



Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

DRAFT FOR DELIBERATION – NOT A FINAL COUNCIL PRODUCT

[DATE]

The Honorable Xavier Becerra
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra,

On behalf of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), we bring to you the following recommendation in support of proposed legislation that would greatly improve our ability to combat antimicrobial resistance (AMR). Antimicrobial resistance is a major global threat that sickens or kills millions each year. Defeating AMR is a matter not only of public health significance but also of global health security because effective antimicrobials are necessary to stop the spread of diseases around the world. Without effective antimicrobial therapy, virtually all aspects of medical care would be impacted, including the ability to care for those undergoing cancer chemotherapy, solid organ transplantation, and other surgical procedures, those in intensive care, as well as premature babies. The availability of effective antimicrobials is a crucial part of our nation's pandemic preparedness, as demonstrated by the need to treat secondary bacterial and fungal infections in COVID-19 patients; indeed, the next global pandemic may be an illness due to a resistant bacteria or fungus.

However, we continue to face a critical deficit in our battle against AMR—a severe lack of new antimicrobial drugs. As resistance emerges and spreads, our options for treatment of severe infections get fewer, and we need new products that can treat infections where others fail. The time to develop these new drugs is now as the pipeline remains inadequate to address current resistant threats. However, private industry is no longer sufficiently investing in developing new antimicrobial drugs because the costs of drug development far outpace the revenues companies can receive from sales, and several small companies with newly FDA-approved antimicrobial drugs have filed for bankruptcy. The cause of this failing pipeline of new antimicrobial drugs is multifaceted, and factors that impact it include how our current payment system and antibiotic prescribing guidelines generally encourage clinicians and hospitals to avoid use of newer, more expensive antimicrobials in favor of less costly older agents when the effectiveness of the therapies is equivalent—which results in lower antibiotic usage and thus lower revenue for newly developed agents.

Two bills introduced into Congress seek to address these root causes—the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act and the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act. Both of these bills are supported by industry, physicians, pharmacists, and patient advocacy organizations as demonstrated by endorsements from the Biotechnology Innovation Organization, Infectious Diseases Society of America, and others.

The PACCARB strongly supports the passage of both DISARM and PASTEUR and the antimicrobial stewardship provisions within. The DISARM Act would modify the hospital payment system to incentivize the use of newer, more expensive antimicrobial drugs in those patient encounters that are appropriate. In the diagnosis-related group (DRG) payment system, hospitals receive a flat payment for treatment of a condition regardless of the costs incurred, leading to selection of the least expensive treatment options. DISARM would provide payment outside of the DRG for use of certain antimicrobial drugs, providing hospitals with the financial freedom to select newer drugs *when appropriate*, and thereby enabling appropriate patient access. To complement this approach, the

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PASTEUR Act would remedy the reduced revenue realized as a result of appropriate and much needed antibiotic stewardship efforts by creating a subscription payment model for new antimicrobial drugs. Under this model, the U.S. Government enters into a purchasing contract that delinks payment from sales volumes, thereby significantly reducing the risk to companies wishing to develop new antimicrobials that fulfill critical needs while still ensuring appropriate use that preserves these new agents for the future. Crucially, the minimum contract size (\$750 million) is sufficiently large to provide a real incentive to change research investment decisions.

Further, the PACCARB firmly believes that the stewardship incentives included in both bills are essential to their success and must be maintained, lest we add more antimicrobials to the market with no resources to ensure their responsible use. To receive DISARM payments, hospitals are required to participate in antimicrobial use and resistance reporting and have antimicrobial stewardship programs, and both DISARM and PASTEUR include creation of grants to support such activities. The details of the stewardship grant programs need to be sufficiently flexible to allow for a variety of activities to include improved reporting, antimicrobial stewardship programs, and patient education. Providing incentives and resources for improved stewardship is crucial for these and any future efforts to support development of new antimicrobial drugs. Without proper stewardship, both current and newly developed antibiotics will rapidly lose utility, as has happened throughout the antibiotic era. Stewardship is the vigilance to protect our antibiotic armamentarium for future generations.

These two synergistic bills will also help achieve two critical goals of the National Action Plan (NAP) to Combat AMR that aim to enhance the development and use of new antimicrobials and encourage more effective stewardship programs; these constitute major efforts undertaken by several federal agencies under the NAP. In addition, the bills also help meet two other NAP goals – improving surveillance activities through better reporting of antimicrobial usage and ensuring future U.S. global leadership by creating and sharing new therapeutic options with other countries. Thus, the bills aid in the HHS commitment to achieve critical progress in nearly all of the NAP goals.

In closing, action on these or similar solutions is urgent to both spur and sustain investment in the pipeline of new antimicrobial drugs. Because of the lengthy development time for new drugs, the time to start is now. Otherwise, when we need the agents because of the rising tide of infections by resistant organisms, we will not have them. Having effective antimicrobial treatment options is also a critical component of pandemic preparedness and global health security. Other countries have recognized this need and already have passed similar legislation; notably, subscription models have been enacted in the United Kingdom and Sweden. The U.S. must act now to maintain our position as a global health leader and innovator and to invest in needed life-saving drugs and in their proper use for all Americans for the present and future.

Sincerely,

Martin J. Blaser, M.D.
Chair

Lonnie J. King, D.V.M., M.S.
Vice Chair

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