

## Center Comments

### Comments from the Center for Biosecurity of UPMC on the *National Strategy for Pandemic Influenza: Implementation Plan*

ON MAY 3, 2006, the Administration released the *National Strategy for Pandemic Influenza: Implementation Plan* (referred to from this point forward as “the Plan”), which is intended to build on the *HHS Pandemic Influenza Plan* released by the U.S. Department of Health and Human Services (HHS) in November 2005. What follows is the Center’s assessment of the new Plan. We highlight those elements that are constructive and commendable, and we discuss the issues and elements of the Plan that require more attention, clarity, and resources.

#### COMMENDABLE DEVELOPMENTS

- **The Plan provides new, more detailed information regarding the government’s assessment of the potential consequences of a flu pandemic of 1918-like severity.** Throughout, the Plan details the likely effects that pandemic influenza would have on both international commerce and society in the U.S. and other countries. The Plan provides useful reviews of issues related to epidemiology, situational awareness, surveillance, and rapid diagnostics. Overall, the portrayal of challenges and consequences is in accord with other major scientific and contingency planning estimations, and we agree with the Plan’s assertion that pandemic preparedness should be a national security priority.
- **The Plan delineates more than 300 specific actions, accompanied by performance metrics and timelines.** We agree that a timeline and metrics for completion of pandemic plans by government departments are needed.
- **The Plan is useful for its description of the stages of federal government response to a pandemic that will serve as the guide for action and policy decisions.** For planning purposes within and outside of the federal government, the Plan describes the triggers for moving from stage to stage and the major actions and

policy challenges of each stage, and it suggests what the messages to the American people will be. This is an important development.

- **The Plan’s business contingency planning is a useful beginning.** The Plan offers sensible recommendations that provide businesses with helpful initial guidance. The specific recommendations are particularly useful, such as those related to infection control in non-healthcare work environments, environmental cleaning requirements, encouragement of non-punitive leave for ill employees, recommendations for use of face masks, and so forth. The Plan notes that the U.S. Department of Homeland Security (DHS) and HHS will issue additional technical guidance for specific business and community sectors in the next 3 to 6 months.

#### AREAS IN NEED OF MORE ATTENTION, CLARITY, AND RESOURCES

- **The Plan’s objectives for pursuing vaccine for a pandemic flu strain for all Americans should be much more ambitious.** If we were to recommend just one action that the federal government could take to achieve a dramatic decrease in the entire range of potential consequences of a flu pandemic, it would be that the government put its weight more fully behind rapid vaccine development, manufacturing, and distribution. Not only would this be the single most important development in preparing the nation for a pandemic, but a sufficiently ambitious program could radically change what the U.S. would be able to offer the rest of the world.

The Plan says that the “primary objective, depending upon availability of future appropriations and the responsiveness of the vaccine industry, is for domestic manufacturers to be able to produce enough vaccine for the entire U.S. population within 6 months of the recognition of a human influenza virus with pandemic

potential.” The American people should not have to wonder whether “future appropriations” and “the responsiveness of the vaccine industry” will be matched to the task. Without question, delivering a nationwide supply of a vaccine to protect the American people should be the eminent, overriding responsibility of the federal government.

The performance measure stated in the Plan stipulates that HHS will establish “within 60 months, domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population.” But why 60 months? That will bring us to summer of 2011. Neither this Plan nor the November 2005 plan makes clear the rate-limiting factors for vaccine production in this country that warrant a 60-month timeline. It is difficult to imagine this is as fast as science and technology would allow.

If more money would accelerate the process, then adequate funding should be appropriated. If industry has surfaced other problems that the federal government could fix, then provisions should be made for doing so.

If the vaccine development process could be accelerated through the temporary recruitment to government service of senior vaccine scientists and program managers, then provisions should be made for doing that. Even if a 60-month timeline were the fastest that money can buy and science would allow under the best of conditions, how will the public know where we are in the process of achieving that goal? Already, it seems we’ve lost track of almost one year: In the fall of 2005, the goal was 2010.

- **Funding for the Plan is not commensurate with the requirements put forth in either this document or the earlier plan of November 2005.** In the fall of 2005, the President requested \$7.1 billion for the national pandemic flu strategy. Congress appropriated \$3.8 billion of that request at the end of last year. The President has requested an additional \$2.3 billion for this initiative, but at this time it is not clear that the requested level of funding will be appropriated in this year’s budget. However, even if this additional funding is made available, it is not adequate for completing the work described in the Plan.

