



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration of Emergency Pursuant to the Federal Food, Drug and Cosmetic Act

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of amendment.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On July 18, 2024, the Secretary amended the April 19, 2013, determination made pursuant to the FD&C Act, regarding the avian influenza A (H79N) virus, and determined pursuant to his authority under the Act that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves biological agents, namely pandemic influenza A viruses and influenza A viruses with pandemic potential.

DATES: The section 564(b)(1)(C) determination that was originally issued on April 19, 2013, is amended as of July 18, 2024.

FOR FURTHER INFORMATION CONTACT: Dawn O'Connell, Administrator and Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 and 564A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the U.S. Department of Health and Human Services (HHS) has the ability to take certain steps to help facilitate the availability of medical countermeasures after one of four determinations under section 564(b) is made: (1) a determination by the Secretary of Homeland Security that there is a

domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a chemical, biological, radiological, or nuclear (“CBRN”) agent or agents; (2) the identification of a material threat by the Secretary of the Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a CBRN agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary [of HHS] that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

After any of these four determinations is made, if other applicable statutory criteria are met, HHS may take actions under section 564A of the FD&C Act to help facilitate the availability of certain medical countermeasures. For example, under section 564A(e), the Director of the Centers for Disease Control and Prevention (CDC) may create and issue Emergency Use Instructions to inform health care providers or individuals about the approved, licensed, or cleared conditions of use of “eligible” medical countermeasures (i.e., “eligible products” as defined in section 564A(a)(1) of the FD&C Act). As another example, under section 564A(b), the U.S. Food and Drug Administration (FDA) may extend the expiration date of eligible medical countermeasures. Based on any of these four determinations, the Secretary of HHS may also declare that circumstances exist that justify an Emergency Use Authorization (EUA), at which point the FDA may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2)

an unapproved use of an approved drug, approved or cleared device, or licensed biological product, if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The Administration for Strategic Preparedness and Response (ASPR) requested that the Secretary amend the April 19, 2013, determination made pursuant to section 564 of the FD&C Act, regarding the avian influenza A (H7N9) virus, to apply generally to pandemic influenza A viruses and influenza A viruses with pandemic potential. As described below, broadening the April 19, 2013, determination to apply to pandemic influenza A viruses and influenza A viruses with pandemic potential—rather than just H7N9 specifically—would appropriately cover the range of known and emerging influenza A viruses that present a significant potential for a public health emergency.

II. Determination by the Secretary of Health and Human Services

On April 19, 2013, pursuant to section 564(b)(1)(C) of the FD&C Act, former Secretary Sebelius determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the avian influenza A (H7N9) virus.

I have determined that the 2013 determination should be amended to cover a broader range of influenza A viruses, namely pandemic influenza A viruses and influenza A viruses with pandemic potential. For purposes of the amended determination, “pandemic influenza A viruses and viruses with pandemic potential” means animal viruses and/or human influenza A viruses circulating in wild birds, domestic animals and/or humans that cause or have significant potential to cause sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naive. Pandemic influenza A viruses and influenza A viruses with pandemic potential present a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens

living abroad because influenza A viruses that may initially be only occasionally transmitted to or between humans have the potential to become highly transmissible in humans and can cause significant morbidity and mortality. For example, the A/H1N1 influenza pandemic in 2009 was caused by a reassortant H1N1 that emerged from a combination of genes that had been present in various strains of swine, avian, and human influenza.

H7N9 is another example of an influenza A virus that presents a significant potential for a public health emergency and would be considered an influenza A virus with pandemic potential. H7N9 has demonstrated the ability to transmit from poultry to humans, causing two separate human case clusters involving over 400 people and resulting in over 100 fatalities from 2013 to 2014. While sustained human-to-human transmission was not seen, familial clusters could not be ruled out. Moreover, some patients treated for illness had treatment-emergent resistance, another concern for pandemic potential.

H5N1 is a third example. From 1997 through April 2024, over 50 percent of human cases of influenza A(H5N1) have been fatal. Although H5N1 is not easily transmissible in humans, it has demonstrated the ability to transmit from poultry to humans, and now likely from cattle to humans. On March 25, 2024, U.S. Department of Agriculture reported that milk samples collected from affected cows on two dairy farms in Kansas and one in Texas, as well as an oropharyngeal swab from another dairy in Texas, tested positive for highly pathogenic avian influenza (HPAI), later confirmed to be Type A H5N1. This is the first time that these bird flu viruses were found in cattle. Since the beginning of April 2024, CDC has reported eight HPAI A(H5N1) human cases associated with the dairy cattle outbreak: one in Texas, two in Michigan, and five confirmed in Colorado. All individuals had occupational exposure to infected animals (either cattle or poultry), and none of the cases has involved severe disease. The current risk to human health posed by HPAI A (H5N1) virus is low. But the cases stemming from dairy cattle represent the first instances of likely mammal-to-human transmission of HPAI A(H5N1). Additionally, we cannot be sure that the cases known to be associated with the dairy cattle

outbreak represent the full spectrum of disease from this currently circulating HPAI A (H5N1) strain, nor can we be assured that the virus will not mutate to cause more severe disease and/or to become more transmissible (e.g., acquire a mutation conferring facile mammal-to-mammal transmission).

Broadening the April 19, 2013, determination to apply to pandemic influenza A viruses and influenza A viruses with pandemic potential—rather than just H7N9 specifically—would appropriately cover the range of known and emerging influenza A viruses that present a significant potential for a public health emergency.

Therefore, I have now amended the April 19, 2013, determination to recognize that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves biological agents, namely pandemic influenza A viruses and influenza A viruses with pandemic potential.

III. Declaration of the Secretary of Health and Human Services

On April 19, 2013, pursuant to section 564(b)(1) of the FD&C Act and subject to the terms of any authorization issued under that section, former Secretary Sebelius declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of avian influenza A (H7N9) virus. That declaration remains in effect until that declaration is terminated in accordance with section 564 of the FD&C Act.

Xavier Becerra,

Secretary,

Department of Health and Human Services.