DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Patrick J. McConnon, MPH
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Council of State and Territorial Epidemiologists
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Suite 303
Atlanta, GA 30341

August 18, 2010

Dear Mr. McConnon:

I would like to thank you for your correspondence to Dr. Hamburg sharing CSTE's position statements on improving investigations of transfusion and transplant transmitted infections. Your letters were forwarded to the Center for Biologics Evaluation and Research (CBER) within the Food and Drug Administration (FDA) for reply. We share and support the concerns you have raised in your letters and hope the following information will help address these issues.

The Department of Health and Human Services (HHS) and the Public Health Service (PHS) agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and FDA) cooperate closely to ensure that there is awareness of emerging infectious threats, that relevant research is performed as needed and that appropriate interventions are put in place. While there is overlap, the CDC has a primary responsibility for surveillance and risk assessment; NIH is charged with basic research; and the FDA is responsible for establishing policies that will ensure the safety of blood and tissue products for patients who need these products. FDA accomplishes this by issuing regulations and/or guidance/recommendations to blood centers and tissue establishments to reduce risk and prevent transmission of disease to recipients by identifying infectious donors. In addition, Health Resources and Services Administration (HRSA) is the agency responsible for oversight of organ procurement and transplantation. You may find it beneficial to contact them directly in this regard.

Both FDA and CDC participate on a committee called the PHS Blood, Organ, and Tissue Safety Working Group (PHS-BOTS), which has representatives from HHS and the PHS agencies. The committee meets monthly to discuss actual and possible threats to blood, tissue, and organ product safety and availability, as well as intervention strategies. The PHS-BOTS reports to the Assistant Secretary for Health's Blood, Organ, and Tissue Senior Executive Council. Additionally, a sub-group of PHS-BOTS meets periodically to examine blood safety threats from infectious agents and brings any such issues to the attention of the larger group. The two CSTE position statements were presented and discussed at the most recent PHS-BOTS meeting on July 29, 2010. Additional follow-up is planned, and FDA will support CDC in its efforts to meet the objectives outlined by CSTE.

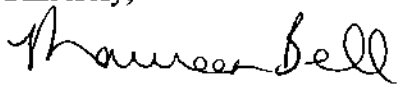
Two ongoing federal initiatives are especially relevant to the objectives of these position statements. First, HHS in cooperation with the PHS agencies has strongly endorsed and supported a national "biovigilance" initiative to improve reporting of adverse events related to transfusion and transplantation. A comprehensive national biovigilance gap assessment white paper was co-chaired by CDC and FDA and can be found at: http://www.hhs.gov/ophs/bloodsafety/biovigilance/index.html. The voluntary, anonymous "hemovigilance" part of the national program was designed as a module within the National Healthcare Safety Network at CDC. This effort was piloted successfully last year and has now started to collect comprehensive data from hospitals regarding transfusion related adverse events, including possible infectious disease transmissions. FDA actively participates in the Steering Committee for this program.

On the regulatory side, FDA has published a proposed rule Safety Reporting Requirements for Human Drug and Biological Products which proposed requirements for reporting transfusion transmitted infections, including bacterial infections (see regulations.gov FDA-2000-N-0108-0006). FDA also has requirements in 21 CFR Part 1271 Subpart E for investigating and reporting deviations and adverse reactions involving communicable diseases related to HCT/Ps.

In addition to active coordination and sponsorship of discussions among PHS Agencies, FDA also encourages exchange of information on emerging infectious diseases through a variety of venues such as advisory committee meetings like the recent, July 2010, Blood Products Advisory Committee meeting where XMRV and babesia were discussed (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm205013.htm). In addition, recent guidance documents have been published on vCJD and a draft guidance on T.cruzi. FDA also has recently sponsored relevant public workshops e.g. "Emerging Infectious Diseases: Evaluation to Implementation for Transfusion and Transplantation Safety Public Workshop" and "FDA Workshop to Consider Approaches to Reduce the Risk of Transfusion-Transmitted Babesiosis in the United States."

FDA recognizes the need for improved State and Local investigative capabilities for transfusion and transplant transmitted infections, and will actively work with the CDC in assisting the CSTE to develop the tools and resources necessary to conduct future efforts in this critical, but challenging area.

Sincerely,



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