Coalition to Stop Flu Public Statement on Highly Pathogenic Avian Influenza Outbreak

May 22, 2024

The Coalition to Stop Flu is actively monitoring developments related to the H5N1 highly pathogenic avian influenza (HPAI) outbreak in domestic cattle and other animals, including the concerning news today of a second human case linked to dairy cows. Our members – which include organizations representing public health and patient advocates, scientists and researchers, health care professionals, emerging biotech companies, health care distributors, and vaccine, antiviral, and diagnostic manufacturers – are appreciative of the rapid federal response and remain hopeful that the virus will not shift to become more transmissible in humans.

Influenza has caused four globalized pandemics in the past century, in 1918, 1957, 1968, and 2009. We will face another influenza pandemic, whether from this H5N1 strain or a future strain. We are optimistic that the past fifteen years of U.S. government investment in pandemic influenza preparedness and response puts the country in a much better position to prevent, prepare for, and respond to the virus. However, more must be done.

In light of emerging data on the breadth of the H5N1 outbreak in domestic cattle, the Coalition urges federal decisionmakers to consider the following recommendations:

- **Interagency Cooperation.** H5N1 is a select agent with pandemic potential that has been the focus of pandemic preparedness by the United States and international partners for more than two decades. Multiple agencies, including the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Administration for Strategic Preparedness and Response (ASPR), and the Centers for Disease Control and Prevention (CDC), share elements of the current response. The new White House Office of Pandemic Preparedness and Response Policy (OPPR) is playing an important interagency coordinating role.
  - **Recommendations:**
    - The Coalition applauds the robust interagency cooperation mechanisms that the Administration has stood up in recent weeks. The Coalition urges the Administration to publicly memorialize these coordination mechanisms and each agency’s role in the current response for the benefit of Congress, public and private stakeholders, and future response efforts.
    - This complex interagency response requires centralized oversight from the White House. OPPR’s role is critical, but its statutory authority and responsibilities are evolving and untested. The Coalition urges the Office to provide periodic updates to Congress and external stakeholders and promptly relay any shortcomings in its ability to coordinate the interagency response.
    - The Coalition urges OPPR to identify areas for improvement and opportunities to further break down silos in the response and to provide a mechanism for feedback from the responding agencies.
• **Risk Assessment.** The responding federal agencies have repeatedly affirmed that the current risk to humans is low.
  ○ *Recommendations:* The Coalition recommends that the responding agencies provide additional transparency into the triggers that would cause reevaluation of this risk assessment and the steps that will be taken should this occur.

• **Data Collection and Surveillance.** Surveillance and testing of farm workers presents numerous, well-documented challenges, including a lack of relevant federal authority. As such, CDC is currently leveraging existing influenza surveillance networks to look for additional human cases. However, if patients do not develop respiratory disease or seek medical care, these networks will not capture their infections. Surveillance of infected animals also remains far below the rates needed to accurately assess the scope of the outbreak and contain further spread.
  ○ *Recommendations:*
    - The Coalition urges CDC to formulate recommendations for human health surveillance necessary to capture potential additional human cases, including potential mechanisms like financial incentives. These recommendations should include surveys of at-risk asymptomatic groups, including dairy farm workers and others that interface with these farms or their animals.
    - The Coalition urges CDC to promptly inform Congress and external stakeholders of these surveillance recommendations, identified obstacles, and the risks if this surveillance is not conducted.
    - The Coalition also urges USDA to develop mechanisms to increase testing and surveillance of dairy cattle, including of asymptomatic animals, to better detect cases and control disease spread. Controlling disease in animals also protects human health.
    - The Coalition appreciates the recent launch of a USDA program to financially incentivize farmers to increase testing and biosecurity practices and compensate for the risk to human health. However, the Coalition urges USDA to establish goals for its surveillance program, including the farm participation rates necessary to accurately evaluate the epidemiology of the outbreak. We urge USDA to provide updates to Congress and external stakeholders on its progress toward these goals and to develop additional mechanisms to achieve these goals should existing programs prove insufficient.
    - The Coalition urges transparency across federal surveillance, including prompt publication of sequences or serological findings on relevant databases, accompanied by sampling dates and locations.
    - The Coalition applauds CDC’s recent release of an influenza A wastewater dashboard and encourages further analysis of the utility of this surveillance mechanism.

• **Antivirals.** While the Coalition applauds the federal government for stockpiling doses of oseltamivir (Tamiflu) in the Strategic National Stockpile (SNS) and facilitating doses in state stockpiles, we are concerned that all oseltamivir doses in the SNS are all at least 15 years old. Additionally, while only a small percentage of sequenced samples in the
current outbreak show potential resistance to oseltamivir, the development of resistance could dramatically shift the outcome of a human pandemic.

