

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

Keep Antibiotics Working (KAW) appreciates the opportunity to comment to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). Our concerns regard the status of the National Strategy for Combating Antibiotic-Resistant Bacteria, as well as delays in other federal agency action in the effort to address the threat of antibiotic resistance. We urge the council to move away from creating lengthy documents that are never implemented and instead focus on making a limited number of concrete recommendations and then regularly following up with agencies to see what has been implemented.

National Strategy:

We would like to know what efforts have been made to update the National Strategy, issued September, 2014¹ which informed the 1st National Action Plan (NAP1)² and formation of PACCARB. In light of the COVID-19 pandemic, elements of the National Strategy should be revised in order to address pandemic preparedness and more specifically the threat of antimicrobial resistant secondary infections associated with viral pandemic pathogens.³ The spread of antimicrobial resistance either to antiviral drugs or to antibiotics used to treat secondary infections greatly limits our ability to respond to pandemics and creates additional strains on our health system.

Gaps in NAP1:

- Failed to start targets for reducing antibiotic use in animals. The first goal of NAP1 includes language to reduce inappropriate antibiotic use in outpatient and inpatient settings by 2020.⁴ However, there are no target goals for reducing antibiotic use in animals. KAW asks that PACCARB recommend that the 2nd National Action Plan (NAP2) be amended to include specific targets for reducing inappropriate antibiotic use in livestock and specifically research and define “inappropriate use” in an animal context.
- Failed to prohibit the continuous use of antibiotics in food animals. In 2013, FDA issued Guidance for Industry #213⁵, which calls for “explicitly defined duration of dosing” on new drug label indications because “giving antimicrobial drugs to food-producing animals at low levels for long periods of time and in large numbers of animals may contribute to antibiotic resistance.” KAW asks that PACCARB ask FDA to move forward and require sufficiently short durations consistent with existing FDA guidelines. If a drug maker would like a duration longer than 21 days it should provide new evidence that the drug is needed for that long and that it is safe with respect to antibiotic resistance.
- Failed to consider antibiotic use in crops.

Federal Agency Accountability: KAW asks that PACCARB make inquiries to federal agencies, including FDA and USDA, to determine the basis for delays in both releasing national reports and reporting data collection from ongoing studies.

- FDA’s Center for Veterinary Medicine (CVM) has yet to release its comprehensive report which will “integrate and analyze available information about antimicrobial use and resistance in animal agriculture to assess progress of efforts to foster antimicrobial stewardship and antimicrobial resistance.”⁶
- In 2017, CVM sought comment on a proposed methodology for applying a biomass denominator to annual data on approved or conditionally approved antimicrobial drugs sold or distributed for use in food-producing animals. However, the adjusted biomass data has not been released.
- CVM is also very behind on updating NARMS. The most recent integrated report and summary is the 2016-2017 report.⁷
- Previously, PACCARB has received presentations from researchers collecting detailed voluntary antimicrobial use data in cattle and in swine under two FDA-funded cooperative agreements that started in 2016.⁸ Since 2016, there has been no public release of these data sets or an analysis of them.
- More generally it would be helpful for PACCARB as part of its mission to advise on CARB related policies to evaluate where there have been delays in reporting on PACCARB related activities. As part of this, PACCARB should not passively accept very long timelines set by agencies for CARB related activities.
- CDC and HHS must more fully monitor and address antimicrobial use and resistance related to the COVID-19 pandemic. Please see our [most recent letter](#) for more details.

¹ https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf

² https://obamawhitehouse.archives.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf

³ <https://static1.squarespace.com/static/5519650ce4b01b71131cb5f9/t/5f0e58c9c48dba1593cfd44f/1594775807336/KAW+Response+to+Pandemic+Preparedness+White+Paper+June2020>

⁴ https://obamawhitehouse.archives.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf

⁵ <https://www.fda.gov/media/83488/download>

⁶ <https://www.fda.gov/files/animal%20&%20veterinary/published/Supporting-Antimicrobial-Stewardship-in-Veterinary-Settings-Goals-for-Fiscal-Years-2019-2023.pdf>

⁷ <https://www.fda.gov/animal-veterinary/national-antimicrobial-resistance-monitoring-system/integrated-reportssummaries>

⁸ “NIAA White Paper 2018 Antibiotic Symposium.Pdf.” Accessed February 4, 2020.

https://animalagriculture.org/resources/Documents/White_Papers/White%20Papers/NIAA_White_Paper_2018_Antibiotic%20Symposium.pdf.

Affairs, Office of Regulatory. “Grants and Cooperative Agreements.” FDA, November 8, 2019. <http://www.fda.gov/federal-state-local-tribal-and-territorial-officials/funding-opportunities/grants-and-cooperative-agreements>.