



IDSAs

Infectious Diseases Society of America

2013-2014 BOARD OF DIRECTORS

President
Barbara E. Murray, MD, FIDSA
THE UNIVERSITY OF TEXAS HEALTH
SCIENCE CENTER
HOUSTON, TX

President-Elect
Stephen B. Calderwood, MD, FIDSA
MASSACHUSETTS GENERAL HOSPITAL
BOSTON, MA

Vice President
Johan S. Bakken, MD, PhD, FIDSA
ST. LUKE'S ID ASSOCIATES
DULUTH, MN

Secretary
Penelope H. Dennehy, MD, FIDSA
HASBRO CHILDREN'S HOSPITAL
PROVIDENCE, RI

Treasurer
Cynthia L. Sears, MD, FIDSA
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

Immediate Past President
David A. Relman, MD, FIDSA
STANFORD UNIVERSITY SCHOOL OF MEDICINE
PALO ALTO, CA

Judith A. Aberg, MD, FIDSA
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
NEW YORK, NY

**Barbara D. Alexander, MD, MHS,
FIDSA**
DUKE UNIVERSITY MEDICAL CENTER
DURHAM, NC

Upton D. Allen, MD, FIDSA
HOSPITAL FOR SICK CHILDREN
TORONTO, ONTARIO, CANADA

Helen W. Boucher, MD, FIDSA
TUFTS MEDICAL CENTER
BOSTON, MA

R. Michael Buckley, MD, FIDSA
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
PHILADELPHIA, PA

Deborah Cotton, MD, MPH, FIDSA
BOSTON UNIVERSITY SCHOOL OF MEDICINE
BOSTON, MA

Stanley C. Deresinski, MD, FIDSA
STANFORD UNIVERSITY SCHOOL OF MEDICINE
PALO ALTO, CA

Louis B. Rice, MD
WARREN ALPERT MEDICAL SCHOOL
OF BROWN UNIVERSITY
PROVIDENCE, RI

Steven K. Schmitt, MD, FIDSA
CLEVELAND CLINIC
CLEVELAND, OH

Chief Executive Officer
Mark A. Leasure

IDSAs Headquarters
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
TEL: (703) 299-0200
FAX: (703) 299-0204
EMAIL ADDRESS:
info@idsociety.org
WEBSITE:
www.idsociety.org

September 16, 2014

The Honorable Shaun Donovan
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Donovan:

On behalf of the Infectious Diseases Society of America (IDSAs) and its Center for Global Health Policy, congratulations on assuming leadership of the Office of Management and Budget (OMB). We look forward to working with you to support the Administration's efforts to reduce the spread of infectious diseases within the United States and around the globe. As the Fiscal Year (FY) 2016 President's Budget Request (PBR) is assembled, we urge OMB to advance allocations and policies that increase the engagement of academia and industry in biomedical research, promote public health interventions that lessen suffering and healthcare costs, and provide quality patient care that emphasizes prevention. **We ask that line-items in these areas, particularly as related to infectious diseases, be prioritized in the FY2016 PBR and have enclosed specific recommendations to this end.**

IDSAs represents more than 10,000 physicians, scientists and other health care professionals devoted to excellence in patient care, prevention, public health, education, and research in the area of infectious diseases (ID). The ID community relies on strong partnerships with the federal government to carry out these activities. However, funding reductions over the last several years have threatened our ability to innovate and lead the world in slowing the spread of diseases. As explained in the recent Coalition for Health Funding report, [*Faces of Austerity: How Budget Cuts Hurt America's Health*](#), public health service agencies constitute just 5.5% of the Department of Health and Human Services (HHS) overall budget, yet many have seen considerable decreases from FY 2010-2014 (adjusted for inflation); -10% at the National Institutes of Health (NIH), -16% at the Centers for Disease Control and Prevention (CDC), and -25% at the Health Resources and Services Administration (HRSA). Further, discretionary health programs are projected to account for just 1.61% of all federal spending in FY 2014. Increased federal investments in areas such as research and development (R&D) for new vaccines, antimicrobials, and rapid ID diagnostics reduce public and private healthcare spending and contribute to fiscal sustainability.

We see several specific areas where the Administration can take a leadership role in promoting individual wellbeing while containing federal healthcare expenditures.

The Administration has appropriately identified antimicrobial resistance as a public health crisis and a priority for increased coordination and resources. This determination is supported by reports from the President’s Council of Advisors on Science and Technology (PCAST), [World Health Organization \(WHO\)](#), and the [CDC](#). It has been estimated that antibiotic resistance alone results in an additional 8 million hospital days and roughly \$26 billion in costs to the healthcare system each year.¹ The CDC **Detect and Protect Against Antibiotic Resistance Initiative** that was proposed to begin in FY 2015 is an example of the increased effort necessary to protect patients and promote public health.

