Antimicrobial Resistance: Examining an Emerging Public Health Threat
House of Representatives Energy & Commerce Committee, Oversight & Investigations Subcommittee
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Chairman Griffith, Ranking Member Castor and distinguished members of the Subcommittee, thank you for holding a hearing on the critical issue of antimicrobial resistance (AMR) and for inviting me to testify on behalf of the Infectious Diseases Society of America (IDSA). IDSA represents over 12,000 infectious diseases (ID) physicians, scientists and other health care and public health professionals specializing in infectious diseases. IDSA has been sounding the alarm about AMR since 2004 with the release of our "Bad Bugs, No Drugs" report. ID physicians are seeing more patients with resistant infections and increasing multi-drug-resistant strains, including those that are highly contagious and resistant to every available antimicrobial drug. While the federal government, with bipartisan action and leadership from the Energy & Commerce Committee, has made important strides to strengthen the federal response to AMR with a One Health approach that covers human health, animal health, agriculture and the environment, significant work remains to protect patient safety and national security and to safeguard modern medicine as we know it.

I will outline why AMR is one of the greatest public health crises of our time; the current state of AMR response efforts, including progress and gaps regarding the antimicrobial drug pipeline, stewardship, prevention, surveillance, data collection and the expert workforce needed to drive these activities; and finally, I will highlight urgently needed solutions, including the bipartisan *Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act* by Representatives Ferguson and Peters.

<u>Antimicrobial Resistance: Undermining Modern Medicine</u>

Antimicrobial resistance refers to pathogens' natural ability to evolve to resist the effects of antimicrobial drugs, ultimately making those drugs ineffective. While resistance occurs in nature, the overuse and misuse of antimicrobials greatly increases the speed at which resistance develops, significantly shortening the time for which antimicrobial drugs remain effective and reducing the number of useful antimicrobials. **Antimicrobials are unlike any other therapeutic in that use in one individual can impact efficacy in the rest of the population.**

In 2019, an estimated 1.27 million deaths worldwide were directly caused by AMR, and AMR played a part in nearly 5 million deaths. This makes AMR a leading cause of death globally.[1] The post-antibiotic era is not just a looming threat — for many patients it is already here.

To fully understand the scale and scope of the AMR crisis, one must first recognize the fundamental role antimicrobials play in human health. **Antimicrobials enable and sustain modern medicine because so many of our modern medical advances carry a risk of infection and rely upon antimicrobials.** Consider procedures like cancer chemotherapy, organ transplants, hip and knee replacements, C sections and other surgeries and complex care. All of these procedures save and enhance human lives, and they all carry risk of infection. Clinicians are only able to provide this care because they have safe and effective antimicrobials to prevent and manage infectious complications. But as our antimicrobial arsenal diminishes, our modern medical gains are unraveling, and patients are facing devastating consequences. Consider a few examples:

- **Cancer**: Cancer and many cancer treatments can weaken the immune system. Infections are a primary or associated cause of death in 50% of patients with cancer, as AMR can make these infections difficult or impossible to treat.[2]
- **Maternal mortality**: Sepsis—the body's overwhelming and life-threatening response to untreated infections that can result in organ failure and death—is the second leading cause of pregnancy-related deaths. AMR exacerbates the risk of sepsis by making infections much more

[1] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext
[2] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21697

difficult to treat. Between 2014 and 2017, infection or sepsis caused 12.7% of pregnancy-related deaths in the United States. Pregnancy-related infections that can lead to sepsis can be related to miscarriages, C-sections, prolonged or obstructed labor, and mastitis (breast infection).[3]

- **Biologics**: Certain biologics that are used to treat a wide range of conditions weaken the immune system, making individuals more susceptible to infections.
- **Implantable medical devices**: Prosthetic joints, pacemakers, implantable defibrillators, ventricular assist devices for patients with serious heart disease, and other implantable devices can easily become infected. In many cases, removal of these devices may be impossible or impractical, and patients may face recurring or chronic infections that can become increasingly resistant.
- **Opioid use**: The opioid epidemic is also fueling the spread of resistant infections, including life-threatening heart valve infections, skin and soft tissue infections, bone and joint infections, and more. The Centers for Disease Control and Prevention (CDC) estimates that individuals who inject drugs are 16 times more likely to experience an invasive methicillin-resistant *S. aureus* (MRSA) infection.[4]
- **Fungal infections**: In March 2023, CDC warned that cases of *Candida auris*, a difficult-to-treat resistant fungal pathogen, have been increasing steadily since they were first reported in 2016. *C. auris* is resistant to multiple antifungal drugs, spreads easily in healthcare facilities, and has high mortality rates.[5]

