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IDSAs Headquarters

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

November 20, 2009

President Barack Obama
The White House
1600 Pennsylvania Avenue NW
Washington D.C. 20500

Prime Minister Fredrik Reinfeldt
On behalf of the EU Presidency
Swedish Government Offices
SE-103 33 Stockholm, Sweden

Dear President Obama and Prime Minister Reinfeldt:

I write on behalf of the Infectious Diseases Society of America (IDSAs), a medical society comprised of more than 9,000 infectious diseases physicians and scientists based in the United States (U.S.) and globally, to applaud your mutual decision to establish a Transatlantic Task Force ("Task Force") to address antimicrobial resistance, an urgent and growing problem that threatens patient safety and public health worldwide. Your commitment to address this critical problem, during the November 2-3 U.S./European Union (EU) summit, provided the necessary gravitas that has been missing from past U.S. and global drug resistance action plans.

Bad Bugs, No Drugs: An 'Impending Disaster'

The increasing number of multi-antibacterial drug-resistant infections worldwide and the diminishing number of new antibacterial drugs in development with the potential to treat these infections represent one of the world's greatest health threats. The World Health Organization (WHO) has supported this premise, identifying antimicrobial resistance as one of the three greatest threats to human health. Two recent reports—one by IDSAs¹ and another by the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA)²—demonstrate that there are few candidate drugs in the pipeline to treat infections due to highly-drug-resistant bacteria. The ECDC/EMA report, for example, found only 15 antibacterial drugs with systemic administration in the development pipeline and only five of these had progressed to clinical trials to confirm clinical efficacy (Phase III or later). Unfortunately, based on past experience, we know that few of these drugs are likely to make it to market. Resistance to the current library of antibacterial drugs is a serious problem in all parts of the world including the Asia-Pacific region, Latin America, Europe and North America. Accordingly, the disincentives for financial commitment to antibacterial drug development are a global problem.

¹ [IDSAs Report on Development Pipeline: "Bad Bugs, No Drugs, No ESKAPE"](#) CID 2009:48 (1 January 2009), Boucher, et al. (<http://www.idsociety.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=13478>)

² [ECDC/EMA Joint Technical Report: "The Bacterial Challenge: Time to React"](#), September 2009 (http://www.emea.europa.eu/pdfs/human/antimicrobial_resistance/EMA-576176-2009.pdf)

Global Commitment to Develop 10 Novel Antibacterial Drugs by 2020 (10 X '20)

*The time has come for a “**Global Commitment to Develop New Antibacterial Drugs**” to address the emerging disaster caused by the confluence of increasing bacterial resistance and a stagnant antibacterial drug pipeline. Despite the good faith efforts of many individuals, professional societies, governmental agencies, and philanthropic groups, the looming crisis has only worsened over the past decade. The problem only can be solved by bringing together global political, scientific, industry, economic, intellectual property, policy, medical and philanthropic leaders to discuss and commit to a sustainable antibacterial drug research enterprise. In IDSA’s opinion, our immediate goal should be the development of “**10 novel antibacterial drugs by 2020**”. Key to advancing antibacterial drug development is the concomitant need to advance the development of improved diagnostic tests specific to multi-drug-resistant infections.*

Global stakeholders must capitalize on each other’s strengths to create a long-term, sustainable research and development (R&D) infrastructure model that provides incentives across the spectrum of the antibacterial drug and related diagnostics research enterprises. Success would be of immense benefit to the health of the citizens of the world. Further, the sustained infrastructure created to achieve this goal would help to recreate the highly skilled scientific workforce that was lost over the past two decades as many companies abandoned antibacterial drug development and would otherwise provide the necessary incentives for perpetual antibacterial drug discovery and development. Microbial evolution causing antibiotic resistance is constant; our collective efforts at antibiotic discovery must be constant, or we risk being permanently overtaken by the microbes.

The discovery of antibacterial drugs in the 1930s and 1940s represented a transformative moment in human history. One of the leading physicians of the 20th century, who bore witness to the pre- and post-antibiotic era, has described the discovery and development of antibacterial drugs as an “awesome acquisition of power” for physicians and their patients.³ Now, 70 years later, in the U.S., EU, and around the world, the challenges posed by infections caused by the multiply-drug resistant pathogens continue to escalate, causing patient morbidity and mortality, as well as increasing health care costs. As a global society, we have a moral obligation to ensure, in perpetuity, that the treasure of antibiotics is never lost and that no infant, child or adult dies unnecessarily of a bacterial infection caused by the lack of effective and safe antibiotic therapies.