As another example, we know that immunizations are one of the most cost-effective ways to protect human health. In the May 20, 2011 “Morbidity and Mortality Weekly Report (MMWR),” the CDC cited an economic analysis which found that the vaccination of each U.S. birth cohort with the current schedule of childhood immunizations prevents roughly 42,000 deaths and 20 million cases of disease, with net savings of nearly \$14 billion in direct costs and \$69 billion in total societal costs. Programs like the **CDC Immunization Grant Program (Section 317)** are essential to these outcomes. While significant gains have been made in increasing childhood immunization rates, much work remains to increase the uptake of recommended immunizations among adults.

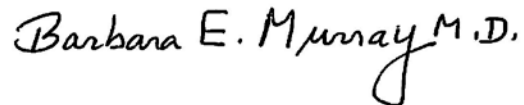
We commend the Administration for recognizing that infectious diseases need to be confronted around the world in order to provide a more secure homeland. We urge the Administration to increase support for initiatives such as the **Global Health Security Agenda, bilateral global HIV and tuberculosis programs, and the Global Fund to Fight AIDS, Tuberculosis and Malaria**.

As you know, the full impact of sequestration will return in FY 2016 unless Congress and the Administration join to find an alternative. We urge the Administration to actively engage Congress to generate a more strategic approach to deficit reduction that does not continue to hamper biomedical innovation, public health and patient care. Once again, we ask that you prioritize public health agencies in the budget formulation process, as they constitute a relatively small portion of the budget but have significant impacts on the lives of Americans and on our ability to realize lasting deficit reduction. **We have enclosed agency-specific recommendations for funding of key ID priorities, including antibiotic resistance, antibiotic and rapid ID diagnostic R&D, immunizations, and HIV/AIDS prevention and treatment.**

¹Roberts, Rebecca R., et.al. “Hospital and Societal Costs of Antimicrobial Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship.” *Clin Infect Dis.* (2009) 49 (8): 1175-1184.

We would welcome the opportunity to have our members, who are experts in their fields and who utilize many of the aforementioned programs, engage OMB to provide additional perspectives. Should you have any questions or comments, please feel free to contact Jonathan Nurse, IDSA's Director of Government Relations at 703-299-0202 or jnurse@idsociety.org. We look forward to continued collaboration with OMB to strengthen federal health and public health programs, as well as to ensure prudent use of taxpayer resources.

Sincerely,

Handwritten signature of Barbara E. Murray M.D. in black ink.

Barbara E. Murray, MD, FIDSA
President, IDSA

Enclosures:

Funding and Policy Recommendations for:

- I. National Institutes of Health
- II. Centers for Disease Control and Prevention
- III. Global HIV and TB Programs
- IV. Food and Drug Administration
- V. Assistant Secretary of Preparedness and Response
- VI. Centers for Medicare and Medicaid Services
- VII. Department of Defense Infectious Diseases Programs

Enclosure I. Funding and Policy Recommendations for the National Institutes of Health (NIH)

National Institute of Allergy and Infectious Disease (NIAID)

- Provide at least the President's FY 2014 request level of \$4,578,813,000 for (NIAID), including the following:
 - Robust funding for NIAID's Division of Microbiology and Infectious Diseases (DMID) antibacterial resistance and antibiotics research and development (R&D);
 - Strong support for the Antibacterial Resistance Leadership Group (ARLG) as well as the new NIH master clinical trials protocol focused on antibiotic-resistant bacterial infections;
 - Support for NIH's newly proposed public private partnership for antibacterial drug development; and
 - Catalyze small business research and development with at least the President's FY 2014 request level of \$121,286,000 for the NIAID Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs, which includes funding for diagnostics research.

Other NIH

- Sustain support for the Point-of-Care Technologies Research Network at the National Institute of Biomedical Imaging and Bioengineering (NIBIB).

NIAID plays an essential role in funding infectious diseases research, including research on new types of treatments for tuberculosis, HIV, multi-drug resistant infections, and other bacterial, fungal and viral diseases, as well as diagnostics and vaccines.

