

Department of Health and Human Services Advisory Committee on Blood Safety and Availability 1101 Wootton Parkway, Suite 250 Rockville, Maryland 20852

February 7, 2006

John O. Agwunobi, MD Assistant Secretary Department of Health and Human Services 200 Independence Ave, SW Room 716-G Washington, DC 20201

Dear Dr. Agwunobi,

The Advisory Committee on Blood Safety and Availability (ACBSA) met January 5 and 6, 2006 in Arlington, VA. to review data on the current status of H5N1 avian flu epidemic with the intent to assess action needed to maintain a safe and adequate blood supply in the event of an avian flu pandemic. The issue of primary importance is assuring that the Nation's blood supply is maintained as best as possible in the event of an avian flu pandemic.

The HHS Pandemic Influenza plan developed by Secretary Leavitt calls for maintaining the national critical infrastructure during an avian flu pandemic. The Committee strongly recommends that our blood system be recognized as a component of our nation's critical infrastructure. As you know, many therapies that we often take for granted would not be possible without an adequate blood supply. Since States will play a significant role in dispersing resources, the acknowledgement of the critical role of the blood system by the Secretary will greatly help national and regional blood agencies participate in avian flu planning at the state level.

The Committee, in following its charter to ensure the safety of blood, also recommends that epidemiologic field studies and basic medical research are needed to answer existing questions regarding viremia in the pre-clinical period of H5N1 infection. Several investigative teams are ready to address these issues but are in need of funding to implement these important studies. We hope that you will be able to promote the need to advance our knowledge regarding these issues.

Specific recommendations of the Committee follow.

Whereas,

a) Evidence suggests the possibility in the near term for a global pandemic of influenza A based recent, highly virulent, human infections with an avian H5N1 virus,

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- 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, and
- 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, and

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- 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, and
 - 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.

I welcome you to your new position, and hope to meet with you in the near future to discuss these matters as well as your thoughts on any areas in which the ACBSA can help in your efforts to ensure the Nation a safe and adequate blood supply.

Respectfully,

Arthur W Bracey, M.D. Chair, Advisory Committee on Blood Safety and Availability

Cc: J Holmberg