Lending your imprimatur to the creation of a Task Force that will focus on “strategies for improving the pipeline of new antimicrobial drugs,” among other important objectives, is a critically important first step. Only after establishing a global commitment to address the antibiotic pipeline problem can global multifaceted solutions be instituted. In 1961, U.S. President John F. Kennedy declared that it was possible for humans to walk on the moon. Many thought the statement was only political and impossible to achieve. History proved Kennedy’s dream was possible in 1969—less than 10 years after the President first committed to act.

Antibacterial Drug Pipeline Work Group (“Work Group”)

*To make the Task Force most effective and to achieve our “**10 novel antibacterial drugs by 2020**” dream, we strongly recommend that the U.S. and EU Task Force establish an Antibacterial Drug Pipeline Work Group (“Work Group”) as a component of the Task Force. The Work Group would focus specifically on the antibiotic drug pipeline problem as this problem requires expertise not essential to the Task Force’s other responsibilities.*

³ McDermott W & Rodgers DE. Social ramifications of control of microbial disease., Johns Hopkins Med J. 1982 151:302-12.

In our vision, the Work Group would:

1. *be established as a public/private entity including experts from the national and international scientific, industry (including small, medium and large pharmaceutical, biotechnology and medical diagnostic companies), medical, economic, intellectual property, reimbursement and other policy, public health, philanthropic and governmental communities. Only through the direct involvement of such experts within and without government can true progress be made in this critical area;*
2. *be co-established by the U.S. and EU, with the U.S. activities being administered from within the White House as a component of or working in close collaboration with the U.S. President's Council of Advisors on Science and Technology (PCAST) and engaging and relying upon the expertise of the White House's National Council of Economic Advisors and with the EU activities being administered from within the European Commission (EC);*
3. *be co-chaired on both sides by either a former or current political leader who has the capacity to assist in turning recommendations into actions or respected non-governmental and international, scientific/philanthropic leaders with an excellent understanding of the economics of the pharmaceutical, biotechnology and medical diagnostic industries;*
4. *include among its members the heads of the U.S. National Institute for Allergy and Infectious Diseases (NIAID), U.S. Food and Drug Administration (FDA), and U.S. Biomedical Advanced Research and Development Authority (BARDA) as well as their EU counterparts within the European Commission's (EC) Directorates General for Research (DG Research), Health and Consumers (DG SANCO), and Enterprise (DG Enterprise), including the EMEA. NIAID and FDA are co-leads of the existing U.S. Interagency Task Force on Antimicrobial Resistance, along with the U.S. Centers for Disease Control and Prevention (CDC). Moving forward, NIAID, FDA, BARDA, and the EC Directorates General and EMEA will be integrally involved in developing and advancing pipeline solutions;*
5. *include CDC, ECDC, and WHO representation for public and global health expertise as well as representation from the U.S. Department of Commerce and its EU counterpart, the EC's DG Enterprise, for expertise in intellectual property rights and the economics of the pharmaceutical, biotechnology, and medical diagnostics industries;*
6. *explore and identify recommendations across a broad spectrum of policy options including those which address regulatory and financial disincentives that negatively impact the antibacterial drug and related diagnostics pipeline. A review of the findings of a new EU-commissioned report titled "Policies and Incentives for Promoting Innovation in Antibiotic Research," drafted by a team from the London School of Economics and Political Science (LSEPS), will be helpful in this regard. A draft version⁴ of the report was released at an EU conference held in Stockholm, Sweden in September 2009; the final report is likely to be published by the end of this year. The LSEPS report provides a good starting point for discussion about the kinds of incentives that will be needed to reach the **"10 novel antibacterial drugs by 2020"** goal. Related to this, the U.S. will need to commission a similar report that addresses the United States' own unique regulatory and economic environments;*

⁴ http://www.se2009.eu/polopoly_fs/1.16814!menu/standard/file/LSE-ABI%20F-Final.pdf