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[3] https://www.sepsis.org/sepsisand/pregnancy-childbirth/
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7045815/#:~:text=Data%20from%206%20sites%20of,develop%20invasive%20MRSA%20infections%20than
[5] https://www.cdc.gov/media/releases/2023/p0320-cauris.html

- **Organ transplants**: More than 42,000 organ transplants were performed in the US in 2022, a 3.7% increase over 2021 and a new annual record.[6] Unfortunately, AMR and the dwindling arsenal of antimicrobial drugs available to support these patients means many of them face death due to infection despite a successful transplant.
- **Cystic fibrosis**: People with cystic fibrosis (CF) face a heightened, life-long risk of infections because of the thick sticky mucus in their lungs. Routine use of antibiotics in CF care is medically necessary, however, too many people with cystic fibrosis find themselves battling difficult-to-treat infections for which existing antibiotics are not effective.

Increasing resistance is forcing ID physicians to turn to older, more toxic antibiotics like colistin—a drug that causes serious kidney damage. Patients are left with the unfathomable choice of dying from their infection or taking an antibiotic that could leave them in need of dialysis for the rest of their life or a kidney transplant. The rapid spread of the transferable gene, mcr-1, which confers colistin resistance, threatens the efficacy of even colistin—a last resort drug for the treatment of many drug-resistant bacterial infections.[7] We must do better.

AMR is also impacting healthy individuals in the community. Rates of a type bacteria that cause resistant urinary tract infections or UTIs (extended-spectrum beta-lactamase (ESBL)-producing Enterobacteriaceae) increased by more than 50% from 2013 to 2019.[8] In fact, increasing numbers of patients with UTIs that were once easily treated with oral antibiotics now require intravenous (IV) antibiotics in the hospital — increasing our health care costs and creating serious disruptions to patients' lives. As another example, an ongoing outbreak of drug-resistant eye infections due to contaminated eye drops has caused blindness in several patients and the need for removal of the eye, a devastating

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[6] https://unos.org/news/2022-organ-transplants-again-set-annual-records/#:~:text=In%202022%2C%2042%2C887%20organ%20transplants,Transplantation%20Network%20under%20federal%20contract.

[7] https://www.nature.com/articles/s41429-023-00622-1

[8] https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

and disfiguring complication. This underscores that resistant infections are a threat to us all and that we must invest in the tools necessary to ensure we can manage such outbreaks with limited negative impacts.

Like so many health conditions, AMR disproportionately impacts historically marginalized populations, though more comprehensive data is needed to fully understand the inequitable impacts of AMR. A few examples:

- Community-associated MRSA rates are higher among Black populations when compared to White populations.[9]
- American Indian and Alaska Native persons have substantially higher population rates of all invasive Group A *streptococcus* disease.[10]
- In February 2023, CDC published a health alert on an increase in extensively drug resistant (XDR) *Shigella* infections. Historically, *Shigella* has largely impacted children under age 5. There is now an increase in *Shigella* infections among men who have sex with men, individuals experiencing homelessness, international travelers and people with HIV.[11]

National healthcare costs linked to infections from six of the biggest AMR threats are estimated to be more than $4.6 billion annually.[12] $1.9 billion of these costs are estimated to be borne by Medicare.[13]

<u>Antimicrobial Resistance: A Threat to Readiness and National Security</u>

The AMR crisis was further exacerbated by the COVID-19 pandemic. In 2020, U.S. hospitals experienced a 15% increase in AMR infections and deaths, though pandemic-related data gaps suggest that the total national burden of AMR may be much higher. Experts do not expect a return to pre-

