

The FDA's Long History of Delay in Combating Antibiotic-Resistant Bacteria

The recent independent expert panel review of the Food and Drug Administration's (FDA's) Human Foods Program¹ found “a culture of indecisiveness and inaction” within the FDA, where “decision-making is unacceptably slow” appearing “sluggish and non-responsive to public health concerns” and suffering from “an aversion to risk that undercuts its public health mandate.” While these criticisms were directed at the broader food program they also apply, as illustrated below, to the FDA's response to the urgent antibiotic resistance crisis.

40 Years of Delayed Public Health Action

- **40-year delay** to end some of the uses of penicillins and tetracyclines for growth promotion and prevention in 2017, after the FDA determined in 1977 that these uses created an unacceptable risk to public health.
- **22-year delay**, so far, in developing a system to monitor antibiotic use in agriculture after the Interagency Task Force on Antimicrobial Resistance, co-chaired by the FDA, in 2001 included monitoring antibiotic use as a top priority.
- **20-year delay**, so far, in updating the ranking of antibiotics by medical importance since first creating the ranking in 2003.
- **5-year delay** to withdraw approval of fluoroquinolone antibiotic use in poultry in 2005 after the FDA determined in 2000 that the Agency had made a mistake in approving fluoroquinolones for use in poultry in 1997.
- **5-year delay** before beginning the relatively simple task of adjusting sales of antibiotics for use in food animals by the animal biomass in 2022 after taking comment on the adopted method in 2017.

More Delays, Plus Critical Gaps: The FDA's 5-year Veterinary Antimicrobial Stewardship Plan, 2018-2023

Critical Gap - No indicators. In 2018, the FDA published a five-year plan to address antibiotic resistance. The plan set out the FDA's “blueprint for guiding its activities over the next five years to combat antimicrobial resistance and preserve the effectiveness of antimicrobial drugs”. Yet it includes no indicators to measure success beyond completion of planned activities.

Critical Gap - No commitment to a follow-up stewardship plan. The five-year plan ends this year with numerous tasks undone. But the FDA has not committed to create and implement another plan to continue the unfinished work or tackle key stewardship goals, not listed in its first plan.

4-year delay. During the **first four years** of the plan, no significant steps were fully implemented, and sales of medically important antibiotics for use in food animals rose by 8%. The action closest to full implementation is the requirement for the small number of medically important antibiotics (accounting for 3% of sales) currently marketed without a prescription to require a prescription starting on June 11, 2023.

6-year delay, so far. The FDA is not on track to issue a final guidance to add durations to medically important antibiotics that do not have them as it has not yet issued even a draft guidance, despite taking initial public comments on this topic in 2016. The plan included a 2023 target for a final guidance, but not even a draft guidance has been published.

¹ Independent Expert Panel for Foods. “Operational Evaluation Of The FDA Human Foods Program.” Reagan-Udall Foundation. December 2022. Accessed March 16, 2023. <https://reaganudall.org/operational-evaluation-fdas-human-foods-programs>.