry Organization