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Attention: Pandemic Influenza Masks Comments
Attention: Pandemic Influenza Antiviral Comments
Attention: Pandemic Influenza Employer Antiviral Comments

Comments from Trust for America's Health

Trust for America's Health (TFAH) is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. TFAH has played a watchdog and advocacy role in the formation of the Administration's federal pandemic influenza strategy. We believe that it is vital that the federal government maintain an open dialogue with the public about the protections that the government can and cannot provide during a pandemic. The three guidance documents are examples of this kind of transparency, and TFAH applauds the Department of Health and Human Services (HHS) for continuing efforts to educate the public.

In June, HHS released three draft guidance documents regarding preparation for pandemic influenza: *Interim Guidance on the Use and Purchase of Facemasks and Respirators by Individuals and Families for Pandemic Influenza Preparedness (Individuals)*; *Proposed Considerations for Antiviral Drug Stockpiling by Employers In Preparation for an Influenza Pandemic (Employers)*; and *Proposed Guidance on Antiviral Drug Use during an Influenza Pandemic (Antivirals)*. TFAH's comments will briefly address each guidance document in turn. Due to the similarity of our feedback for each proposed guidance, we are submitting our comments in a single document.

Use of Facemasks by Individuals

Regularly publishing guidance on social distancing and hand and cough hygiene is a necessary first step in protecting the public, because public awareness of these measures will be crucial to containing an outbreak. Scarcity of vaccines and antivirals means that

social distancing will likely be an important infection mitigation strategy. However, TFAH is concerned about the extent to which HHS is relying on individuals to stockpile personal protective equipment. It is not reasonable to expect even the most cautious household to stockpile the recommended 20 respirator masks or up to 100 facemasks per family at a cost of \$35 to \$70, especially in these tough economic times. The federal government should enhance its stockpile of protective equipment, so that at least low-income and at-risk individuals, including the elderly and those living in group settings, have access to the same protections other Americans will enjoy.

It is also simply unrealistic to believe families will believe it is a priority to stockpile masks and respirators in advance of an influenza pandemic. Most individuals do not believe influenza pandemic is the most imminent threat to themselves and their families, and it has already proven difficult to motivate state and local health departments and hospitals to maintain such stockpiles. If HHS believes that families should procure masks and respirators, then the Department should launch a public awareness campaign, that provides Americans with information about the need for personal and family pandemic planning, the types of masks they will need, the level of protection they offer, where to buy them, and when and how to use them. TFAH recommends the Administration include dedicated funding for such public education efforts.

We also remain concerned that the Food and Drug Administration has not yet approved respirator masks for children, who maybe more susceptible to infection than adults. According to an October 2007 report released by TFAH and American Academy of Pediatrics, children are especially effective vectors of disease because of limited understanding of hygiene and cough etiquette and constant proximity to peers and caregivers. The report recommended HHS convene an independent task force to study and make recommendations about the use of personal protective equipment by children during an influenza pandemic. Again, TFAH urges HHS to take immediate further steps to examine and resolve this gap in preparedness planning.

Stockpiling of Antivirals by Employers

Asking employers and families to take tangible steps to prepare in advance for a pandemic influenza outbreak is a step in the right direction. However, the federal government must assure that all Americans have access to the protections HHS recommends. The guidance suggests voluntary stockpiling of antivirals by corporate America, which may be economically feasible for some businesses, but certainly not all businesses. Stockpiling will be difficult for businesses that lack warehouse space, operate on slim margins, and employ part-time or uninsured employees. An employee of a small to mid-size company should not be penalized because the enterprise cannot afford the costs of acquiring, storing and dispensing antiviral medications during an influenza pandemic. The federal government must do all it can to protect *all* Americans from a potential influenza pandemic, especially those who are employed on the frontlines of health delivery and in critical infrastructure positions.