NIAID is supporting a growing portfolio of research on antibacterial resistance and related diagnostic tools. Bacterial infections are becoming increasingly resistant to existing antibiotics, and the number of new antibiotics in development has plummeted. Key federal government and media reports have called for greater investment in the development of new antibiotics. We appreciate the resources NIAID has devoted to this urgent public health need, but also recognize that the Institute needs greater overall funding to more comprehensively address resistance without compromising its other research priorities. We recommend an increased NIAID/DMID investment for antibacterial resistance and related diagnostics research, with a corresponding increase in NIAID's overall budget.

In 2013, NIAID/DMID began funding the [Antibacterial Resistance Leadership Group \(ARLG\)](#), tasked with developing, designing, implementing, and managing an antibacterial resistance clinical research agenda. The ARLG's key areas of focus include early clinical evaluation of new antibiotics, strategies to optimize use of existing antibiotics to limit development of resistance, diagnostics research, infection control, stewardship, and novel activities to prevent the development of resistance. Given the enormity of research needs in this area and the tremendous potential for breakthroughs to save lives and improve public health, IDSA urges the Administration to provide NIAID with sufficient resources to robustly fund the ARLG.

A recent [IDSA report](#) highlights the need for advancements in diagnostic tools for bacterial, viral and fungal infections. Rapid point-of-care diagnostics improve physicians' ability to identify the pathogen causing an infection and prescribe appropriate treatment in a timely manner, which increases the likelihood of positive patient outcomes. In addition, investment in diagnostics R&D and clinical integration are crucial components of any comprehensive strategy to address antibiotic resistance. Rapid diagnostics help physicians determine whether an infection should be treated with an antibiotic, and are needed to help reduce the unnecessary use of antibiotics that drives the development of resistance. Diagnostics are also urgently needed to help identify patients eligible for antibiotic clinical trials and to guide infection control practices. We urge the Administration to dedicate sufficient resources to support of research and development for new rapid diagnostic tests for infectious diseases.

During the current era characterized by multiple scientific breakthroughs in HIV/AIDS research, it is critical to continue and expand support for NIAID's Division of AIDS (DAIDS). The DAIDS plays a key role in U.S. leadership on HIV/AIDS research, from basic science to therapeutics development, to clinical trials on vaccines, microbicides and other prevention strategies. The agency's work is essential to meeting the goals of the President's National HIV/AIDS Strategy as well as advancing AIDS research. This includes the seminal role of the AIDS Clinical Trials Groups (ACTGs), the world's largest network of expert clinical and translational investigators and therapeutic clinical trials units, including sites in resource-limited countries. These investigators and units are the cornerstone of global HIV/AIDS research, treatment, care, training/education enterprise, and their work is already at risk due to cut-backs imposed by sequestration.

Office of AIDS Research (OAR)

The NIH OAR plays a critical role coordinating the scientific, budgetary, legislative and policy elements of the NIH AIDS research program across the Institutes. Now more than ever, it is important to maintain a robust AIDS research portfolio to build on the remarkable successes of the past couple years, including the HIV Prevention Network Trial 052 study that found treating an HIV-infected partner reduced transmission risk to an uninfected partner by 96%. Sustained investment in AIDS research is a critical component of realizing the end of AIDS as envisioned by the President.

Enclosure II. Funding and Policy Recommendations for the Centers for Disease Control and Prevention (CDC)

IDSAs recommends that the CDC be prioritized in the FY 2016 PBR given the central role that the agency plays in a wide range of public health issues such as antibiotic resistance (AR), emergency preparedness and response, HIV/AIDS prevention and care, and global health security. We note that the FY 2015 PBR included budget authority for the CDC below FY 2003 levels. Across the country, funding reductions to the CDC are impeding state and local public health and prevention activities. In addition to ensuring a strong public health infrastructure and protecting Americans from public health threats and emergencies, CDC programs are crucial to reducing healthcare costs.

We support increased resources for the CDC in FY 2016 and in particular:

- Much stronger funding for programs with the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) is necessary to address antibiotic resistance.
 - In the FY 2015 PBR, \$30 million was proposed for the **Detect and Protect Against Antibiotic Resistance Initiative**, \$32 million for the **National Healthcare Safety Network (NHSN)**, and \$30 million for the **Advanced Molecular Detection (AMD) Initiative**. These allocations represent only a fraction of what CDC needs to support a comprehensive federal response to AR. According to [recent comments](#) by Dr. Frieden, these FY 2015 funding levels should be considered "...a down payment for our country to start tackling one of the biggest health threats of our time." **IDSAs calls on the Administration to significantly increase support for these programs in the FY 2016 PBR.**
 - Strong funding is also needed for the Epidemiology and Laboratory Capacity Program as well as the Emerging Infections Program.
 - Increased funding for Vector-Borne Infectious Diseases is needed to address existing and emerging threats.
- Strong support for the National Center for Immunizations and Respiratory Diseases (NCIRD), especially the Section 317 Program and influenza preparedness activities
- Increased funding for CDC preparedness and response activities, especially Public Health Emergency Preparedness Grants, and the Strategic National Stockpile
- Increased support the National Center for HIV, Viral Hepatitis, STD and TB Prevention
- Continued investment in the Global Health Security Initiative
- Increased support for the CDC Global AIDS Program.

