

April 17, 2023

RE: 2023 reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

We appreciate the opportunity to comment on the 2023 reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

New infectious diseases caused by viruses or bacteria constantly emerge and spread across the world, posing a deadly threat to human and animal health. Of those new threats, 3 out of every 4 emerge from animals before crossing over into humans; in recent years, these have included not only COVID-19, but also Monkeypox, Ebola, H1N1 swine flu, and SARS. Because dangerous new diseases originate in animals more often than not, the federal efforts that fall under PAHPA simply must follow a One Health approach to be effective. One Health is the commonly used term to describe an approach that recognizes this reality and therefore integrates public health activities across human, animal, and environmental domains.

Unfortunately, most U.S. efforts to date to improve pandemic preparedness have NOT included significant funding and actions that reflect the commonplace transfer of pathogens between animals and people, and address that likelihood. The [National Health Security Strategy 2019–2022](#), for example, acknowledges the importance of promoting a One Health approach to early warning detection and diagnosis but fails to include actions to carry out such an approach. Congress should not make the same mistake in reauthorizing PAHPA. ***PAHPA reauthorization must include a much more robust effort to make sure that the environment and animals, especially food-producing animals, are fully integrated into federal pandemic and health preparedness funding and activities.***

SPECIFIC RECOMMENDATIONS

In adopting a One Health approach to pandemic preparedness, Congress must include action to address the on-going crisis of antimicrobial resistance that is rendering essential drugs ineffective and thus ending millions of lives each year around the world. As Congress considers strengthening the nation's preparedness, we must optimize the integration of pandemic readiness with combating antimicrobial resistance using a One Health framework. We recommend PAHPA include the following:

1) Strengthen Biosurveillance Systems to Quickly Identify New and Emerging Infections

The nation's ability to quickly identify novel pathogens spreading through our food production system suffers from a significant gap. There was a recent failure to detect the spread of *Salmonella Infantis* in poultry before it became industry-wide, for example, which subsequently led to a significant outbreak of human infections. Similarly, highly pathogenic avian influenza is spreading currently, with frequent transfers between food animals and wildlife. No system is in place to identify where it will occur next, or to adequately control its spread. What the nation urgently needs is robust surveillance for early detection of pathogens appearing where food animals are being raised as well as in wildlife. A national system for surveillance of zoonotic pathogens of course must include monitoring for pathogenic

bacteria, as well as viruses; it should monitor for antibiotic-resistant pathogens, in addition to viral pathogens, and include monitoring in animals as well as the environment. Congress should provide public health officials the authority to access farms for disease monitoring and investigation, including data gathering. These crucial data on infections must then be analyzed and reported in a transparent manner that utilizes a One Health approach.

2) **Set Bold, Comprehensive Targets Across Sectors and Gather Data to Measure Progress**

Establish national targets and timelines for antibiotic use reductions in human medicine and in food animal production, as was recommended by both the [Government Accountability Office](#) and a [commission](#) of independent experts in 2017. Robust data will be needed to track progress toward these targets. All hospitals will be required to submit use and resistance data to the CDC through the National Healthcare Safety Network starting in 2024. No similar system exists for reporting antibiotic use in food animal production, even though nearly twice as many medically important antibiotics are used in that industry as are used in human health care. The creation of a system to monitor antibiotic use in food animals has been an FDA priority since 2001, but it still hasn't happened. Monitoring of antibiotic use in food animals should include the collection of antibiotic use data from feed distributors, who provide nearly two-thirds of the antibiotics given to food-producing animals. All distributors of medicated feeds containing a medically important antibiotic should be required to submit all veterinary feed directive orders electronically to the FDA on an annual basis along with associated feed distribution records. Current regulations require feed distributors to maintain these records and make them available to the FDA on inspection, but the FDA hasn't consistently gathered or reported on them.

3) **Strengthen Antimicrobial Stewardship**

As recommended in the [report](#) adopted by the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria at the March 24, 2023 meeting, the government's pandemic preparedness policies must be updated to include "Infection Prevention and Control and Antimicrobial Stewardship." In 2018, the FDA issued its [first 5-year action plan around veterinary antibiotic stewardship](#), a plan which expires by September 2023. There is, however, no mandate for the FDA agency to continue issuing stewardship plans. Congress should require FDA to issue a new stewardship action plan by the end of this year, and every five years thereafter to coincide with PAHPA reauthorization. Doing so would ensure there is no lapse in FDA veterinary antimicrobial stewardship efforts. In addition, Congress should require the following to be included in the new plan:

a) Any priority actions from FDA's previous action plan which were never completed should be completed in the first two years. In particular, FDA must issue a final duration limits guidance document before the end of 2025.

b) An accompanying timetable to reflect congressional intent that all FDA-approved antibiotic products will carry labels with clearly defined duration limits by the end of 2028, the next time PAHPA is expected to be reauthorized. (The FDA has long recognized that animal feed antibiotics prescribed and used with excessive or no duration limits would violate FDA definitions of judicious use and be inconsistent with good stewardship. However, one-in-three medically important antibiotics currently carry labels allowing this type of use.)

4) **Equity**

Pandemic disease threats, including both antibiotic resistance and COVID-19, disproportionately impact socioeconomically vulnerable populations and communities of color. Therefore, all of the aforementioned topics relating to pandemic preparedness and antibiotic stewardship must be addressed through the lens of equity and diversity. We need to ensure equity intersects with combating resistance and ensure the entire United States public is being adequately protected from these threats.

5) **FDA legislative proposals**

The FDA included [multiple legislative proposals](#) as part of its FY 2024 budget request to Congress. IWe urge that two of them would make sense as part of Congress' 2023 reauthorization of PAHPA, because each of them would expand the availability of additional tools needed to help address coming pandemics. They are:

- a) "Expansion of FDA Tools to Provide Oversight of FDA-Regulated Products"; and
- b) "Enhance Authorities Regarding Postmarket Safety of Animal Drugs."