

ATTACHMENT B



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

MAY 30 2006

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

Arthur W. Bracey, M.D.
Chair, Advisory Committee on Blood Safety and Availability
1101 Wootton Parkway, Suite 250
Rockville, MD 20852

Dear Dr. Bracey:

I am very pleased with the deliberation of the Advisory Committee on Blood Safety and Availability on the issue of influenza pandemic preparedness. While we cannot be certain when a potential pandemic will affect the nation, we need to consider all aspects of preparedness at this time. Each of your recommendations is being carefully considered within the Department.

As the Nation's Blood Safety Officer, I recognize that blood and plasma products are critical elements of the comprehensive healthcare infrastructure, as are essential personnel to ensure that those products are collected, processed, distributed, and used appropriately. The knowledge gap in assessing a potential influenza pandemic and resolving critical scientific questions is challenging. We continue to work with DHHS agencies to ensure that scientific questions are answered and that adequate global and domestic surveillance programs are in place to protect the blood supply and prevent transmission through transfusions.

I appreciate the role that the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism has in the blood community. The Department recognizes the importance of the private sector in maintaining this critical element of the healthcare infrastructure and will continue to work with the Task Force to ensure that a comprehensive check list is prepared for local implementation.

Please thank the Committee for their outstanding consideration of an extremely important issue. I look forward to hearing more details of the overall blood preparedness plan.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John O. Agwunobi", is written over a horizontal line.

John O. Agwunobi
Assistant Secretary for Health

Whereas,

- a) Evidence suggests the possibility in the near term for a global pandemic of influenza A based on recent, highly virulent, human infections with an avian H5N1 virus,
- b) The HHS plan for pandemic influenza recognizes the priority to preserve critical infrastructure in our society,
- c) Ensuring the safety and availability of blood and blood products, including plasma products, is a critical public health need,
- d) Although the scope and impact of the potential pandemic are uncertain, the availability of blood products is likely to be highly compromised during an influenza pandemic,
- e) Data have suggested the possibility that influenza viruses may be present in the blood, organs and tissues of asymptomatic donors
- f) Influenza surveillance data, which come from diverse sources, are limited in scope, timeliness and integration
- g) Risk education and communication to the public, delivered by scientific and medical experts, are essential components of preparedness for pandemic influenza
- h) Preparedness of the blood and plasma systems for pandemic influenza would contribute to the general disaster preparedness

The Committee recommends that the Secretary take immediate steps to:

1. Establish national recognition of the blood and plasma systems (collection, processing, distribution and use) as key elements of the critical infrastructure under the HHS plan, specifically including facility staff, and committed blood and plasma donors
2. Assure full funding of research to resolve critical scientific questions regarding the potential impact of pandemic influenza on blood, organ and tissue safety and availability:
 - a. Foster collaborations with investigators in countries affected by the current H5N1 influenza outbreak to promote studies of possible viremia in asymptomatic persons, including recent case contacts
 - b. Support studies of H5N1 and other potential pandemic strains in suitable animal models, including non-human primates, to investigate viremia and organ localization

of infectivity in preclinical, clinical, and convalescent stages of disease; transfusion transmissibility of virus if present in blood; and impact of infection and/or drug treatment on the accuracy of donor screening tests

- c. Support studies of influenza viremia during annual outbreaks of non-pandemic strains, including studies on blood and plasma donors, and product recipients
 - d. Support development and validation of quantitative models for blood availability and utilization in an influenza pandemic and the potential value of candidate interventions to prevent shortages
3. Provide targeted federal support to enhance global and domestic surveillance for seasonal and pandemic influenza,
 4. Recognize the central role of the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism in the development and implementation of a national strategy to address potentially massive blood and blood product shortages during a pandemic of influenza by
 - a. Assuring blood and plasma systems' input into key federal policy making and communication
 - b. Promoting communication and cooperation amongst state and local public health authorities and appropriate blood collection organizations, hospitals, medical professional organizations and patient advocacy organizations
 5. Develop national principles under which state and local public health authorities and health care providers can prioritize allocation of and minimize disparities in blood and blood products availability and use during critical shortages