



Biotechnology Innovation Organization
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April 28, 2022

The Honorable Rosa DeLauro
Chair
Subcommittee on Labor,
Health and Human Services,
Education & Related Agencies
U.S. House Committee on Appropriations
2362-A Rayburn House Office Building
Washington, DC 20515

The Honorable Tom Cole
Ranking Member
Subcommittee on Labor,
Health and Human Services,
Education & Related Agencies
U.S. House Committee on Appropriations
1016 Longworth House Office Building
Washington, DC 20515

Dear Chairwoman DeLauro and Ranking Member Cole:

The Biotechnology Innovation Organization (BIO) is the largest biotechnology trade association, representing approximately 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Our members are working every day to solve the greatest challenges facing society—whether it is finding a cure for cancer, protecting the public against bio-terror threats, feeding hungry people nutritious food, or generating renewable fuels, renewable chemicals, and other biobased products. We support public policies, including government funding for key agencies and programs that unleash our members' scientific innovation potential and grow the biobased economy. BIO members urge you to actively support the following priorities as you consider the Fiscal Year 2023 Labor, Health and Human Services, Education and Related Agencies Appropriations Act:

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND (PHSSEF)

Strategic National Stockpile

BIO requests appropriations of \$1,657 billion for the Strategic National Stockpile (SNS) for FY 2023. This funding, which is the SNS estimated need outlined in most recent FY 2018-22 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget, enables the SNS to acquire and replenish critical medical countermeasures (MCMs), such as vaccines, therapeutics, diagnostics, and other biopharmaceutical products as well as medical supplies and equipment, so that the Federal government can respond rapidly and effectively during a public health emergency. This professional judgement is the best assessment available for the funding needs for the SNS in lieu of a new PHEMCE Multiyear Budget, and it should be noted that the FY 2018-22 budget was written well before the COVID-19 pandemic and the present need for a robust and expanded SNS.



The risk of a chemical, biological, radiological or nuclear (CBRN) event is as likely as ever. Were one to occur on U.S. soil tomorrow, the SNS is the only federal resource readily available to respond once state and local MCM supplies are depleted. The current COVID-19 outbreak has highlighted the need for robust funding for the SNS, to ensure it is well maintained, replenished, and fully stocked both in terms of MCMs and medical supplies.

Strategic procurement and stockpiling of MCMs are necessary to protect Americans' health and save lives during an emergency. Many MCMs, such as vaccines and drugs against smallpox, anthrax, and pandemic influenza, have no commercial market. Companies that are developing these types of products rely on the SNS for procurement and sustainment. Without adequate funding, potential developers will lose the incentive to develop these products, and the Nation will be unable to adequately respond to a wide array of health security threats. Further, the SNS holds supplies of biopharmaceutical products that are available commercially but only in limited quantities, and this stockpiling allows for rapid mass deployment during an emergency.

Pandemic Influenza

BIO supports \$382 million to support pandemic influenza activities for FY 2023, including \$35 million in annual appropriations and \$347 million in no-year funds. The development and manufacturing of influenza vaccines, therapeutics, and diagnostics by industry is dependent on Federal funding to support the scale and scope of USG requirements.

There is no commercial market for products like H5N1 or H7N9 vaccines. Through FY 2013, the program was funded through significant supplemental appropriations. Those funds have been spent and additional funding is necessary to maintain a robust R&D pipeline and sustain the capabilities the U.S. has developed.

The September 2019 "Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health" acknowledges that the current domestic enterprise for manufacturing influenza vaccines has critical shortcomings. Funding for BARDA's pandemic influenza activities in FY 2023 will support work on the development of more effective, longer lasting vaccines, as well as novel antivirals and therapeutics and rapid diagnostics. These additional funds are critical to meeting the needs and objectives expressed in the EO with respect to preventing the spread of influenza viruses and protecting the United States from future pandemics.