The Center has informally estimated, for example, that the cost just to prepare America’s hospitals for a pandemic will be approximately \$5 billion (\$1 million per hospital  $\times$  5,000 U.S. hospitals) [see T. Inglesby Comments at Senate Roundtable on All Hazards Medical Preparedness and Response, U.S. Senate Subcommittee on Bioterrorism and Public Health Preparedness, April 5, 2006, for more detail on this estimation: [http://www.upmc-biosecurity.org/pages/resources/hearings/inglesby-allhazardsmedpreandresponse.](http://www.upmc-biosecurity.org/pages/resources/hearings/inglesby-allhazardsmedpreandresponse.html)

html]. Developing and stockpiling vaccines and drugs are also unavoidably expensive endeavors. During the briefing of the Plan on May 3, it was asserted that agencies will have to find money in their own budgets to cover these costs. This sounds fiscally responsible at first blush, but in reality, it may mean that agencies will not be able to execute their parts of the Plan. For example, developing the animal health protection strategy called for in the Plan will cost far more than is now allotted in the U.S. Department of Agriculture’s (USDA) budget for pandemic planning issues.

- **Hospitals receive insufficient attention in the Plan.** The Plan does not attend adequately to the requirements of hospitals, nor does it clearly recognize that the continued functioning of hospitals in a pandemic should be a top federal and local planning objective. The Plan does acknowledge many of the grave challenges hospitals will face in a pandemic: depleted supplies, severely limited access to life-saving equipment, scarcity of staff to provide patient care, and overwhelmed intensive care units. That said, the Plan presents solutions that are incongruent with the problems hospitals will face. For example, the Plan emphasizes creation and deployment of Federal Medical Contingency Stations, without any clear indication of the funding and operations required to deploy them. At best, these stations would make only small contributions to efforts to meet the healthcare needs of communities during a pandemic.

It would make far more sense to pursue a rigorous plan to ensure that America’s hospitals can continue to provide care in a pandemic. At the very least, plans must be in place to ensure continuity of hospitals’ operations so that baseline community healthcare needs can be met, such as treating heart attacks, delivering babies, and caring for victims of car accidents. The *HHS Pandemic Influenza Plan* of November 2005 provided a prodigious list of tasks for hospitals to pursue, but it did not provide a sense of how hospitals should prioritize those tasks or how they should accomplish or pay for them.

It would also make sense to focus on developing an effective plan for encouraging and providing resources to people so they will stay home if they are mildly to moderately ill in a pandemic, which would help avoid overcrowding hospitals. Blogs and web communities have for some time been actively seeking specific information on how individuals can better prepare themselves and plan to care for sick family members at home. The federal government should work with local governments and the appropriate healthcare organizations and/or NGOs to make this kind of information and ongoing community dialogue and planning possible. It could benefit communities around the country.

The Plan's objectives for improving the numbers and organization of medical volunteers are a move in the right direction. Proposed steps include improving credentialing processes through the Emergency System for Advance Registration of Volunteer Health Professionals Plan (ESAR-VHP), with the goal of establishing full functionality in all states within 12 months. This would be an important accomplishment. Also proposed is a 20% expansion of the Medical Reserve Corp (MRC) over the next 12 months. The utility of this remains to be seen and ultimately depends on the concept of operations established for the MRC, as well as the recruitment methods that are adopted and the training that is supplied. It would be helpful if HHS worked to improve the overall organization of the federal government's medical and nonmedical volunteer programs and to clarify how the MRC, the National Disaster Medical System, ESAR-VHP, the American Red Cross, and other volunteer and disaster-related federal programs will work together in planning for and responding to a health crisis. [See also *Critical Next Steps for Hospital Pandemic Preparedness: Recommendations for Federal Government Action*, <http://www.upmc-biosecurity.org/pages/publications/hospitalpreprecs-060418.html>, which offers the Center's analysis of the challenges facing hospitals as they prepare for a pandemic.]

- **Some of the Plan's proposed options for disease containment are unclear and/or misguided.** The Plan notes in one place that it is unlikely that disease will be contained overseas during a pandemic, but the Plan also says that "the primary strategy for protecting human health must be . . . prevention of emergence of a pandemic strain, if possible, or rapid containment of a human outbreak at its source." This statement implies that government officials believe that halting the spread of disease overseas is a primary objective. History has demonstrated that flu pandemics have never been controlled in this manner, and there is no reason to believe they will be in the future.