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

IDSAs strongly supports the Administration's decision to provide increased resources to the NCEZID in the FY 2015 PBR for efforts to combat antimicrobial resistance. IDSAs recommends that this effort be enhanced in the FY 2016 PBR to reflect the new priority that the Administration has placed on dealing with AR. Several public health authorities have stated the need for enhanced prevention, surveillance, stewardship, and research and development for new antibiotics and rapid infectious diseases diagnostics. The CDC report [Antibiotic Resistance Threats in the United States 2013](#) has been joined by the World Health Organization's [Antimicrobial Resistance Global Report on Surveillance](#) and the upcoming President's Council of Advisors on Science and Technology (PCAST) report on antimicrobial resistance in

highlighting the public health crisis and recommending federal interventions. Given that NCEZID plays a central role in these activities, it is essential that it be provided new resources.

Detect and Protect Against Antibiotic Resistance Initiative

This initiative would establish regional prevention collaboratives to implement best practices for antibiotic use and infection prevention, create a detection network of five regional labs to speed up identification of the most concerning threats, improve antibiotic stewardship, and develop an isolate library that will help facilitate the development of desperately needed new antibiotics and diagnostics. The CDC projects that over five years the initiative will lead to a 50% reduction in health-care associated *Clostridium difficile* (C. diff), 50% decline in health-care associated carbapenem-resistant *Enterobacteriaceae* (CRE), 30% decline in invasive methicillin-resistant *Staphylococcus aureus* (MRSA), 30% decline in health-care associated drug-resistant *Pseudomonas* spp., and 25% reduction in drug-resistant Salmonella infections. These bacteria claim thousands of lives annually. CRE, for one, have become resistant to all or nearly all currently available antibiotics. Further, nearly 50% of those who develop bloodstream infections from CRE die.

National Healthcare Safety Network (NHSN)

The NHSN tracks deadly healthcare-associated infections (HAIs), including those caused by antimicrobial-resistant pathogens. IDSA urges the Administration to sustain the level of support provided in the FY 2015 PBR through FY 2016, which is urgently needed to support the uptake of the new Antibiotic Use and Resistance (AUR) reporting module by healthcare facilities across the country. The AUR will create the first antibiotic prescribing index to benchmark antibiotic use across health care facilities. The module will help state and local health departments and CDC identify hot spots for resistant bacteria, as well as linkages between use and resistance. The module will provide information necessary to improve prescribing practices and identify and stop outbreaks.

Advanced Molecular Detection (AMD) Initiative

IDSA urges the Administration to continue to support the Advanced Molecular Detection Initiative. The AMD will allow CDC to more quickly determine where emerging diseases come from, whether microbes are resistant to antibiotics, and how microbes are moving through a population. The AMD initiative will strengthen CDC's epidemiologic and laboratory expertise to effectively guide public health action. CDC scientists recently used AMD to quickly (less than 72 hours) determine that the Liberian Ebola virus, which infected two Americans assisting with treatment, was nearly identical to the virus circulating in Guinea and Sierra Leone and 97% similar to the virus that first emerged in 1976. AMD can show exactly where mutations are occurring in a pathogen, or in this case, if no mutations are taking place. In an outbreak, this information helps physicians on the ground guide optimal treatment..

Emerging Infections Program (EIP)

The EIP is a network of 10 state public health departments (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN) and their academic partners. EIP activities go beyond health departments' routine functions by addressing the most important issues in infectious diseases; maintaining flexibility for emergency response; developing and evaluating public health interventions; and focusing on projects that lead directly to the prevention of disease. The EIP has yielded tremendous returns

on investment with their ability to quickly translate surveillance and research activities into informed public health policy and practice.

Vector-Borne Infectious Diseases

IDSA recommends that the Administration increase funding to state and local health departments to enable rapid and early detection, and prevention and control, of existing and emerging vector-borne infectious diseases. Funding for the CDC Division of Vector-Borne Diseases (DVBV) has been reduced significantly since its high in FY 2002. Decreases in federal support for such activities have impeded state, local, and ultimately national surveillance capacity.