7. *identify scientific challenges that need to be addressed and consider new research opportunities that the U.S. and EU should fund to advance antibacterial drug and related diagnostics discovery and development;*
8. *immediately examine U.S. and EU funding levels specific to antibacterial drug and related diagnostics discovery and development and recommend supplemental funding targets in this area consistent with the urgent needs; and*
9. *be a transparent process—Work Group meetings/calls must be open to the public and meeting materials and transcripts must be made publicly available.*

The Task Force's Other Critical Responsibilities: Appropriate Use and Infection Prevention

At the same time the Work Group focuses on the drug and related diagnostics pipelines, the U.S., EU, WHO and global community must continue to work towards attenuating the serious problem of drug resistance. We strongly believe that aspects of recommendations 1 through 9 (above) also are relevant to the Task Force's responsibilities related to: (a) the appropriate uses of antibacterial drugs in the medical and veterinary communities, and (b) prevention of both health care- and community-associated drug-resistant infections. For example, we believe the Task Force, as a whole, should be a public/private initiative with non-governmental experts directly represented, its focus should be global, and its processes should be transparent. Also, of great importance, as with the drug pipeline problem, numerous components of the U.S. and EU governments will be necessary to tackle the appropriate use and prevention issues. Indeed, the United States' own Interagency Task Force on Antimicrobial Resistance has representation from eleven (11) different agencies representing six (6) U.S. departments. For this reason, the idea of nesting the appropriate use and infection prevention efforts under a single department or directorate general likely will not take full advantage of the U.S. and EU governments' breadth of expertise and abilities to respond effectively and would most likely result in an insufficient response. To address these concerns, we believe the U.S. and EU Task Force activities, as a whole, should be administered from within the White House, perhaps in conjunction with PCAST, and the European Commission, respectively.

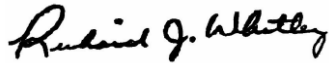
Conclusion

*As the new Transatlantic Task Force gets underway, IDSA seeks a “**Global Commitment to Develop New Antibacterial Drugs**” from U.S., EU and other global leaders to take all necessary actions to ensure that 10 novel systemically administered antibacterial drugs will be brought to market by 2020 and to compose the new Task Force in a way that makes this **10 X '20** commitment a reality. Naysayers will immediately discount the **10 X '20** commitment as radical, impossible, and unacceptable to political leaders in the U.S. and EU, industry, academe, governmental experts, and the international scientific and medical communities. Objections are inevitable, but easily nullified by recognition of the magnitude of the problem and the moral imperative incumbent upon all stakeholders to make it happen. Without a global commitment to create and maintain the necessary sustainable infrastructure, the inventory of safe and effective antibiotics will inevitably shrink as the bacteria grow ever more resistant. This need not happen, if we all work together to make the **10 X '20** commitment a priority.*

As President Kennedy forecast, we can walk on the moon within 10 years, if we commit to this goal.

IDSA stands ready and willing to work with the U.S. and EU governments and the Task Force's members as this extremely important initiative advances. Please contact Robert J. Guidos, JD, IDSA's vice president for public policy and government relations, at rguidos@idsociety.org or by phone at 703-299-0202 should you have any questions or comments.

Sincerely,



Richard Whitley, MD, FIDSA
President

cc: Kathleen Sebelius, MPA, Secretary, U.S. DHHS
Anthony Fauci, MD, FIDSA, Director, U.S. NIAID
Margaret Hamburg, MD, Commissioner, U.S. FDA
Tom Frieden, MD, Director, U.S. CDC
Robin Robinson, Ph.D, Director, U.S. BARDA
Robert Madelin, Director General, DG SANCO, EU Commission
Heinz Zourek, Director General, DG Enterprise, EU Commission
Jose Manuel Silva Rodriguez, Director General, DG Research, EU Commission
Melody Barnes, JD, Director, Domestic Policy Council, The White House
Dr. John Holdren, co-chair, PCAST; Director, Office of Science and Technology Policy
EOP, The White House
Dr. Eric Lander, co-chair, PCAST; Director, Broad Institute of MIT and Harvard
Dr. Harold Varmus, co-chair, PCAST; President, Memorial Sloan-Kettering Cancer
Center
Göran Hägglund, Minister for Health and Social Affairs, Sweden
John Monahan, Acting Director, U.S. HHS, Office of Global Health Affairs
Rep. Henry Waxman, Chair, U.S. House Energy and Commerce Committee
Senator Tom Harkin, Chair, U.S. Senate Health, Education, Labor and Pensions
Committee