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[9] https://www.cdc.gov/drugresistance/pdf/health-equity-antibiotic-resistance-fs-508.pdf
[10] https://www.cdc.gov/drugresistance/pdf/health-equity-antibiotic-resistance-fs-508.pdf
[11] https://emergency.cdc.gov/han/2023/han00486.asp
[12] https://www.cdc.gov/drugresistance/solutions-initiative/stories/partnership-estimates-healthcare-cost.html
[13] https://academic.oup.com/cid/article/74/6/1070/6374434

pandemic levels without concerted action.[14] Any emergency resulting in high levels of hospitalization, particularly high levels of ventilator use and overwhelmed hospital staff, creates a ripe opportunity for the spread of secondary drug-resistant infections.

Hurricanes and other natural disasters can also increase the spread of infections, including drug-resistant infections. Loss of electricity increases the risk of food spoilage and foodborne illness. Interrupted access to safe water can lead individuals to turn to rivers or other ad hoc water sources. This approach, along with the presence of floodwaters, can increase the risk of illness caused by waterborne pathogens. Studies have found higher levels of pathogenic bacteria and antibiotic resistance genes in floodwaters and soil in the Houston area following Hurricane Harvey.[15][16] Conditions in crowded emergency shelters and severely damaged homes can significantly increase the spread of infection as well.

Addressing AMR is important for bioterror readiness and national security, as agents used by bioterrorists may be genetically engineered to resist current antimicrobials.[17] The World Health Organization (WHO) has estimated that if 50 kg of *Y. pestis* were to be released as an aerosol over a city with a population of 5 million, 150,000 people might fall ill with pneumonic plague, 36,000 of whom would die.[18] Drug-resistant strains of *Y. pestis* have been reported, which can increase mortality.[19] As another example, modeling suggests that deliberate release of aerosolized *F. tularensis* over London would result in an estimated 130,000 infections and 24,000 deaths.[20] Natural resistance is already

[14] https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf
[15] https://pubs.acs.org/doi/10.1021/acs.estlett.8b00329
[16] https://pubmed.ncbi.nlm.nih.gov/33077230/
[17] https://books.google.com/books?hl=en&lr=&id=IiGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-zSVfBI-1p_9TT4#v=onepage&q&f=false
[18] https://apps.who.int/iris/bitstream/handle/10665/39444/24039.pdf
[19] https://journals.asm.org/doi/full/10.1128/AAC.00306-06
[20] https://www.liebertpub.com/doi/abs/10.1089/bsp.2011.0004

observed in tularemia, and the overuse of fluoroquinolones, one of the main treatments for this infection, in the last two decades has led to treatment failure and relapses in tularemia patients.[21]

Military service people, who are often critical first responders in emergencies, can be at heightened risk for resistant infections, as combat wounds and burns can easily become infected. In the current conflict in Ukraine, patients are presenting with highly complex, multidrug-resistant musculoskeletal infections from gunshot and bomb wounds. Physicians identified multiple pathogens, including *Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter baumannii, E. coli* and fungal pathogens. Infections showed high rates of resistance to some of our most powerful antibiotics: 72% were resistant to carbapenems and newer cephalosporins (ceftazidime-avibactam and ceftolozane-tazobactam), 39% were resistant to cefiderocol, 20% to colistin and 96% to ciprofloxacin.[22] International travel makes it very easy for drug resistant pathogens to spread across the globe.

Insufficient Antimicrobial Pipeline

Despite the urgent and increasing need for novel antimicrobials to treat resistant infections, the current pipeline has fewer than 50 antibacterial therapeutics in clinical development worldwide — only only a handful of which are for the most threatening gram-negative pathogens — a critical area of need.[23] Given that most drugs in development do not ultimately secure FDA approval, and that there is a wide array of drug-resistant bacteria and fungi for which new therapies are needed, the current pipeline is grossly inadequate. The last FDA approval of an antibiotic was in November 2019.