The most prominent change in the guidance is the recommendation that employers consider stockpiling prophylactic antiviral medications, particularly if their employees will be at high risk of exposure. Many businesses and healthcare facilities have already proven reluctant to stockpile *treatment* antivirals for even their frontline staff. According to the manufacturer, the number of oseltamivir regimens purchased by the private sector decreased dramatically from over 2 million in 2006 to 140,000 in 2007.¹ Some businesses have expressed concern about changing directives from the federal government, the expense and logistics of stockpiling, and the likelihood of a pandemic even occurring. Even healthcare facilities have been hesitant to purchase antivirals for their employees. A Centers for Disease Control and Prevention (CDC) survey of hospital administrators found that only 34 percent of respondents thought their institution would plan to purchase antivirals in accordance with the proposed guidance.² TFAH maintains that the role of antiviral stockpiling is the responsibility of the federal government. However, if HHS is intent on implementing guidance that requires private sector stockpiling, the federal government must do more than simply encourage businesses to purchase antivirals and personal protective equipment. At a minimum, HHS should clarify with the corporate community, what if any of the federal antiviral stockpile, will be available to employers in critical industries. Additional public-private partnership strategies might include providing tax incentives for businesses to stockpile; storage cooperatives between businesses and government; and legal assurances that government will not appropriate private stockpiles.

Antiviral Use During a Pandemic

TFAH is encouraged that HHS continues to request public comment regarding its recommendations on antiviral usage. The process must remain transparent and an open dialogue must continue if there is to be cooperation from the public during a pandemic outbreak. Clearly, scarcity and planning will be major issues as Americans wait for a well-matched vaccine once an influenza pandemic begins. The guidance reflects HHS' efforts to engage the public and public health experts in developing prioritization guidelines.

However, we believe the guidance places too much responsibility for protecting Americans in the hands of non-governmental groups. Once again, the HHS guidance depends on private sector stockpiling to achieve an adequate level of protection: "...implementation will require governments, healthcare organizations and other employers, and families and individuals as appropriate, to purchase and stockpile sufficient antiviral drug supply to support these strategies." The guidance explicitly recognizes that states are unlikely to purchase their full allocation of antivirals, yet still relies on employers and families to take on this responsibility.

TFAH is concerned that there are no incentives for the private sector and individuals to stockpile antivirals, and therefore depending on them to stockpile will leave major gaps in preparedness planning. Accumulating and warehousing antivirals is not as simple as purchasing respirators at the local pharmacy. In addition to the cost of the medications themselves, which run around \$50-70 per course for non-governmental purchase,³

individuals will have to visit a physician to obtain a prescription for oseltamivir or zanamivir. If HHS is going to implement the expanded use of antivirals recommended in the guidance, which would require 195 million regimens, the federal government must plan to procure them, which would necessitate additional appropriations for federal purchase and storage of antivirals in the next budget request.

One area mentioned but not addressed in the guidance is the shelf-life of antivirals. The Shelf-Life Extension Program will help to protect and maintain the federal antiviral purchases; however, the 31 million regimens purchased by states are not presently eligible for the program. TFAH's *Ready or Not? 2007* report and the Institute of Medicine's recent report, *Antivirals for Pandemic Influenza*,⁴ include recommendations for extending the Shelf-Life Extension Program to include state and privately held stockpiles of antivirals. While HHS officials have reportedly held internal discussions about possible solutions to this problem, we recommend that this issue receive priority attention.

Conclusion

The government must assure all Americans are protected, regardless of where they live or where they work. In the event of a pandemic outbreak, leaving the massive costs and logistical responsibilities to businesses and individuals, without the assurance of equal access to key prevention strategies, like antivirals and respirator masks, is not an option. HHS needs to take on a larger role in stockpiling countermeasures and/or incentivizing other stakeholders to stockpile and Congress should appropriate the funds to do so. While shared-responsibility among the federal government, state and local governments, the private sector and individuals may seem appealing, it is imperative to remember that in a severe influenza outbreak, as a nation, we are only as prepared as the weakest link.

¹ Koonin, Lisa M. MN, MPH, U.S. Centers for Disease Control, and Benjamin Schwartz, M.D., U.S. Department of Health and Human Services. "Antiviral Stockpiling: Stakeholders Perspectives, Findings and Analysis," Presentation to the Institute of Medicine Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic (Washington, D.C. January 7, 2008).

² Ibid.

³ "Prescriptions for Flu Remedies Likely to Surge," MSNBC, (Oct. 8, 2004).
<http://www.msnbc.msn.com/id/6205436/>

⁴ Institute of Medicine of the National Academies. "Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program." (Washington, D.C.: The National Academies Press, April 2008).