The Plan calls for "layered, risk based measures" of containment. Some of these measures might be reasonable based on evidence, best available judgment, or practical experience. For example, as a practical matter, it is likely that schools will be closed at the very start of a community's confrontation with a pandemic. This action will likely be taken whether ordered by officials or not, even if, as is the case right now, there is no evidence base to suggest that this action would have any effect on the community spread of a flu virus.

Wisely, the Plan does not seem to support closing borders. However, it does indicate that border screening would be pursued, at points prior to, during, and upon arrival from travel. All of these methods are out-

lined in the Plan, and all have serious potential consequences and little proven ability to stop the spread of disease. Thirty-five million people were screened at airports in four Asian nations for potential SARS infection during that outbreak, and not one case of SARS was detected [see "Nonpharmaceutical Interventions for Pandemic Influenza, International Measures," in *Emerging Infectious Diseases* at: <http://www.cdc.gov/ncidod/eid/vol12no01/pdfs/05-1370.pdf>]. Such screening measures are also completely out of accord with the sound planning assumptions put forth in this Plan, which state that people who become ill may shed virus before they are sick and that some people with flu will never show clinical signs of disease. [See also "Comments from the Center for Biosecurity of UPMC on Proposed Revisions to Federal Quarantine Rules," in *Biosecurity and Bioterrorism* at: <http://www.liebertonline.com/doi/pdf/10.1089/bsp.2006.4.204>, which details why we believe the CDC's quarantine rule is ill-conceived.]

Of special concern is the Plan's discussion of large-scale geographic quarantine: "Geographic quarantine (Cordon Sanitaire), by force if necessary . . . even if [it] proves unsuccessful, [may delay] the spread of the disease [and] could provide the federal government with valuable time to activate the domestic response." There is no evidence that this kind of quarantine would slow the spread of flu, but it could have severe adverse consequences. It should be eliminated from further consideration.

In all, the Plan makes unrealistic assumptions about and overemphasizes what could be done to stop travel, and it pays too little attention to what will have to be done to ensure that travel and trade are sustained for the 12 to 18 months over which a pandemic will course. The disease containment options most strongly supported by science and/or practical experience are voluntary isolation of sick individuals, either at home or in hospital, vaccination, and prophylactic use of antivirals. Voluntary community actions such as limiting the gathering of crowds during the pandemic's peak may be helpful. A public education campaign that emphasizes staying home when sick, washing hands after contact with a sick person, and other such measures also would be useful. Beyond these measures, we strongly commend the Administration's stated intent to spend a great deal of time examining other disease containment strategies that may or may not be effective, as well as its goal of reaching stronger scientific and health consensus on what should be done.

- **The international component of the Plan needs to provide far more vaccine and antiviral acquisition assistance for resource-poor countries.** Absent a clear solution that will help resource-poor countries get

these medical resources, the international efforts of the U.S. will have limited utility in stopping the spread of pandemic flu in other countries or diminishing its potential consequences. The announcement of the President's International Partnership on Avian and Pandemic Influenza last fall did signal U.S. intent to work with other countries and multilateral organizations in planning and responding to a pandemic. The Plan also underscores the importance of supporting multilateral organizations, perhaps most importantly, the World Health Organization (WHO). The Plan also rightly stresses training, coordinating, and collaborating; the development of protocols, standards, and diagnostics; and the staffing of foreign locations and rapid response teams. These are important goals, but the Plan does not describe how the U.S. will achieve these goals, and the President's proposed budget for this work won't cover its costs. HHS, the USDA, and especially the Department of State (DoS) are being asked to do a great number of these tasks globally, but in the FY2006 pandemic appropriation, DoS, for instance, was provided with just \$16 million.

More important, the Plan does not explain how "priority" countries will be encouraged or assisted to build capacity and/or stockpiles of vaccine or medicines. The Plan seeks to "increase by 50% the number of priority countries that have plans to increase production capacity and/or stockpiles," but the gross inadequacy of vaccine and antiviral reserves in the world is clear, and global production capabilities are sharply limited. What is needed is an operational plan—set forth by the U.S. and other countries willing to lead on this issue—for radically augmenting global flu vaccine development and production capacity so that countries around the world can at some point have realistic opportunities to acquire pandemic vaccine supplies. This effort should be the centerpiece of the international component of the Plan.