Novel antimicrobials must be used appropriately by prescribers with sufficient expertise to limit the development of resistance; this means ensuring that these precious medicines are not overused. This is essential from a clinical and public health perspective but creates a serious barrier to private

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21 https://ami-journals.onlinelibrary.wiley.com/doi/full/10.1111/j.1751-7915.2008.00063.x
22 https://www.cidrap.umn.edu/antimicrobial-stewardship/clinicians-describe-challenge-treating-multidrug-resistant-war-wounds
23 https://www.who.int/publications/i/item/9789240047655

sector investment in antimicrobial innovation. Currently, federal and commercial payers reimburse for antimicrobials when they are used, so judicious use to preserve effectiveness severely limits the ability of an antimicrobial developer to earn a return on their investment.

Between 2010 and 2019, 18 new antibiotics were approved by FDA, which is an improvement from the 11 new antibiotics approved from 2000-2009. However, only one of those 18 antibiotics had a new mechanism of action, and it was the first such antibiotic approved since the 1980s.[24] This underscores the need not only to strengthen antimicrobial research and development but more specifically to incentivize the development of truly novel antimicrobials.

Federal support from the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Disease (NIAID) has been critically important to the development of more recently approved antibiotics, and their funding for CARB-X has strengthened the pre-clinical antimicrobial pipeline. However, we see plain evidence of failures in the market for antimicrobials: There has been a disturbing number of instances in which small companies successfully bringing a new antibiotic to market are then pushed to file for bankruptcy due to the broken antimicrobials market that provides little to no opportunity to earn a return on investment. There is an urgent need for a novel solution that will revitalize and sustain antimicrobial innovation and availability.

Potential Role of Phage Therapy[25]

Non-traditional therapies, such as phage therapy, may also have a useful role in treating resistant infections, and additional research should be pursued to inform optimal clinical use of phage therapy. Experimental phage therapy can be considered for a variety of infections not responding to antibiotics, including respiratory tract infections, infections involving devices that cannot be removed, UTIs, gastrointestinal infections and more. Recent clinical data on phage therapy has been generated

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[24] https://www.bio.org/sites/default/files/2022-02/The-State-of-Innovation-in-Antibacterial-Therapeutics.pdf

[25] https://journals.asm.org/doi/10.1128/aac.02071-21#:~:text=In%20general%2C%20phage%20therapy%20should,not%20amenable%20to%20source%20control

primarily in compassionate use settings in conjunction with antibiotic therapy. Many cases were associated with apparent successful response of resistant infections that were not resolving with antibiotics alone, suggesting that in those cases, there may have been an additive effect of the phage-antibiotic combination. Much current phage data does not come from clinical trials with a control group, and failures of phage therapy are less likely to be reported, all of which limits our understanding of phage therapy. Phage therapy is currently limited to treatment of bacterial infections; however, data are emerging to indicate that fungal pathogens such as *Aspergillus* can be treated in the future.

Phages do not have reliable activity against all strains of any bacterial species, underscoring the potential importance of phage susceptibility testing (PST) to inform selection of phage therapy. Standardized PST methodologies should be developed to support this testing. Because of the potential for resistance to develop to phages during treatment, PST can confirm continued efficacy throughout treatment or identify the need for a new phage or phage cocktail.

Randomized controlled trials of phage therapy are needed to inform and understand treatment indications, route of administration, dosing, duration of therapy, optimal phage cocktail combinations and phage-antibiotic combinations, and development of resistance. In addition to clinical trials, a systematic approach to data collection from compassionate use cases and availability of such data to clinicians, including clinical failures, would be helpful for clinicians, and a common database to collect and access such data should be established.

Antimicrobial Stewardship

Overuse and misuse of antimicrobials in any setting—human medicine, animal health, agriculture, the environment—drives the development of resistance, and a One Health approach to combating AMR is critical. From March-October 2020, about 80% of patients hospitalized with COVID-19 received antibiotics.[26] COVID-19 is caused by a virus, and therefore does not respond to antibiotics, though antibiotics may be appropriate for the minority of patients with secondary bacterial infections. Even before the pandemic, about half of hospitalized patients were prescribed antibiotics, with 30%-50% of those prescriptions estimated to be inappropriate or unnecessary.[27]

Antimicrobial stewardship programs in hospitals aim to optimize antibiotic use to ensure that patients receive the right drug for the right bug with the right dosing and duration. These programs have been found to improve patient outcomes, reduce inappropriate antibiotic use, and lower health care costs.[28,29] Nationwide, 98% of hospitals report having implemented all seven of the core elements of antimicrobial stewardship recommended by CDC[30] and as required by the Joint Commission and the Centers for Medicare and Medicaid Services (CMS). Despite this important progress, there remain many important opportunities to improve antimicrobial therapy and reduce inappropriate antibiotic use in hospitals.