Project BioShield Special Reserve Fund

BIO supports \$920 million for the Project BioShield Special Reserve Fund (SRF) for FY 2023, with funds to remain available until expended, \$200 million of which for AMR programs within



the BioShield SRF. This request is based upon the need outlined for the SRF in the FY 2023 HHS Budget Congressional Justification.

Congress created the Project BioShield Special Reserve Fund (SRF) in 2004 to encourage the development and procurement of medical countermeasures (MCMs) to protect against threats like anthrax, Ebola, and smallpox which have little or no commercial market. Since the establishment of the SRF, BARDA has successfully transitioned 30 MCM candidates to Project BioShield, of which 18 have been delivered to the Strategic National Stockpile and 6 have achieved FDA approval. Over 70 companies and institutions have been able to advance their MCM research programs through Project BioShield advanced development and/or procurement contracts.

BARDA's success in developing a robust pipeline of more than 200 MCM candidates against intentional and natural biological threats means that more products will be transitioning from BARDA advanced research and development (ARD) development to BioShield procurement. This necessitates additional resources to meet the needs required by bringing additional successful products forward. Additionally, in December 2019, SRF funds supported a contract for a company following approval of its antibiotic—a phase in which small biotechs that develop new antibiotics are particularly vulnerable. Additional funding is needed to expand this approach to better support the antibiotics market. These funds will demonstrate the federal government's commitment to the development of these vital national health security products.

Biomedical Advanced Research and Development Authority (BARDA)

BIO supports \$1.284 billion for BARDA for FY2023, of which \$300 million would support the research and development of novel antimicrobial products. This funding is essential to our nation's ability to prepare for, respond to, and recover from public health emergencies, whether naturally-occurring, like the Zika and Ebola outbreaks, or deliberate, such as a chemical, biological, radiological, and nuclear (CBRN) attack. The FY 2023 HHS Budget Congressional Justification requests this funding for BARDA in order to address all CBRN threats identified as "material threats" by the Department of Homeland Security (DHS).

The BARDA pipeline currently includes over 200 candidate medical countermeasures (MCMs) such as broad-spectrum antimicrobials, rapid diagnostics, and next-generation products to address chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases (EID). Increased funding for BARDA activities is needed to advance MCMs currently in the BARDA pipeline, provide funding for additional MCMs reaching the critical stages of preclinical and clinical development, invest in novel manufacturing capabilities, and support products to address antimicrobial-resistant threats through the Broad-Spectrum Antimicrobials (BSA) and CARB-X programs.



The BARDA broad spectrum antimicrobials program and CARB-X leverage public/private partnerships to develop products that directly support the government-wide National Action Plan for Combating Antibiotic-Resistant Bacteria and have been successful in developing new FDA approved antimicrobials. Despite this progress, the pipeline of new antimicrobials in development is insufficient to meet patient needs, and \$300 million in funding is needed to help achieve the goals of the 2020-2025 Action Plan to accelerate basic and applied research for developing new antimicrobials. Additional funding will help prevent a post-antibiotic era in which we lose many modern medical advances that depend upon the availability of antibiotics, such as cancer chemotherapy, organ transplants and other surgeries.

Additionally, BIO strongly supports the President's Budget's request for \$775 million for Emerging Infectious Diseases (EID). Covid-19 will not be the last emerging infectious disease that the US will need to respond to. Support for capacity and capability building for medical countermeasures (MCMs) and our public health system is critical to protecting our national health security from EID threats. Investments must be made now to ensure national stability through preparedness and quick resolution of an outbreak when any EID arises. Funding during a crisis is often too late, as development of drugs, vaccines, diagnostics, and platform technologies takes time; and as COVID-19 demonstrated, that delay risks lives and costs more money than upfront investments in these MCMs and rapid response capabilities.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Section 317 Immunization Program

BIO requests that the Committee provide \$943.5 million to the CDC for the Section 317 Immunization Program in line with the President's FY2023 budget. Vaccinations are one of the most cost-effective public health approaches to reducing healthcare costs because they prevent disease before it occurs and spreads through our communities. The Immunization Program funds are used to not only purchase vaccines for those in need but also to provide critical support for the people and systems that make immunization programs work, including surveillance of vaccine-preventable diseases, outbreak response, immunization information systems (IIS), and vaccine safety monitoring.