○ **Recommendations:**
  - The Coalition urges the Administration and Congress to prioritize replenishing and diversifying the current antiviral stockpile.
  - The Coalition also encourages the Administration to facilitate the availability of doses to state health departments.
  - Additionally, the Coalition recommends that the Administration consider ways to provide access to prophylactic antiviral doses to farms, as well as the establishment of test-to-treat initiatives in occupational health settings should additional human cases emerge.

● **Vaccination.** Flu vaccination rates remain well below national goals, and are substantially behind pre-pandemic rates for vulnerable populations like children and pregnant people. Mis- and disinformation, declining public trust, access and coverage challenges, and vaccine fatigue all play a role in these declining rates.

  ○ **Recommendation:**
    - The Coalition encourages the Administration, CDC, and other agencies to ensure clear public messaging about potential H5N1 vaccination and how it differs from traditional seasonal flu vaccines. Given the continued efforts to combat vaccine hesitancy and the decline in seasonal flu vaccine coverage rates across all age groups, with emphasis on communities of color and rural communities, the Coalition urges the Administration and CDC to begin planning communication strategies and effective messaging well ahead of the 2024-2025 seasonal flu vaccination season.
    - The Coalition also encourages Congress to prioritize and support expanding immunization infrastructure funding to ensure our public health system is ready to respond to H5N1 without compromising routine immunization efforts.

● **Stockpile Deployment.** Due to long-term preparedness investments from Congress, the U.S. has a small stockpile of “pre-pandemic” influenza vaccine through ASPR. In addition to antivirals, the SNS also holds some personal protective equipment, such as goggles, face shields, gowns, and masks.

  ○ **Recommendations:**
    - The Coalition recommends that ASPR provide additional information to Congress and public and private stakeholders on any obstacles to quickly deploying these assets and whether there are anticipated shortfalls in the event of a local outbreak.

● **Legislative Action.** The Coalition urges Congress to consider long-overdue legislative action to modernize the federal programs responsible for seasonal and pandemic influenza preparedness and response.
○ **Recommendations:**
  - The Coalition urges Congress to consider The Influenza Act (H.R. 5846/S. 3219), introduced by Rep. Larsen (D-WA) and Sen. Baldwin (D-WI), which presents a critical starting point in this effort.
  - The Coalition also urges Congress to complete its reauthorization of the Pandemics and All-Hazards Preparedness Act.

- **Funding.** Funding levels for the responding agencies remain well below the assessed need. For example, prior to this H5N1 outbreak, the interagency body responsible for defining requirements for medical countermeasures (the Public Health Emergency Medical Countermeasures Enterprise) called for $1.2 billion in funding for pandemic influenza at ASPR for 2025. The current funding level is $335 million. Additionally, Congress recently rescinded remaining Covid-19 pandemic preparedness funding that could have been used for this response.
  - **Recommendations:**
    - Congress should be prepared to consider additional funding for the responding agencies if needed, and we urge USDA, CDC, and ASPR to begin making budgetary assessments for different scenarios and sharing these with key Congressional stakeholders.
    - Congress should also fully fund the National Influenza Vaccine Modernization Strategy, which outlines a vision for the United States’ influenza vaccine enterprise to be highly responsive, flexible, resilient, scalable, and more effective at reducing the impact of seasonal and pandemic influenza viruses.

- **Congressional Oversight.** Multiple congressional committees share oversight authority for agencies involved in the federal response. The fact that this response involves both animal and human health presents complications and heightens the need for appropriate oversight.
  - **Recommendations:**
    - The Coalition urges Congress to exercise oversight over the response, with a particular focus on the interagency cooperation, roles, and responsibilities. Importantly, this oversight must be cross-cutting and not itself siloed based on Committee jurisdiction.
    - Multiple committees – including some that have not historically engaged on infectious disease issues – have a role to play. These committees should prioritize investigations and hearings on this issue before it potentially reaches a public health emergency stage.

The Coalition applauds federal policymakers for responding to the evolving H5N1 outbreak rapidly and with full recognition of the potential threat to human lives. We urge the Administration, agencies, and Congress to consider the recommendations above, and look forward to our continued partnership to end the threat of seasonal and pandemic influenza.
About the Coalition to Stop Flu

The Coalition to Stop Flu is a multi-sector advocacy coalition dedicated to ending deaths from seasonal and pandemic influenza. The Coalition’s federal policy agenda is aimed at saving lives, saving money, and protecting public health by enhancing the U.S. influenza ecosystem, including ensuring adequate funding for priority influenza programs. The Coalition’s members include Alvogen; the American Heart Association; the American Society for Microbiology; the Association of Immunization Managers; the Association of Public Health Laboratories; the Association of State and Territorial Health Officials; the Asthma and Allergy Foundation of America; CSL Seqirus; Eradivir; Families Fighting Flu; Genentech; GSK; the Global Health Investment Corporation; the Healthcare Distribution Alliance; IDBiologics; Immunize.org; the Infectious Diseases Society of America; Inovio; the National Association of City and County Health Officials; the National Foundation for Infectious Diseases; Pfizer; Sanofi; Trust for America’s Health; and Vaccinate Your Family.

###