While many hospitals can meet stewardship requirements on paper, they often lack the resources and experienced staff necessary to fully implement medically recommended stewardship protocols and to extend the benefits of stewardship to all patients. Studies have found consistent gaps between necessary levels of physician and pharmacist staffing and existing staffing levels. A 2018 study found that each 0.50 increase in physician and pharmacist full-time employee (FTE) support for a stewardship program predicted a 1.48-fold increase in the odds of the program demonstrating effectiveness.[31]

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[26] https://www.cdc.gov/drugresistance/covid19.html#:~:text=Antibiotic%2FAntifungal%20Use%3A%20COVID%2D19%20Impact&text=Almost%2080%25%20of%20patients%20hospitalized,they%20can%20contribute%20to%20resistance.
[27] https://academic.oup.com/cid/article/63/12/1/2282817
[28] https://academic.oup.com/cid/article/66/7/995/4851152
[29] https://pubmed.ncbi.nlm.nih.gov/27246783/
[30] https://www.cdc.gov/antibiotic-use/stewardship-report/current.html
[31] https://doi.org/10.1093/cid/ciy255

The COVID-19 pandemic further stressed hospital budgets, diverting resources from stewardship programs despite the unprecedented need for stewardship to manage high levels of antibiotic use among hospitalized patients with COVID-19.[32] In many hospitals, stewardship teams led the complex administration of COVID-19 therapeutics, which was an appropriate use of limited human capital resources given their expertise. This work included evaluating treatments for COVID-19 in clinical trials, developing treatment guidelines and educating providers as data rapidly evolved, partnering with state and local health departments, assessing patient risk factors to prioritize limited quantities of therapeutics, and devising innovative strategies to reach rural and other underserved populations. These efforts were crucial to reducing COVID-19 hospitalizations and deaths, but came at the expense of traditional antimicrobial stewardship.

Outpatient antibiotic prescribing decreased overall during the COVID-19 pandemic, but prescribing rates still vary widely across the U.S., with some states in the South having prescribing rates more than double the rates in states in other regions.[33] However, antibiotics were frequently prescribed for COVID-19, despite the fact that antibiotics are not effective against viruses. A study published in the *Journal of the American Medical Association (JAMA)* reported that among Medicare beneficiaries who had an outpatient visit for COVID-19 in the first year of the pandemic, more than 30% received an antibiotic.[34] Prior to the pandemic, CDC estimated that at least 30% of antibiotic prescriptions in outpatient settings are unnecessary, and total inappropriate antibiotic use may be as much as 50% of all outpatient antibiotic use.[35] Additional resources are needed to support implementation of stewardship in outpatient settings.

AMR Surveillance and Data Collection

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[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7375214/

[33] https://www.cdc.gov/antibiotic-use/stewardship-report/current.html

[34] https://jamanetwork.com/journals/jama/fullarticle/2791077

[35] https://www.cdc.gov/antibiotic-use/data/outpatient-prescribing/index.html

We need to understand where resistance is happening and how antimicrobials are being used to best target prevention and treatment strategies. The CDC National Healthcare Safety Network (NHSN) includes the Antibiotic Use and Resistance (AUR) module, which collects and provides actionable data to inform and evaluate efforts to optimize antibiotic use. More than 2,400 acute care hospitals across the United States had submitted at least one month of antibiotic use data as of August 2022. Of those hospitals, 2,283 reported in the past 12 months (July 2021 – June 2022). This represents a significant increase in reporting in the last several years, but gaps in data persist and more comprehensive reporting will better inform the current state of AMR in the U.S.

