

TO: Senate and House Conferees on H.R. 3010, the FY 2006 Labor, Health And Human Services, Education, and Related Agencies Appropriations Bill, *Pandemic Influenza Preparedness*

FROM: The Working Group on Pandemic Influenza Preparedness

DATE: November 10, 2005

Introduction

The undersigned organizations have come together as the Working Group on Pandemic Influenza Preparedness because we all believe that pandemic influenza poses a major threat to the nation's public health, security, and economy.

Accordingly, we believe that the U.S. government's preparedness efforts should be commensurate with the threat. To that end, we commend the Administration for issuing an outline for a government-wide pandemic response, a revised pandemic plan for the Department of Health and Human Services (DHHS), and a request for funds to implement them. While we may differ on some of the specifics outlined in the documents released last week, the fact that they were issued is a major step forward. At the same time, however, there are a number of issues that the Conferees must address.

Inadequate Funding

It is clear that that the revised pandemic flu preparedness plan issued by DHHS reflects the professional judgment of leading health and scientific experts. Our concern is that that Administration's budget request does not provide sufficient resources to assure nationwide implementation of all aspects of the plan, including state and local public health preparedness efforts, hospital surge capacity and related priorities, and the U.S. obligation to support international efforts to identify and contain a flu pandemic overseas.

State and local health departments will be at the forefront of the pandemic response. Yet the Administration's proposal sets the additional federal investment in state and local preparedness at only \$100 million, not nearly enough to allow them to prepare. In contrast, the Senate provided \$600 million for state and local pandemic preparedness in the FY 2006 Labor Health and Human Services bill. At a minimum, we support the Senate mark, and in addition call on the Congress to restore funding for general state and local public health preparedness, which may be cut this year by up to \$130 million.

We are also concerned that there are inadequate funds for risk communication and for including other critical medicines and supplies to the Strategic National Stockpile (i.e., ventilators, syringes, gloves, intravenous antibiotics) that will be in high demand.

Funding for pandemic hospital preparedness is a major component of the national response. The DHHS plan correctly recommends wide-ranging, complex, and costly measures that are critical to hospital preparedness. However, it does not suggest any means for funding such efforts. Nor does the President's pandemic flu budget request. Without any financial incentives, few if any hospitals will be able to implement the Department's guidance.

At the international level, the Administration's budget request may improve surveillance efforts, but it fails to address the need for programs exploring the environmental linkages to the spread of bird flu. Moreover, it remains unclear how the U.S. will respond to requests from other countries to donate vaccine, medicines, expertise or health care infrastructure in the event of a pandemic. We believe

that it is in the nation's enlightened self-interest to do more internationally in the attempt to diminish the rate and scope of a future flu pandemic.

Pandemic Vaccine Development and Procurement

We are especially concerned about the revised plan's lack of information with respect to how the U.S. will produce adequate supplies of pandemic vaccine or treatment medication in the short or medium term. The goal of having a vaccine for every American is laudable. We believe that the Administration's multi-pronged approach, which includes vaccine research and development, retrofitting domestic facilities for emergency production of vaccine, encouraging the creation of additional egg-based and cell-based vaccine production facilities, and developing a vaccine registry to monitor vaccine safety, distribution, and use during a pandemic, is appropriate. However, the DHHS plan does not detail the elements of the "crash program" for vaccine production referenced by the President in a recent speech at the National Institutes of Health, nor does the plan address any strategies for maximizing U.S. or global vaccine supplies, especially given the limitations of existing production systems. Since adequate vaccine supplies of pandemic flu vaccine are the central defense against illness, death and widespread economic destruction, a clearly articulated U.S. vaccine production strategy and timeline are essential.

We urge the Congress to make the requested funding available on an as-needed basis, rather than spread out over four years, with the goal of accelerating the 2010 timeline for producing enough vaccine to vaccinate every American within six months of a pandemic.

Issues around vaccine liability and compensation need to be addressed immediately to avoid hampering research and development issues. In addition, we want to avoid a repeat of the problems associated with the smallpox vaccination program. We urge the Conferees to provide funds necessary for the creation of a compensation system and to make funds available to DHHS so that the department can develop and test vaccine distribution and tracking systems.

Antiviral Stockpile

The Administration's plan and budget request reflect a move toward stockpiling enough antivirals to cover approximately 75 million people, enough to treat 25 percent of the U.S. population – the amount the World Health Organization (WHO) suggests as a target. The Administration's budget request provides for the federal purchase of 44 million courses of antiviral drugs for treatment, with another 6 million courses for domestic containment. This is a step in the right direction. However, we are deeply concerned about the Administration's strategy to leverage state tax dollars to purchase the remaining 31 million courses of antiviral drugs with a 25 percent federal subsidy. Germs don't respect jurisdictional boundaries, and public health officials must have the flexibility to provide the medication where outbreaks are most severe. Requiring each state to purchase antivirals separately does not make sense from a health or economic perspective. Reliance on states to pay for a substantial portion of the cost of purchasing enough antiviral medication to cover their populations amounts to an unfunded mandate to the tune of \$510 million over a very short time frame. If this holds, states will likely either raise taxes or find offsets from already under funded health programs to address this mandate. We hope that Congress will address this issue immediately by requiring the federal government to protect Americans by purchasing the full 75 million antiviral treatment courses. The level of protection Americans receive should not be determined by where they live and the current fiscal position of their states.

In addition to encouraging the production of vaccines, we also need to bolster U.S. production capacity of antivirals – not only to protect Americans, but also for global prevention and control efforts. In addition to ensuring an adequate supply of effective antivirals, we need to determine the

most effective and efficient strategies for their use during a pandemic, including the most effective doses, timing for administration and the best methods of administration.

Clarify Assumptions and Guidance

The revised DHHS plan lacks clarity and precision in its articulated disease containment options. For example, it is misleading to suggest that there is any rational or practiced use of large-scale quarantine or that we will have ample warning of a pandemic as it spreads methodically from Asia to U.S. shores. It also is confusing to suggest that local authorities should make the calls regarding the closure of airports or other large transportation hubs. On complex matters such as these, which may have implications for other parts of the nation, the federal government should provide clear guidance and make recommendations based on its expertise.

One more important point of clarification is warranted. The chain of command is unclear. The national strategy calls for the Department of Homeland Security to be in charge of the overall domestic incident management and federal coordination, essentially divorcing the expertise that will be needed to respond to a complicated health threat from the top chain of leadership. A pandemic flu response must be driven by public health experts who are already trained to control a spreading disease with support from emergency preparedness officials, not the other way around.

The clock is ticking as the threat is growing. The Administration's strategy, plan, and budget request help move the country toward better preparedness. Congress must now act expeditiously to address the plan in order to ensure that America is as prepared as possible to face this serious threat. We believe that the Administration's budget request, coupled with recent appropriations actions by the U.S. Senate, should provide the Conferees with the flexibility to craft a thoughtful solution that will allow the nation to invest in the technology, medicines, state and local public health infrastructure improvements, and surge capacity necessary to save lives and mitigate suffering.

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Please direct all inquiries or comments to Jeff Levi (jlevi@tfah.org), Kim Elliott (kelliott@tfah.org) or Rich Hamburg (rhamburg@tfah.org). All can be reached by phone at 202-223-9870. Trust for America's Health is committed to sharing information with all members of the Working Group on Pandemic Flu Preparedness or directing specific inquiries to participating organizations.