June 6, 2018

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

The undersigned organizations, representing healthcare providers, public health experts, and consumers are committed to advancing public health, including through supporting research and development (R&D) to respond to global threat of antimicrobial resistance (AMR). We are encouraged by the attention given to AMR by members of the Energy and Commerce Committee in the Health Subcommittee's June 6th hearing, 'Examining Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).' We welcome the discussion on the need for incentives to promote development of new antibiotics.

We write to urge you to ensure that any incentives introduced through PAHPA or any other initiatives prioritize public health needs. Incentives should promote added therapeutic value and come with conditions to ensure appropriate needs-driven R&D and affordable access for people in the U.S. and globally. The REVAMP Act under consideration for inclusion in PAHPA does not meet these criteria and should be rejected.

New tools to combat AMR are urgently needed

AMR is a critical public health concern in America and globally. From war-wounded in Jordan to an ongoing outbreak of deadly multidrug-resistant tuberculosis (MDR-TB) in Minnesota, drug-resistant infections are everywhere, including infections that can only be treated with the very last lines of antibiotics; and everyday health care providers witness the lack of access to existing tools (from technology to human resources) that could help prevent infections in the first place. Members of Congress must consider a focus on drug-resistant tuberculosis (DR-TB), which accounted for more than one-third of all deaths caused AMR[1]. Each year, 23,000 Americans die due to antibiotic resistance[2] and in 2016, there were 674 cases of DR-TB domestically[3]. Although the U.S. sees less DR-TB cases compared to the rest of the world, treatment costs dramatically escalate with increasing resistance. The U.S. Centers for Disease Control and Prevention (CDC) estimates that a single case of MDR-TB costs $160,000 to treat, and upwards of $500,000 to treat extensively-drug resistant TB (XDR-TB) – much of this funding drawn from already scarce public health resources.[4]

[1] MSF. Open letter from MSF to the Meeting of the G20 Health Ministers (2017). Available from: http://www.msf.org/en/article/open-letter-msf-meeting-g20-health-ministers
[2] CDC. Antibiotic/antimicrobial resistance (2018). Available from: https://www.cdc.gov/drugresistance/index.html
[3] CDC. Trends in tuberculosis (2016). Available from: https://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm
[4] CDC. The costly burden of drug-resistant TB in the U.S. (2017). Available from: https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/costly-burden-dr-tb-508.pdf

For these reasons, comprehensive efforts are needed to bring forth new, affordable and effective tools necessary to combat AMR. This includes not only the development of new antibiotics, but also actively exploring the untapped potential in repurposing of old, forgotten and withdrawn antibiotics. We need to ensure that both existing and innovative drugs address the needs of all populations: for example, by ensuring oral and pediatric formulations, providing evidence for clinical practice on how antibiotics are used in combination, promoting new diagnostic and vaccine technologies, promoting sustainable implementation of new technologies within health programs and piloting and scaling improved antimicrobial use practices. New tools to combat AMR should be affordable for all who need them.

Incentives should reward needs-driven, affordable innovation to put people's health first

In 2016, all UN Member States, including the United States, recognized the urgent need for appropriate and affordable tools to combat the growing challenges of AMR.[5] The U.S. and other Member States committed to R&D efforts that are "needs-driven, evidence-based and guided by the principles of affordability, effectiveness, efficiency and equity" and acknowledged "the importance of delinking the cost of investment in research and development on antimicrobial resistance from the price and volume of sales (…) to facilitate equitable and affordable access." Any incentives introduced through PAHPA, or any other initiative, to promote the development of antibiotics, should be consistent with these international commitments. As such, they should come with appropriate conditions and safeguards to ensure therapeutic benefit and affordable access, and should facilitate collaboration, data sharing and pooling of IP rights, where appropriate. Incentives should delink the financing of R&D from the expectation of high prices or sales, and focus on delivering affordable therapeutic advances.

Incentives should not waste limited public resources or come at the expense of safe, appropriate, accessible products

Market entry rewards or other funding and incentives introduced *without* appropriate conditions to prioritize public health needs, focus on added therapeutic benefit, and ensure affordable access can easily leave us with high public costs and high prices on rewarded products, without necessarily addressing the most critical needs. High prices prevent equitable access by making medicines unaffordable for some, while profits driven by high sales volume would provide an incentive to maximize sales, undermining the ability of countries to implement adequate stewardship measures.

Other proposals have been made to incentivize development of antibiotics with the creation of transferable intellectual property (IP) incentives.[6] Transferable IP vouchers would extend the monopoly of other medical products through lengthening patent, data or market exclusivity, but would not ensure added therapeutic value or affordable access to antibiotics developed. Moreover, people in need of affordable access to the products on which these vouchers are applied would pay the price. The U.S. and countries around the world grapple with the growing challenge of unaffordable medicines. Delaying generic and biosimilar competition on other highly priced therapies diminishes people's access to medicines, causes financial hardship, and strains health program resources.

[5] United Nations. Draft political declaration of the high-level meeting of the General Assembly on antimicrobial resistance (2016). Available from: https://www.un.org/pga/71/wp-content/uploads/sites/40/2016/09/DGACM_GAEAD_ESCAB-AMR-Draft-Political-Declaration-1616108E.pdf

[6] For example: https://www.statnews.com/2018/04/11/innovation-new-antibiotics-fight-superbugs/; https://www.jnj.com/about-jnj/company-statements/antimicrobial-resistance-policy-statement; https://www.pfizer.com/files/about/Policy-Position-on-Antimicrobial-Resistance-8-17-17.pdf

Past U.S. efforts to promote development of antibiotics have focused on extending monopolies and altering clinical requirements for antibiotic drugs to be granted approval through the ADAPT and GAIN[7] Acts. These programs have not sufficed to provide the innovation that is needed to combat antimicrobial resistance. As you consider new incentives for AMR, we urge you not to introduce any new, additional or extended exclusivities or to lowering regulatory standards related to evaluating a product's safety and efficacy as an incentive to encourage R&D.

Congress can play a positive role in delivering the treatments and other tools needed to combat AMR globally

We urge Congress to reject the inclusion of incentives without appropriate conditions or transferable IP vouchers in PAHPA legislation or any other initiatives, including by rejecting the REVAMP Act. Rather, we strongly recommend the Committee consider alternative incentives that both catalyze the R&D needed to fill the gap on new treatments and tools to combat AMR, while actively prioritizing affordable access to these new lifesaving innovations downstream for communities hardest-hit by AMR and in desperate need. Strategies such as prize incentives can be designed to strategically seed innovative development for affordable tools to address AMR along the clinical trial pipeline through market entry – and can appropriately reward the costs and risks of innovation.

Thank you for your consideration. We would welcome the opportunity for further discussion on these issues and alternative proposals to catalyze need R&D to combat AMR.

Sincerely,

Doctors Without Borders/Médecins Sans Frontières USA

National Physicians Alliance

People of Faith for Access to Medicines

Public Citizen

Treatment Action Group

Cc: Members of the House Committee on Energy and Commerce

[7] Deak D, Outterson K, Powers JH, Kesselheim AS. Progress in the Fight Against Multidrug-Resistant Bacteria? A Review of U.S. Food and Drug Administration–Approved Antibiotics, 2010–2015. Ann Intern Med. 2016;165:363–372. doi: 10.7326/M16-0291