CMS included a requirement for antibiotic use and resistance reporting in their fiscal year 2023 Inpatient Prospective Payment System final rule. IDSA supports this requirement, which will help ensure that antibiotic stewards, clinicians and key decision-makers have access to more comprehensive antibiotic use data, enabling us to track antibiotic use and resistance over time, evaluate stewardship interventions, identify best practices and improve antibiotic use. It is critical that health care facilities not yet reporting antibiotic use and resistance data be provided resources necessary to begin reporting. It is also critical to provide CDC with resources necessary to support NHSN users, analyze and share data, and promote health professional education and appropriate antibiotic use.

Workforce Needed to Combat Antimicrobial Resistance

The ID workforce that is needed to respond to AMR is in crisis. ID physicians and other ID health care and public health professionals are needed to care for patients with resistant infections, lead antimicrobial stewardship and infection prevention and control activities, and conduct surveillance and research, including clinical trials. For patients with serious infections, including those caused by resistant pathogens, ID physician care improves outcomes, decreases mortality, shortens hospital stays, and lowers health care costs.[36,37]

Workforce shortages coupled with lower pay and a lack of financial incentives for recruitment and retention persist among ID health care professionals, including ID physicians, clinical microbiologists, nurses, pharmacists, physician assistants and infection preventionists. In 2022, nearly 80% of U.S. counties lacked an ID physician,[38] and only 56% of ID physician training programs filled their positions for the 2023 appointment year, compared to most other physician specialties for which nearly all of their programs filled their positions.[39] A quarter of health care facilities have reported a vacant infection preventionist position and a 2019 survey showed a vacancy rate for clinical microbiologists of more than 10%. Communities without ID health care professionals are less equipped to respond to AMR.

IDSA has conducted extensive outreach and mentoring to medical students and residents, and we routinely find high levels of interest in the field of ID, but financial challenges consistently pose barriers to recruitment. ID physicians are among the lowest paid medical specialists, earning even less than general internal medicine physicians who lack the additional years of training that an ID physician undergoes.[40] High levels of student debt often understandably drive physicians to higher paying specialties, leaving our nation without enough experts to combat AMR. Without action to recruit, train and retain the next generation of ID specialists, we can expect to see an increase in mortality due to infectious diseases for years to come.

Solutions

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[36] https://academic.oup.com/jid/article/216/suppl_5/S588/4160394
[37] https://academic.oup.com/cid/article/58/1/22/372657
[38] https://www.acpjournals.org/doi/10.7326/m20-2684
[39] https://www.nrmp.org/wp-content/uploads/2023/04/2023-SMS-Results-and-Data-Book.pdf
[40] https://www.medscape.com/slideshow/2022-compensation-overview-6015043?icd=login_success_email_match_norm

IDSA is grateful for the Energy & Commerce Committee's long history of leadership on AMR, including passage of the *Generating Antibiotic Incentives Now (GAIN) Act* in 2012 and enactment of the Limited Population Antibacterial Drug (LPAD) review mechanism in 2016 as part of the *21st Century Cures Act*, which helped improve the regulatory environment for the study and evaluation of new antibiotics and antifungals to address unmet needs in limited patient populations.

The National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) was launched in 2015 and provided an important framework for a coordinated, comprehensive federal response to AMR. The second iteration of the plan was released in 2020 and largely aims to build upon the progress made since 2015. The five goals of the plan, which IDSA supports, are: 1) slow the emergence of resistance and prevent resistant infections; 2) improve One Health surveillance; 3) advance development and use of diagnostics; 4) advance research and development of antibiotics, other therapeutics and vaccines; and 5) improve international collaboration. We greatly appreciate the leadership of Representatives Buddy Carter and Chellie Pingree in leading an annual letter urging Congress to provide sufficient funding to BARDA, CDC and NIAID to advance critical AMR efforts. These resources have supported improved surveillance, clinician education about AMR, research and innovation, and it is critical that funding for these efforts continues. In addition, the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) convenes key experts to provide a diverse array of perspectives, including frontline clinicians, to help inform federal AMR response activities. The PACCARB's recommendations have allowed federal efforts to benefit from a wide range of expertise, and the PACCARB should be reauthorized so this important work may continue.