- **The Plan does not specify how priorities for vaccination and distribution of antivirals would be established.** The Plan notes that the federal government will "work to ensure the production and distribution of vaccine . . . to State, local, and tribal entities, and the acceleration of research, development, testing, and evaluation of vaccines and therapies during the outbreak," which appears to be a sensible goal; however, the details of execution are not provided. For instance, how will or how should the federal government or state or local governments decide who should receive limited vaccine or medical resources? Will HHS be working with the private sector to purchase and distribute vaccine, as seems to be called for in the *HHS Pandemic Influenza Response Plan*: "[HHS will] facilitate vaccine procurement, distribution, and tracking, working with

private partners" . . . "distribution of pandemic vaccine to health departments and providers will occur via private-sector vaccine distributors or directly via manufacturer"?

If so, it appears this approach conflicts with the recommendation of the National Vaccine Advisory Committee (NVAC), which unanimously recommended that, in the event of a pandemic, the federal government should purchase all influenza vaccine and that it should be distributed "through systems established by state, local and Federal agencies in advance of a pandemic" [Helms, CM. Letter from Chair of the National Vaccine Advisory Committee (NVAC) Regarding the NVAC, June 7–8, 2005; Meeting and NVAC/ACIP, July 19, 2005; Joint Committee Meeting, August 10, 2005. Available at: <http://www.hhs.gov/nvpo/nvac/documents/chairletter.pdf>. Accessed May 4, 2006]. Regardless of the specifics of this part of the Plan, they must be made clear to state and local planners. No one in local planning communities now understands who will get vaccine and antiviral drugs and who won't.

- **The Plan's assumptions about surveillance and situational awareness are not clear, and the related goals are problematic.** The Plan calls for real-time disease surveillance in communities. If that means developing a program to actively track cases of flu in a community during a pandemic, then that makes great sense. Communities should certainly be building that capacity if they can find the resources to do so. In addition, building more robust electronic connections to support rapid and sustained dialogue among health officials, hospital leaders, and elected officials during a crisis should be a top priority as is noted in the Plan. Such efforts will enhance and improve the situational awareness that is essential to managing a health crisis such as a pandemic.

In the past, a primary goal of BioSense, a surveillance program highlighted by the Plan, has been to try to uncover the earliest cases of flu or other disease outbreaks. While this idea has intellectual appeal for obvious reasons, it has not been demonstrated to be feasible in prototype; however, the program continues to receive substantial funding and support. Approaches such as this, which pursue the wrong type of surveillance program, are both a waste of money and a distraction that keeps public health departments and leaders from the work they should be doing.

Finally, the Plan indicates that DHS will be involved in surveillance activities, but the level and the nature of that involvement is unclear. The goals and potential value of the DHS National Biosurveillance Integration System are unclear. The Plan notes that DHS and HHS have signed a memorandum of understanding to ensure coordination of border screening activities and infor-

mation sharing for contact tracing during an outbreak. But DHS should not be part of contact-tracing programs. Not only does DHS lack institutional experience with this, but during a pandemic, if people believe they are being traced or sought by DHS, rather than by local health authorities or the CDC, they may be frightened and reluctant to get medical care.

- **The Plan's strategy for protecting animal health needs greater elucidation.** The proposed actions and expectations for protecting animal health have budget implications that exceed the USDA's 2006 budget allocation for Pandemic Flu Preparedness. Expansion of the domestic supply of bird vaccines is proposed, with the target of 110 million doses, but the concept of operations for using the vaccine is not stated. For example, it does not say which flocks will receive priority, how 110 million chickens would be immunized, or how this would affect global trade. There should be a particular premium on funding a bird vaccine development program and an urgent effort to decide, through national and industrial policymaking, how the vaccine would be used to prevent or respond to a major bird flu pandemic in the U.S.

Test and slaughter is the only tool currently available for controlling outbreaks of highly pathogenic avian influenza (HPAI), but to date this strategy has not stopped the rapid spread of H5N1 to countries around the world. Conceived properly, a major new bird vaccine development effort and implementation plan could not only have great importance in the U.S., but could also have highly valuable consequences for other countries struggling to control the spread of H5N1 in flocks.

## CONCLUSION

In summary, the *National Strategy for Pandemic Influenza: Implementation Plan* has advanced the national pandemic planning efforts in a number of ways. But some of the most critical elements of national planning need much more attention, clarity, and resources in order to make this country resilient in the face of a pandemic.

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