



**Statement of the Infectious Diseases Society of America presented at the
Interagency Task Force on Antimicrobial Resistance (ITFAR) Meeting
November 15, 2012, Washington DC**

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to share our views on the current U.S. response to antimicrobial resistance with the Interagency Task Force on Antimicrobial Resistance (ITFAR). IDSA appreciates the tireless efforts of all the ITFAR agency representatives, and we continue to advocate for the resources you need to do this critical, life-saving work.

IDSA represents nearly 10,000 infectious diseases physicians and scientists. Our members view antimicrobial resistance and the lack of new antimicrobials in development (particularly antibiotics) as a serious threat to our nation's public health, patient safety, and national security. The longer we wait to address this growing health care crisis, the larger and more costly the problem will become both in terms of lives lost and health care expenditures wasted.

IDSA comes before the task force today to highlight five areas that must be strengthened for the ITFAR effort to achieve its full potential. IDSA and other medical, public health and patient organizations have sought to strengthen these same five areas through legislative, regulatory, and administrative means, including the Strategies to Address Antimicrobial Resistance (STAAR) Act, which 26 organizations have endorsed (see Attachment A).

1. Strengthen ITFAR's Leadership and Ability to Coordinate Actions and Facilitate Greater External Input and Collaboration

As advocated in the STAAR Act, IDSA highlights the need for a strong, centralized coordinator of the federal government's efforts to combat antimicrobial resistance, including through implementation of ITFAR's Action Plan to Combat Antimicrobial Resistance. Specifically, IDSA calls upon the Secretary of the Department of Health and Human Services (HHS) to designate an office and director within the Assistant Secretary for Health (ASH) or the Assistant Secretary for Preparedness and Response (ASPR) to oversee coordination of ITFAR activities. We also continue to advocate for the creation of a formal advisory board of non-government antimicrobial resistance experts to meet and dialogue with ITFAR on a regular basis. We are very pleased that the Senate Appropriations Committee included these recommendations in its report accompanying its Fiscal Year (FY) 2013 funding legislation. We also are pleased that the Centers for Disease Control and Prevention (CDC) has established its own Antimicrobial Resistance Work Group, but a broader advisory group is needed to advise the full ITFAR.

We continue to call for the inclusion of benchmarks in the Action Plan to establish timelines for completing projects and measuring progress.

Finally, experience has shown that public-private collaborations are critical to the success of public health initiatives of this scale. However, the revised ITFAR Action Plan provides little detail on how the participating agencies will work with the private sector to achieve goals that would be difficult, if not impossible, to complete without private sector collaboration, including with healthcare systems and institutions, professional societies, and the pharmaceutical and diagnostics industries. IDSA urges ITFAR to better define its vision to support future public-private collaborations.

2. Support Robust Data Collection and Surveillance

Several important data collection and surveillance initiatives are underway in the U.S. through CDC's National Healthcare Safety Network (NHSN), Emerging Infections Program (EIP), and Prevention Epi-Centers Program; the multi-agency National Antimicrobial Resistance Monitoring System (NARMS) (coordinated by CDC, the Food and Drug Administration [FDA] and the U.S. Department of Agriculture [USDA]); and the Department of Defense's (DoD) Multidrug-resistant organism Repository and Surveillance Network (MRSN). These efforts include measuring antimicrobial use in hospitals, and collecting data on antimicrobial resistant infections in hospitals, in food, and in U.S. soldiers serving abroad. Having these data are critical in determining the prevalence of resistant infections and in monitoring the impact of measures such as antimicrobial stewardship and infection prevention. IDSA strongly supports each of these programs and would like to see them further strengthened with greater investments.

Even given the value NHSN, EIP, Prevention Epi-centers, NARMS, and MRSN provide, IDSA remains deeply concerned about the lack of detailed, publicly available data on both resistance trends and human antimicrobial use in humans, food animals and other areas of agriculture and food production in the United States. The U.S. is far behind other countries in collecting and benefiting from data on antibiotic consumption and resistance. The Danish Integrated Antimicrobial Resistance Monitoring and Research Program (DANMAP) performs continuous monitoring of data on both consumption and resistance in humans, food animals, and food. Human consumption data is collected from the pharmaceutical industry and the Danish Medicines Agency, while DANMAP's "VetStat" system collects food animal data by species from pharmacies, farms, feed mills, and veterinary practitioners. On a Europe-wide level, the European Surveillance of Antimicrobial Consumption (ESAC) system collects human and more limited animal consumption data from 34 countries, while the European Antimicrobial Resistance Surveillance System (EARSS) collects resistance data.

In the report accompanying its FY2013 funding legislation, the Senate Appropriations Committee requested a report from the CDC regarding the type and scope of data collected in the U.S. on antibiotic consumption and resistance trends compared to such data collected worldwide. The agency was also asked to identify barriers to improved data collection. This report could provide excellent baseline data upon which the U.S. can build in future years.