In recent years, the CDC Immunization Program has become reliant upon transfers from the Prevention and Public Health Fund. Given the importance of the program, BIO urges the Committee to provide dedicated funding for the Immunization Program to provide CDC and state and local health departments that rely on CDC funding more certainty around the sustainability of the Program.



Influenza Planning and Response

BIO supports the President's proposed increase of \$40 million, to a total funding level of \$251 million, for CDC's influenza planning and response activities, which are aimed at detection, response, and prevention of both seasonal and pandemic influenza. On average, influenza is responsible for more than 200,000 hospitalizations and \$10 billion in direct medical costs annually. As has been seen with the last pre-covid statistics of the 2019-2020 season, during which there were an estimated 34 million cases of flu resulting in at least 20,000 deaths in the U.S., seasonal influenza can be severe and unpredictable, and requires an annual reassessment of virus strains included in the seasonal vaccine and continuous attention by CDC. CDC provides leadership in strengthening surveillance and diagnostic capacity; improving public awareness and provider knowledge about influenza; and enhancing our international, Federal, State, and local partnerships for quick response to epidemics.

Antimicrobial Resistance Programs

BIO strongly supports increased funding for the CDC's programs to expand our nation's ability to detect, respond to, and prevent antimicrobial resistant infections, which are estimated to play a part in nearly 5 million deaths per year, globally. These programs are part of a broader interagency investment in antimicrobial resistance.

BIO's request for CDC includes at least \$397 million for the Antibiotic Resistance Solutions Initiative to expand antibiotic stewardship across the continuum of care, double state and local grant awards, expand the AR Laboratory Network globally and domestically to strengthen the identification, tracking and containment of deadly pathogens, support antimicrobial resistance (AMR) research and epicenters, and increase public and health care professional education and awareness.

The request also includes \$100 million to modernize and automate the National Healthcare Safety Network (NHSN), which collects hospital acquired infection data to inform CDC prevention strategies. This increase would help alleviate reporting burden and speed access to actionable data. Specifically, funding would bolster data collection on antibiotic use and resistance in healthcare facilities, expand COVID-19 reporting, and provide technical support for more than 65,000 users of NHSN.

Additionally, BIO requests \$175 million for the Advanced Molecular Detection (AMD) Initiative), which allows CDC to more rapidly identify emerging resistant diseases to more effectively guide public health action and spur the innovation needed to detect and respond to deadly pathogens. Funding would enable federal, state, and local public health laboratories to expand the use of pathogen genomics and other advanced laboratory technologies to bolster integration of



genomics into infectious disease surveillance and response and improve antimicrobial stewardship.

Finally, the CDC global health activities are critical for preventing, detecting, and responding to infectious disease threats, including rising antimicrobial resistance, before they reach domestic soil. For the CDC Center for Global Health Division of Global Health Protection, \$842.8 million is needed to expand global health capacity and enhance infectious disease surveillance, improve antibiotic use, train disease detectives, and provide technical assistance to 30 countries. The CDC is a key implementor of the Global Health Security Agenda, which includes substantial activities to prevent growing AMR.

NATIONAL INSTITUTES OF HEALTH (NIH)

BIO wants to express its deep gratitude for your continued, steadfast support of the National Institutes of Health (NIH) and supports the President's Budget request of \$62.5 billion total program level.

Due to this critical funding, more life-saving and life-changing medical advances are closer to reality and are providing hope to millions of patients whose diseases and conditions await the next generation of treatments or cures. Pulling back now on this momentum would be devastating to patients and families in every state.

In addition to being a difference-maker for the lives of many children and adults is NIH's unmistakable economic impact in every state. Data released on last year by United for Medical Research shows that increases to the NIH budget since 2015 have contributed to steady increases in jobs and economic activity over this period.