While funding for the CDC DVBD has decreased, the public health threats it confronts have grown. For example, in late 2013 we began to see cases of Chikungunya among non-travelers in the United States. Chikungunya is a debilitating viral disease that most commonly causes fever and joint pain. The disease is spread to people by infected mosquitoes. Cases of the disease are expected to grow significantly in the United States. Dengue and Dengue hemorrhagic fever, also spread by mosquitoes, infect up to 100 million people annually. Puerto Rico experienced its largest outbreak in 2010 and Florida has reported local cases for the first time in 75 years. Many experts have called for strengthening surveillance of vector-borne diseases to ensure that we are able to rapidly identify and respond to outbreaks.

National Center for Immunization and Respiratory Diseases

Section 317 Immunization Program

According to the February 2014 CDC Morbidity and Mortality Weekly Report (MMWR), adult immunization rates remain low for most recommended vaccines. Each year in the United States, more than 40,000 adults die from illnesses that are preventable through vaccination.

An estimated one million adults develop herpes zoster (shingles) each year. Roughly half of all cases are in individuals 60 years and older. Severe complications of shingles increase with age and can often be seen in the form of debilitating pain. In October 2013, the Advisory Committee on Immunization Policy reaffirmed its recommendation to vaccinate adults 60 years of age and older. Unfortunately, unnecessary barriers continue to prevent older adults from being able to access the vaccine to prevent zoster and its severe complications..

Also of tremendous concern, fewer than 60 percent of individuals over age 50 have received a Tdap (tetanus, diphtheria and pertussis) vaccine in the past 10 years. Given recent outbreaks of pertussis, or whooping cough, in the U.S., which are among the largest such outbreaks in our country during the past half century, it is particularly important to ensure that more individuals receive this vaccination.

Although the Affordable Care Act requires insurers to cover immunizations, this alone will not guarantee access or utilization. Section 317 funds are critical to help providers obtain and store vaccines; establish and maintain vaccine registries; educate providers and the public about vaccine recommendations, effectiveness and safety; and promote universal vaccination of health care workers.

During the 2012-2013 influenza season, only an estimated 72% of health care workers received the influenza vaccination. We ask that the Administration continue efforts towards the goal of 100% influenza vaccination for health care workers.

Influenza preparedness activities

CDC plays a critical role in seasonal and pandemic influenza preparedness and response, including conducting critical surveillance activities that better inform response efforts and providing public communications regarding influenza prevention and treatment. Preparedness and response efforts require public health infrastructure and countermeasures as well as long-term governmental coordination and planning. Lack of sufficient funding for these efforts could lead to an increased incidence and severity of influenza, as well as increased hospitalization costs and mortality. In the long term, continuously funded efforts will be more cost-effective than the periodic emergency supplemental funding approach that historically has been used to fund such efforts.

Global Health Security Initiative

IDSAs support the Administration's efforts to expand its Global Health Security initiative, as deadly pathogens know no national boundaries. The initiative enables CDC to support the creation of sustainable emergency management programs to manage emerging threats; enhance early detection; and effectively respond to global epidemics, outbreaks, and other public health emergencies. New funding will also accelerate the development of new diagnostics tests and build capacities to test for new pathogens globally. Despite improved technologies and knowledge, dangerous gaps remain in the global workforce, tools, training, surveillance capabilities, and coordination that are crucial to protect against the spread of infectious disease.

This initiative will use current CDC platforms in innovative ways and add significant new components to CDC's work. Activities will include development of essential public health systems (i.e., core laboratory, surveillance, and information exchange systems) as well as the building of local technical capacities in other countries. After establishing a new baseline, external investments will be reduced, as other nations assume greater financial responsibility to sustain their own GHS activities.

The Director of the CDC, Dr. Tom Frieden, recently cited the ongoing outbreak of Ebola in West Africa as an example of the need for the resources provided through this initiative. According to Dr. Frieden, "When we invest the time and resources to help other countries protect their own people, we help protect Americans, too."

Public Health Preparedness and Response Activities

CDC supplies the bulk of preparedness funding to state and local health departments, which are on the front lines of an emergency response and have seen their workforce severely eroded in recent years due to budget cuts. A stable, well-trained workforce and infrastructure must be in place to respond to public health emergencies—capacity and expertise cannot be built overnight. Increased funding is needed to provide coordination, guidance and technical assistance to state and local government agencies; to support the Strategic National Stockpile of medical countermeasures (including vaccines, antibiotics, antivirals, and rapid diagnostic tests); to

strengthen and sustain epidemiologic and public health laboratory capacity; and to provide clear and effective communications to the public and health care providers during an emergency.