It is also critical that we address gaps in existing efforts, specifically with regard to antimicrobial innovation, stewardship and the AMR workforce. The PACCARB released a March 2023 report, "Preparing for the Next Pandemic in the Era of Antimicrobial Resistance," and recommended urgently needed efforts to strengthen antimicrobial stewardship, infection prevention and control, the ID workforce, data sharing, and medical countermeasure innovation.[41]

PASTEUR Act

The bipartisan *PASTEUR Act* would have a transformative impact on antimicrobial innovation, revitalizing the discovery and development of truly novel antimicrobials by providing a predictable, reasonable return on investment for novel antimicrobials. The federal government already pays for antimicrobials through various health programs including Medicare, Medicaid, Tricare and Veterans Affairs (VA), but it pays in a way that fails to incentivize innovation and appropriate use. Conversely, *PASTEUR* is smart spending. **Under *PASTEUR*, the federal government would pay for the value rather than volume.** *PASTEUR* would allow the federal government to enter into contracts with antimicrobial developers to pay set fees for a steady supply of a novel antimicrobial.

Importantly, *PASTEUR* is designed to deliver truly novel antimicrobials that provide important clinical benefits for patients. To receive a contract under *PASTEUR*, antimicrobials must meet certain characteristics, including "improving clinical outcomes for patients with multi-drug-resistant infections." Additional characteristics include treating an infection for which there is unmet need, being a new class of antibiotic, having a novel target or novel mechanism of action, or having an improved route of administration, such as oral. The more characteristics the drug meets, the higher the value its contract can be. An interagency committee, advised by non-government experts, will develop a list of infections for which new antimicrobial drugs are needed and regulations regarding the drug characteristics and how the characteristics will adjust the monetary value of a subscription contract.

PASTEUR would also support appropriate use of antimicrobials by providing urgently needed funds to hospitals and long-term care facilities to support their antimicrobial stewardship programs. Priority for these funds would be given to rural, critical access and safety net hospitals.

[41] https://www.hhs.gov/sites/default/files/paccarb-pandemic-preparedness-report.pdf

More than 200 organizations have called upon Congress to enact *PASTEUR* this year on any moving legislative vehicle, including reauthorization of the *Pandemic and All Hazards Preparedness Act (PAHPA)*.[42]

AMR Workforce Investments & Physician Reimbursement

In addition, Congress must take steps to ensure the availability of the expert ID workforce needed to combat AMR, including ID physicians, ID physician-scientists, clinical microbiologists, infection preventionists, pharmacists and nurses. We must make ID a financially feasible choice for health care professionals by addressing student debt, improving reimbursement, and providing sufficient resources for training and early career development. Specific recommendations include:

- Fund implementation of the Public Health Loan Repayment Program and the Bio-Preparedness Workforce Pilot Program to incentivize individuals to pursue careers in public health and ID in shortage areas. IDSA greatly appreciates that Representatives Crow, Burgess, Trahan, Miller-Meeks and Fitzpatrick led a letter urging the Appropriations Committee to provide these needed resources.[43]
- Enhance Medicare reimbursement for ID physicians, through one or more of the following approaches: Increase the value of the codes most frequently billed by ID physicians (i.e., inpatient evaluation and management codes); provide a Medicare payment bonus for ID physicians (e.g., similar to the Medicare payment bonus for primary care physicians and general surgeons); and create new mechanisms to pay for critical population health activities to combat AMR that benefit the general patient population, but are not necessarily directly tied to the care

[42] https://www.pewtrusts.org/-/media/assets/2023/03/pasteur-stakeholder-support-letter-2023-committee-on-energy-and-commerce.pdf
[43] https://www.idsociety.org/globalassets/idsa/policy--advocacy/federal-funding/fy24-public-health-loan-repayment-and-bio-preparedness-pilot-program-house-appropriations-letter.pdf

of an individual patient (e.g., leading stewardship programs, infection prevention and control programs and outpatient parenteral antimicrobial therapy or OPAT programs).

- Increase NIAID funding to support training and early career ID and AMR researchers.

Once again, on behalf of IDSA, thank you very much for your attention to the critical issue of antimicrobial resistance and for inviting me to testify. We look forward to working with you and your colleagues to advance the solutions necessary to confront the AMR crisis, protect modern medical gains and save lives.