Also, in support of this goal, strengthening and building upon the surveillance and laboratory capacity of CDC's intramural and extramural programs and laboratories could intensify our national capacity to monitor emergence of resistant pathogens, facilitate a response to outbreaks, assess resistance patterns, study the epidemiology of resistant infections, improve the accuracy of resistance testing and reporting, and help develop novel diagnostic tests capable of detecting

resistance. Additionally, regional prevention collaboratives, which could be established with state health departments under CDC's leadership, could identify resistant pathogens being transmitted across health care settings and implement evidence-based interventions to interrupt and prevent the transmission of such pathogens. CDC's prevention Epi-centers already conduct critical infection control and prevention research on antibiotic-resistant infections, but their work must be expanded. The Epi-centers can do more to evaluate interventions to prevent or limit the emergence of resistance, facilitate public health research on the prevention and control of resistant organisms, and assess the effectiveness of surveillance and prevention programs in health care settings. CDC's EIP conducts surveillance on resistant organisms. Strengthening this program can enhance the capacity to evaluate the impact of public health interventions on resistant infections occurring at the interface of the community and healthcare settings.

3. Promote Antimicrobial Stewardship

IDSA supports the adoption of antimicrobial stewardship practices in all human health and veterinary care settings across the country to help curb inappropriate antimicrobial use. A new study of antibiotic stewardship programs at children's hospitals found such programs resulted in a significant decrease in antibiotic usage—ranging from a 37% decrease in the early months, to 13% at the end of the observation. CDC's Get Smart program plays an important role in educating providers and patients about appropriate antibiotic use, but more must be done. IDSA urges CDC to pilot and test health care quality measures to help providers, facilities, and health systems measure and benchmark appropriate antimicrobial use. CDC also should work with standard setting organizations to determine if any such measure is suitable for national quality reporting.

However, stewardship efforts cannot fall to CDC alone. IDSA, in conjunction with the Society for Healthcare Epidemiology of America (SHEA) and the Pediatric Infectious Diseases Society (PIDS), released a joint policy statement on antimicrobial stewardship in which we recommended that the Centers for Medicare and Medicaid Services (CMS) require participating healthcare institutions to develop and implement physician-led antimicrobial stewardship programs in all healthcare facilities, including hospitals, long-term care facilities, long-term acute care facilities, ambulatory surgical centers, and dialysis centers. IDSA also has urged the Food and Drug Administrations' (FDA) Center for Veterinary Medicine (CVM) to adopt strong regulations to ensure that antimicrobials are used judiciously in food animals under the supervision of veterinarians. Finally, in support of greater stewardship on the human side, IDSA supports creation of a Limited Population Antibacterial Drug (LPAD; see page 4) approval mechanism at FDA.

4. Strengthen and Support Resistance Research

On the topic of research, IDSA is highly supportive of the National Institute of Allergy and Infectious Diseases' (NIAID) establishment of a clinical trials network on antibiotic-resistant bacterial infections, and we are advocating for Congress to provide increased funding for this important effort as \$10 million/year is insufficient to support the critical and urgent projects that the network could and should undertake. \$100 million annually, although still insufficient to fulfill all of the research needs, is a more reasonable amount for the initial years of the network.

IDSA and 25 other organizations endorsing the STAAR Act also call upon NIAID to quickly organize a blue ribbon panel of experts to create an antibacterial resistance strategic research plan to assist in prioritizing critical research. NIAID leaders have said they view the research section in the Action Plan as their strategic plan, but IDSA leaders do not view that section as sufficiently comprehensive and detailed to provide a road map for future research in this area. NIAID previously brought together experts to work with the institute to develop comprehensive strategic research plans on HIV/AIDS, biodefense, and tuberculosis. Resistance research is deserving of similar attention. The Senate Appropriations Committee recommended that NIAID take this action in its report accompanying its FY2013 funding bill. We support the Senate's recommendation.

Finally, IDSA remains concerned about the overall level of funding NIAID commits annually specific to antibacterial resistance (as opposed to the broader category of antimicrobial resistance) as well as research and development efforts on antibacterial drugs and related diagnostics. We continue to call for a total funding level of \$500 million to expand NIAID's support for research on antibacterial resistance, including discovery of new antibacterials and related diagnostics. By demonstrating a strategic and financial commitment to antibacterial research as a top priority, NIAID can help recruit new investigators into antibacterial resistance research.

5. Advance Product Development

IDSA remains committed to stimulating antibiotic and related diagnostics research and development (R&D) through the removal of economic and regulatory disincentives and other tools. We applaud the steps agencies already are taking to implement the antibiotics provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA) and look forward to participating in continued efforts beyond this legislation.

a. Antibiotic Economic Incentives.

FDASIA requires HHS to conduct a study on antibiotic and antifungal incentives, and IDSA hopes the HHS study will recommend tax incentives for antibiotics and related diagnostics similar to the 50% credit that has successfully spurred Orphan Drug R&D. However, IDSA would propose that such a credit be transferable so that start-up companies with no profit might sell credits earned and then reinvest that income into additional R&D.

