



ABSAs Influenza Pandemic Plan Position Paper

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Pandemic Plan
National Vaccine Program Office
Hubert H. Humphrey Building, Room 725H
200 Independence Avenue, SW
Washington, DC 20201

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Dear Sirs:

The American Biological Safety Association (ABSAs) is an organization of biological safety practitioners who work in a variety of academic, governmental, healthcare and private work environments. ABSAs has many members in the United States, Canada, and in other countries. We are recognized as a leading authority in the field of biological safety.

We have reviewed the Draft Pandemic Influenza Preparedness and Response Plan that was published in the August 27, 2004 issue of *The Federal Register*. Please consider the following comments:

Specific biosafety levels should be assigned for activities detailed in the document. Points of reference that may need to be noted are the Laboratory Safety Guidelines from the National Institutes of Health (NIH) and the American Society for Microbiology (ASM). At minimum, guidance as spelled out in the most recent edition of *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* should be specifically detailed as the point of reference for appropriate biosafety levels for laboratory testing of diagnostic specimens. Additional safe work practices may be instituted upon receipt or isolation of a novel virus, but appropriate containment must be in place before the virus is cultured. If a site is unable to provide adequate containment, it will need to seek out

and identify in advance of a pandemic an appropriate reference laboratory where these activities can be conducted. The BMBL does not currently address recommended biosafety levels for the virus production activities mentioned in the document, but the NIH and ASM references do provide more specific guidance for this activity. There will be many challenges for laboratories during a pandemic, and they should have clear points of reference for safe work practices and containment during their preparation activities.

The document should address medical surveillance and reporting of febrile illness for research and production staff (and family members) working with possible pandemic strains. As the recent Severe Acute Respiratory Syndrome (SARS) incidents in Asia demonstrate, even knowledgeable staff can transmit the virus into the community. In addition, the possibility of asymptomatic individuals transmitting virus should be considered in any surveillance program.

The public may be quick to seek treatment for perceived illness, especially if disease information is communicated to the public through the media and not through health care professionals. Increased demand for evaluation and treatment by the "walking well" will likely place additional pressure on a health care system that will already be strained. Most of these requests will come through outpatient visits to physicians and clinics that may not be reached by the Public Health Training Network (PHTN) and other training forums. There will be a critical need to provide accurate technical information to health care professionals in the medical community. There will also be a need to provide accurate information that can be readily understood by the public at large

during a pandemic.

The Centers for Disease Control and Prevention (CDC) has a sampling and surveillance program in place to monitor influenza during the flu season. This program should be structured for rapid expansion to screen a large number of patient samples, at least in the initial stages of an outbreak. The anthrax bioterrorism incidents in 2001 showed that many sections of the public health network, such as the state health labs, can be quickly overwhelmed by unusual demands (i.e., requests to analyze mysterious white powders).

The plan indicates that the U.S. Department of Agriculture (USDA) has surveillance mechanisms for avian influenza and other potential sources of new strains. The National Institutes of Health (NIH) should work with the USDA to assure that veterinary staffs are aware of appropriate biosafety precautions to observe when sampling suspected animal outbreaks in order to prevent direct transmission of the virus to humans.

Both the summary and the annex discussing vaccine production mention “reverse engineering” and “reassortment” as methods to improve the growth of influenza strains in eggs (or tissue culture) for vaccine production. The NIH Office of Biotechnology Affairs (OBA) may wish to consider convening a

panel to issue additional guidance regarding biosafety practices and containment for such recombinant DNA activities. USDA should be involved as well because of the risk to the poultry industry.

Since information and data will need to be developed regarding the virulence of this virus it will also be important to preserve viral cultures for future reference and for present characterization in the management of the pandemic. Reference should be made to appropriate standards of the U.S. Department of Transportation (USDOT) or the Dangerous Goods Regulations of the International Air Transport Association (IATA) for sites to note and follow in the preparation of shipments of these materials.

Thank you for providing ABSA with the opportunity to participate in the review of this draft plan. ABSA members are prepared to be of further assistance in developing a more useful and current document. We wish you well in the finalization of your plan of action.

Sincerely,



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President, American Biological Safety Association

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