Within the NIH budget, BIO requests that the Committee provide \$585 million for AMR research and development in FY 2023 to allow the National Institute of Allergy and Infectious Diseases (NIAID) to address AMR while carrying out its broader role in supporting infectious disease research. Increased FY2023 funding would support the training of new investigators to improve ID research capacity; strengthen clinical trial infrastructure to boost preparedness; enhance basic, translational and clinical research on mechanisms of resistance, therapeutics, vaccines and diagnostics; and support the development of a clinical trials network to reduce barriers to research on difficult-to-treat infections as outlined in the 2025 National Action Plan.

There is no more powerful investment than one that improves the public's health, provides hope to patients and families affected by disease and fuels the economy.



HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

Vaccine Injury Compensation Program Direct Operations

BIO support the FY 2023 President's Budget request of \$26.2 million. This request will support administrative expenses to process approximately 2,560 claims, which includes reducing the backlog by 480 claims or approximately 27 percent. This request will also support administrative expenses for medical review staff, contractors to conduct medical reviews to reduce the backlog of claims, and medical experts for reviews and expert testimony to the Court. The funding request also covers costs associated with the claims award process, follow-up performance reviews, and information technology and other program support costs

The Vaccine Injury Compensation Program (VICP), created by the National Childhood Vaccine Injury Act in 1986, provides a no-fault alternative to litigation for individuals injured by vaccines. An excise tax paid by vaccine manufacturers on every vaccine sold contributes to a Vaccine Injury Compensation Program Trust Fund, which is jointly administered by the Health Resources and Services Administration (HRSA) and the Department of Justice (DOJ). The Trust Fund cannot be used for HRSA's administrative expenses, which are allocated through the annual appropriations process.

While the number of claims remains small in comparison to the number of vaccines administered each year, in recent years the Program has seen a sizable increase in cases; the funds allocated to the program have not matched this increase in workload. Additional resources will help the Division of Injury Compensation staff do the necessary research for injury table additions in a timely manner, and ultimately, help confirmed injury claims to receive compensation more quickly.

Office of the Secretary

In 2019, the HHS National Vaccine Program Office (NVPO) and the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) were merged into the Office of Infectious Disease and HIV/AIDS Policy (OIDP). Within OIDP, the Division of Vaccines serves a unique role in convening diverse federal and non-governmental stakeholders to examine and set national vaccine policy. Directed by the Assistant Secretary for Health (ASH), OIDP provides leadership over the National Vaccine Advisory Committee (NVAC) and provides expertise on a set of priorities not focused on by other HHS agencies, including adult immunization, vaccine confidence, and vaccine safety. The FY23 funds requested will provide for staffing and administration of the Office to support OIDP's unique projects at a level commensurate to that previously appropriated to the separate NVPO and OHAIDP offices.



Advanced Research Projects Agency for Health (ARPA-H)

Along with other policies in Cures 2.0, BIO believes ARPA-H would help provide scientists, research, and entrepreneurs with the policy and regulatory framework needed to ensure groundbreaking biomedical innovation continues and helps more patients in more communities access the medicines they need to live healthy lives.

ARPA-H should adopt approaches toward innovation, operating culture, partnering, contracting, outcomes-orientation, and funding mechanisms that draw from the best practices established through current models for advanced research projects agencies, namely the Defense Advanced Research Projects Agency (DARPA) and Advanced Research Projects Agency – Energy (ARPA-E). It is important that ARPA-H should be designed and charged to deliver breakthrough technologies, system capabilities, and platforms that accelerate innovations in health and medical product development across disease states.

Thank you for your consideration of these requests. Should you have any questions or comments regarding these requests, please contact Lizzy Fox, Director of Federal Government Relations, at lfox@bio.org. We look forward to working with you throughout the appropriations process.

Yours sincerely,

A handwritten signature in black ink, appearing to read "M. McMurry-Heath".

