

June 25, 2021

Comments for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB)

Keep Antibiotics Working (KAW)¹ appreciates the opportunity to comment to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) and would like to provide the council with some of our concerns regarding efforts to address the threat of antibiotic resistance.

FDA Accountability: A One Health Approach, which recognizes the interconnection between the health of food animals and the health of people in a shared environment, is essential for tackling antibiotic resistance. The Food and Drug Administration (FDA) as the regulator of antibiotics used in animals must play an important role in addressing the urgent public health crisis of antibiotic resistance. However, its efforts to protect public health have been too limited and too slow. The FDA's major planned action to address antibiotic overuse on farms, which is a significant driver of antibiotic resistance, is to set duration limits for medically important antibiotics that currently do not have them. In 2016², the FDA requested public comments on setting duration limits for medically important antibiotics but then waited over 48 months until January 2021 to release a [Concept Paper outlining an approach](#). The concept paper fails to prioritize public health in determining how long drugs can be used in animals and sets an incredibly long timeline for action. The FDA has [indicated](#) that it does not anticipate a final rule until June 2024 and the Concept Paper then includes an implementation timeline of an additional 4 to 6 years. This establishes a potential completion of implementation in the year 2030, 14 years after the FDA first accepted comments on setting durations in 2016. The PACCARB must hold the FDA accountable to an expedited timeline for implementation and ensure all label changes are completed by the end of 2025.

Please also see the included letter to Secretary Xavier Becerra urging the action of the Department of Health and Human Services on three actions to slow the spread of antibiotic resistance.

¹ Formed in 2001, Keep Antibiotics Working is a coalition of 20 advocacy organizations that joined together to ensure that untreatable superbugs resulting from the overuse of antibiotics on farms do not reverse the medical advances of the past century.

² 81 Fed Reg. 63187 (September 14, 2016).