The National Center for HIV, Viral Hepatitis, STD and TB Prevention

It is essential to maintain support for critical HIV prevention activities for individuals with HIV infection and expand routine screening for high risk populations, including youth, men who have sex with men, and minority women injection drug users, if we are to reduce rates of new infections among the most vulnerable and most heavily impacted populations. In addition, sustained investment in HIV-related surveillance remains a key component of the National HIV/AIDS Strategy to monitor and evaluate implementation efforts and to appropriately target resources and interventions to populations and communities most in need. The President has recognized the need to accelerate implementation of high-impact public health interventions to improve HIV prevention and care in the United States through his Executive Order on “The HIV Care Continuum Initiative” (July 15, 2013).¹ Implementation of the ACA will increase access to important preventive services, including routine HIV screening, in medical settings. However, it will NOT replace the urgent need to expand investments in public health and support the President’s initiative by addressing the weak links not addressed by health insurance along the HIV care continuum. Support for HIV screening and other prevention interventions outside of medical settings also will be critical to reach the populations where we see alarming increases in HIV infections and who also are less likely to engage with the health care system, including youth and men who have sex with men.

Increasing rates of gonorrhea are a critical concern because drug-resistant strains of *Neisseria gonorrhoea* have reduced our ability to treat these infections. In some parts of the country, there are no effective oral antibiotics to treat gonorrhea.

Within the US, tuberculosis remains a serious public health issue. All U.S. states continue to report cases of TB annually. Drug resistant TB poses a particular challenge to state public health budgets due to the high costs of treatment and intensive health care resources required. Treatment costs for multi-drug resistant (MDR) TB range from \$100,000 - \$400,000 per patient and the costs for extensively drug resistant (XDR) TB, which the U.S. had 15 cases of between 2008 and 2012, can be over \$1 million. There are also 8 – 10 million people in the U.S. with latent TB infection. But due to funding cuts, some state and city programs are unable to effectively operate TB infection programs, a core element of TB elimination efforts in the U.S.

We ask you to put the U.S. back on the path to TB elimination by providing \$243 million in the President’s FY2016 budget for CDC’s domestic TB elimination program, as authorized under the Comprehensive TB Elimination Act (P.L. 110-392).

¹ White House Executive Order: Accelerating Improvements in HIV Prevention and Care in the United States through The HIV Care Continuum Initiative (July 15, 2013) (accessed on-line 10/17/13 at: <http://www.whitehouse.gov/the-press-office/2013/07/15/executive-order-hiv-care-continuum-initiative>)

Enclosure III. Funding and Policy Recommendations for Global HIV & TB Programs

It is critical that the Administration's budget proposal respond to the opportunities to end the HIV pandemic by providing adequate resources for the President's Emergency Plan for AIDS Relief (PEPFAR), Global Fund, and the global HIV/AIDS portfolio at the CDC to ensure that scientific knowledge translates into lifesaving programs. Many countries have reached a "tipping point" in their HIV epidemics by scaling up treatment so that the numbers of individuals on treatment exceed new HIV infection. Continuing scale-up of antiretroviral treatment and other evidence based interventions holds the promise of dramatically reducing HIV incidence while saving lives and preserving communities. After years of investment, it is critical that we maintain the momentum now possible with the knowledge that has been gained, largely through U.S. funded research.

We respectfully request that you include a budget of at least \$5.038 billion for the bilateral global AIDS program (PEPFAR) and \$1.35 billion for the lifesaving work of the Global Fund in the FY 2016 budget. Among its important contributions to global health, Global Fund is the leading donor for tuberculosis control efforts in developing countries, including the critical response to multi-drug resistant tuberculosis. To effectively respond to the tuberculosis pandemic, we request a budget of \$400 million for the United States Agency for International Development's (USAID) global TB program to support evidenced based TB diagnosis and treatment in the most affected countries, while also providing critical funding for the development of new TB drugs, diagnostics and vaccines. We also urge your support for robust funding for the President's Malaria Initiative and other global health programs aimed at expanding immunization coverage, treatment for neglected tropical diseases and programs aimed at reducing maternal and child mortality from treatable or preventable infectious diseases.

Enclosure IV. Funding and Policy Recommendations for the Food and Drug Administration (FDA)

Greater support is needed for FDA's activities related to antimicrobial resistance and antibacterial and antiviral drug review as well as food safety and security.