Michelle McMurry-Heath, MD, PhD

Attachment: FY23 LHHS Priorities Chart



Summary of Infectious Disease Budget Requests and Appropriations

(in millions of dollars)

	HHS PROGRAM	FY 20 Conf. (HR 1865)	FY 21 BIO Ask	FY 21 Omni	FY22 BIO Ask	FY 22 PB	FY22 Omni	FY23 PB	FY23 BIO Ask ¹
B I O D I S E A S E	BARDA (total) • ARD • Broad Spectrum Antimicrobials (BSA) Program • CARB-X	561.7	1,635	598.7	1,635	823	745	828	1,284
	Emerging Infectious Disease								775
	BioShield SRF	735	1,040	770	1,110	770	780	770	920
	Pandemic Flu² (no-year)	225	1,414.5	252	1,414.5	300	265	347	347
	Pandemic Flu¹ (annual)	35	127	35	127	35	35	35	35
	Strategic National Stockpile	705	1,080.7	705	1,657.2	905	845	975	1,657.2 ³
	ASPR preparedness & response innovation			2	15	2	5	2	2
	FDA MCM				178				
	NIAID MCM				2,065				
	Hospital Preparedness Program	275.5		280.5		292	280	292	292
	State/Local Preparedness & Response Capability (PHEP coop agr)	675		695	695		715		715
	CDC Infectious Disease Rapid Response Fund	85		10	50	35	20	35	35
HHS Coordination Operations and Response Element (H-CORE)	-	-	-	-	-	-	133	133	

¹ FY 23 Professional Judgement Budget Level

² Request includes BARDA funding only – does not include NIH or CDC.

³ FY 22 SNS Professional Judgement Budget Level



Summary of Infectious Disease Budget Requests and Appropriations

(in millions of dollars)

HHS PROGRAM	FY 21 BIO Ask	FY21 S-FAR Ask	FY 21 Final	FY 22 BIO Ask	FY22 S-FAR Ask	FY 22 Final	FY 23 PB	FY 23 BIO Ask
BARDA								
AMR programs	230	230	118	300 (PHEMCE +30%)	300	+at least 25 (143)	185	300
BioShield SRF	140	140	-	200 (PHEMCE +30%)	200	-	150	200
CDC								
AR Solutions Initiative	230	200	172		672	182	197	197
Advanced Molecular Detection	37.5	37.5	30		60	35	30	175
National Healthcare Safety Network	25	25	21		100	21	-	100
Center for Global Health	-	-	592.8		-	646	-	
- Global Health Protection	275	275	203		456.4	253	353.2	842.8
FDA								
Combating Antibiotic Resistant Bacteria		≥12			+20	0		+20
NIH (NIAID)								
AMR research		550	525		600	540		585
AMR Incentive A proposal designed to combat antibiotic-resistant bacteria by encouraging the development of innovative antimicrobial drugs. This proposal would provide annual payments from a contract valued between \$750 million and \$3 billion to the developers of newly approved antimicrobial drugs.	-	-	-	-	-	-	BiB states financing estimates were not available at the time of Budget publication	

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Summary of Infectious Disease Budget Requests and Appropriations

(in millions of dollars)

	HHS PROGRAM	FY 20 Conf. (HR 1865)	FY 21 BIO Ask	FY21 Omni	FY22 BIO Ask	FY22 Omni	FY23 PB	FY23 BIO Ask
V A C C I N E S	CDC Immunization Program (Section 317) • PPHF	615.8	710	613	1,100	650.8	943.5 • 419	943.5 419
	CDC Flu Planning & Response	187.6	216	201	241	211	251	251
	HRSA Vaccine Injury Compensation Program Direct Operations	10.2	16.2	11.2	11.2	11.2	26.2	26.2
	HRSA Countermeasure Injury Compensation Program	-	-	-	-	-	15	15
	HHS Office of Infectious Disease & HIV/AIDS Policy (OIDP)	7.6	10	7.5	10	7.5	7.7	7.7
	Viral Hepatitis	-	-	39	-	39	54.5	54.5