Although FDASIA calls for HHS to release its report within five years, IDSA strongly urges the Department to move much more quickly. Waiting a full five years to complete the report would fail to recognize the urgency of the antibiotic crisis and would miss the opportunity to provide valuable information to Congress in advance of congressional consideration of the next Prescription Drug User Fee Agreement (PDUFA) reauthorization. Moreover, given the Eastern Research Group (ERG) study (commissioned by HHS and FDA), which already is underway and should be complete in early 2013, it does not make sense to wait five years before reporting back to Congress.

b. Productive R&D Public-Private Collaboration.

The FDASIA-required report referenced above includes reference to a study of potential R&D public private collaborations (PPC). We hope HHS's study will include a review of the existing European Union (EU) PPC, the Innovative Medicines Initiative (IMI), which recently launched a NewDrugs4BadBugs project focused on antibiotics for serious resistant pathogens. An unprecedented sharing of information (among companies, academic institutions and government entities) will be a significant and valuable outcome from the EU initiative. The focus of the overall program will be to develop better networks of researchers, create more fluid trial designs and provide incentives for companies to participate. We also strongly encourage HHS to include the Department of Defense (DoD) in the discussions around building a strong and sustainable PPC to foster development of new antibiotics and related diagnostics in the U.S. We have heard there is interest at DoD to work with HHS on this effort.

c. Limited Population Antibacterial Drug Approval Mechanism

IDSA strongly encourages FDA to continue efforts to address regulatory issues that currently challenge antibiotic R&D. We look forward to the development of pathogen-focused antibacterial drug development as well as the review and revision of existing clinical trial guidance documents. IDSA has recommended establishment of a Limited Population Antibacterial Drug (LPAD) approval pathway for drugs to treat serious or life-threatening infections where few or no satisfactory therapeutic options exist. IDSA strongly believes the LPAD mechanism will be a game changer for antibiotic R&D and for improving antibiotic stewardship. Under LPAD, safety and effectiveness would be studied in substantially smaller, more rapid, and less expensive clinical trials—much like the Orphan Drug (OD) Program permits for other rare diseases. LPAD products then would be narrowly indicated for marketing and use in small, well-defined populations of patients for whom the drugs' benefits have been shown to outweigh their risks. The development of related diagnostics will be extremely helpful to ensure LPAD drugs are being used appropriately.

d. Centralized Specimen Repository to Support Diagnostics R&D and Other Research.

Lastly, IDSA calls on NIAID to establish a clinical specimen repository (not isolates) that includes urine, sputum, blood and tissue whose microbial content is known and validated, and which includes relevant accompanying clinical information. Such a repository will help support the development and validation of new rapid, point-of-care diagnostics, which we all agree are critically needed to address the antimicrobial resistance crisis. We ask that FDA work with IDSA and other stakeholders to develop collection protocols and other standards for the repository that will satisfy FDA's regulatory requirements. Researchers (government and industry funded) should have access to these specimens for high-quality, priority studies. The repository could ultimately be self-sustaining through fees paid by diagnostics and pharmaceutical developers for access to specimens. IDSA is pleased that the Senate Appropriations Committee, in the report accompanying its FY2013 funding legislation, urged NIAID to study the feasibility of establishing such a repository.

Conclusion

Again, IDSA thanks the ITFAR for holding this important meeting and providing IDSA the opportunity to provide comments. We look forward to continuing to work with the ITFAR and all of its members to advance these important policy goals.

ATTACHMENT A

ORGANIZATIONS ENDORSING THE STRATEGIES TO ADDRESS ANTIMICROBIAL RESISTANCE (STAAR) ACT

The following organizations have endorsed the STAAR Act:

- Alliance for the Prudent Use of Antibiotics (APUA)
- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American Association of Critical-Care Nurses (AACN)
- American College of Physicians (ACP)
- American Dental Association (ADA)
- American Medical Association (AMA)
- American Pharmacists Association (APhA)
- American Public Health Association (APHA)
- American Society of Health-System Pharmacists (ASHP)
- Association for Professionals in Infection Control and Epidemiology (APIC)
- Council of State and Territorial Epidemiologists (CSTE)
- Food Animal Concerns Trust (FACT)
- Infectious Diseases Society of America (IDSA)
- International Society of Microbial Resistance (ISMR)
- Michigan Antibiotic Resistance Reduction Coalition (MARR)
- National Association for Sport and Physical Education (NASPE)
- National Athletic Trainers Association (NATA)
- National Foundation for Infectious Diseases (NFID)
- National Parent-Teacher Association (PTA)
- Pediatric Infectious Diseases Society (PIDS)
- Premier, a healthcare alliance serving 2,100 nonprofit hospitals and 58,000 healthcare sites
- Society for Healthcare Epidemiology of America (SHEA)
- Society of Infectious Diseases Pharmacists (SIDP)
- Trust for America's Health (TFAH)
- Union of Concerned Scientists (UCS)