In order to ensure development of urgently needed new antibiotics, FDA must maintain a leadership role in providing innovative clinical trial design guidance documents and working with new antibiotic sponsors in a timely manner. To effectively carry out these important tasks, FDA must support high level personnel with clinical experience. The agency also needs funding for Critical Path initiatives specific to antibacterial drug development. We also support robust funding for FDA's regulatory science initiative to address scientific issues related to drug, vaccine and diagnostic development, for NARMS, and to protect our nation from foodborne threats, both natural and manmade. Increased support is also needed for the Center for Devices and Radiological Health (CDRH), which is important to ensure access to safe and effective new rapid infectious diseases diagnostics. Such tests are critical to appropriate use of antibiotics and identification of patients to serve on clinical trials of new antibiotics.

Enclosure V. Funding and Policy Recommendations for the Assistant Secretary for Preparedness and Response (ASPR)

ASPR plays a key leadership role in coordinating federal efforts to sufficiently protect the nation from biothreats, pandemics and emerging infections. **IDSA supports the following investments:**

- \$636 million for the Special Reserve Fund for MCM procurement to remain available until expended. (\$255 million was appropriated in FY 2014. \$636 million is required each year for the next four fiscal years to achieve the \$2.8 billion over five years (FY 2014-2018) authorized in the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) (*\$415 million was included in the President's Budget.*)
- Increased funding for the Biomedical Advanced Research Development Authority (BARDA) for advanced development for FY 2015. (*\$415 million was included in PAHPRA and in the President's Budget.*)

Special Reserve Fund for Medical Countermeasures

We support robust funding for medical countermeasure (MCM) development and procurement through the Biomedical Advanced Research and Development Authority (BARDA) and the Project BioShield Special Reserve Fund (SRF). In 2004, Congress created the ten-year SRF to support MCM development and stockpiling. This funding has been integral to stockpiling important medical countermeasures to protect the public and cultivating a development pipeline containing over 80 candidate products. However, those funds expired at the end of 2013 and the continued development of these national security products, and new ones, is now dependent on the annual appropriations process.

Biomedical Advanced Research and Development Authority (BARDA)

IDSA supports robust funding for BARDA to facilitate advanced R&D of medical countermeasures, including therapeutics, diagnostics, vaccines, and other technologies, including new antibiotics for both intentional attacks and naturally emerging infections. BARDA is a critical source of funding for public-private collaborations for antibiotic R&D, and greater investment is needed in this key area.

Independent Strategic Investment Firm

IDSA supports the establishment of the Medical Countermeasure Strategic Investor (MCMSI), proposed by the ASPR in August 2010. The MCMSI would be a non-government, non-profit entity that would partner with small "innovator" companies and private investors to address urgent needs, first focusing on: (1) novel antimicrobials for multidrug-resistant organisms, (2) novel mechanisms for disrupting pathogenesis through host pathway targeting, and (3) multiuse platform technologies for diagnostics, vaccines/prophylaxis, and therapeutics.

Enclosure VI. Funding and Policy Recommendations for the Centers for Medicare and Medicaid Services (CMS)

Medicare

We appreciate the need to hold down future Medicare and Medicaid expenditures. We think the focus of this effort needs to be on developing innovative strategies to promote quality, improve efficiency, and avoid unnecessary expenditures. Cutbacks to eligibility, benefits, and provider reimbursement rates should be avoided, as these policies only will make it harder for vulnerable populations to access lifesaving, cost-effective care, such as HIV treatment.

Antimicrobial Stewardship

In an effort to slow the spread of antimicrobial resistance and decrease associated treatment costs, CMS should require that all health care facilities, including hospitals, long-term care facilities, long-term acute care facilities, ambulatory surgical centers, and dialysis centers, implement an antimicrobial stewardship program (ASP) as a condition of participation in Medicare and Medicaid. ASPs have demonstrated effectiveness at reducing inappropriate antibiotic use (a key driver of resistance) and reducing health care costs.

Diagnostic Test Reimbursement

The CDC has identified the need for new diagnostic tests, which can help guide appropriate use of antimicrobial drugs and thus limit the development of resistance, as a priority to improve patient care. However, tests must be reimbursed appropriately both to incentivize the development of new tests and to ensure that tests are appropriately integrated into patient care. IDSA urges the Administration to act swiftly to implement the diagnostic test provisions of the **Protecting Access to Medicare Act of 2014**. The legislation sets forth additional factors for the Secretary of Health and Human Services (HHS) to consider in determining the payment amount for new clinical diagnostic laboratory tests under gapfilling procedures which are used when no comparable existing test is available. It directs the Secretary to convene an independent advisory panel to inform and make recommendations to the Secretary regarding clinical laboratory tests, and requires the Secretary to make publicly available an explanation of the payment rate for the test.

Physician Payment Reform

IDSA supports efforts to repeal the Medicare Sustainable Growth Rate and consolidate the separate reporting programs into one Value-based Payment (VBP) program that determines incentives. However, we believe that after a decade of Medicare updates that have not kept pace with inflation, positive Physician Fee Schedule (PFS) updates for at least the first several years of a transition are necessary. Many physicians will be unprepared to transition to a new model in the near-term and even modest annual increases to their PFS payment rates will help ensure their viability. These steps will help to achieve the Administration's goal of increasing access to care.

Enclosure VII. Funding and Policy Recommendations for the Department of Defense's (DoD) Infectious Diseases Programs

There are multiple DoD programs critical to addressing infectious diseases needs. As an example, antibiotic resistance is a public health crisis that poses particular challenges to the care of wounded military personnel. Increasingly, many critically injured patients are infected with drug-resistant pathogens that demonstrate resistance not just to first-line antibiotics, but to all the major antibiotic classes. This situation limits treatment options to second-line drugs with greater toxicity. In some cases, **there are no drugs that can successfully treat these infections.** In its own surveillance report on antimicrobial resistance released in March 2011, the Armed Forces Health Surveillance Center stated that – compared with past wars – **acquisition of multidrug-resistant infections rose significantly during the conflicts in Iraq and Afghanistan.**²

A study published in 2010 of patients admitted to a military level I trauma center in San Antonio, Texas, found a significant increase in antibiotic resistance rates over a 7 year period. During that time, the percentage of infections caused by *Acinetobacter baumannii* (a dangerous gram negative superbug that has been a particular problem among soldiers) with multi-drug resistance **rose from 4% to 55%.** This dramatic increase was seen in both combat casualties and local patients, demonstrating that soldiers who contract these deadly infections overseas are bringing them home where they can spread to other patients.³

Two key DoD programs that need robust funding are:

Multidrug Resistant Organism Repository and Surveillance Network (MRSN)

The MRSN comprises a microbiology laboratory, organism repository and a seven-facility network of Army hospitals around the world that treat both soldiers and military family members. Participating hospital laboratories submit all targeted multidrug resistant organisms (MDRO), along with clinical and demographic information, to the central laboratory. The repository performs extended analyses, preserves the specimens, and relays clinically relevant information to hospitals, medical leaders and policymakers to guide empirical therapy and enhance outbreak or emerging pathogen detection. The network is currently targeting Methicillin-resistant *Staphylococcus aureus* (MRSA), and multidrug-resistant *E. coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa* and *Acinetobacter baumannii*.

The MRSN is already positively impacting patient care and producing cost savings at participating hospitals. For example, the MRSN played an important role during a recent fatal outbreak of MRSA in a neonatal intensive care unit (NICU). Due to timely feedback from the MRSN, there was an immediate relocation of infants in the NICU, intensified and repeated cleaning of the pods that housed the infants, and the implementation of a new infection-control policy wherein all admissions to the NICU are now actively screened for MRSA. An infectious diseases clinician at the outbreak facility stated, “It is totally plausible that without feedback from the MRSN, nosocomial transmission of the implicated strain would have continued, resulting in increased morbidity and more lives lost.” In addition, during the first year of its existence, on eight separate occasions, MRSN participation allowed four facilities to conduct

² Antimicrobial resistance surveillance in the AFHSC-GEIS network. BMC Public Health. 2011;11(4 March)

³ Infect Control Hosp Epidemiol. 2010 Jul;31(7):728-32. doi: 10.1086/653617.

outbreak investigations or expand existing surveillance programs without diverting clinical laboratory resources or burdening microbiology laboratory with extra workload beyond their capacity.

The MRSN needs strong funding to achieve its ultimate mission of integrating multiple levels of analysis for timely management of antibiotic resistance across the entire military health care system.

Military HIV Research Project (MHRP)

The MHRP is an integral component of the U.S. response to the HIV/AIDS epidemic, conducting HIV research in Kenya, Tanzania, Uganda, Nigeria, Mozambique and Thailand, while also providing PEPFAR-funded prevention, care and treatment services in these communities. MHRP has developed powerful and effective partnerships with the CDC, USAID, and the U.S. Peace Corps as well as with African governments and academia. The collaboration between MHRP and the PEPFAR program has created an important platform for operational research that improves services and enhances our knowledge about effective disease management. Recent progress towards the development of an HIV vaccine came largely as a result of the MHRP's landmark RV144 study in Thailand.