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Dear Dr Parekh:

The Department of Health and Human Services' (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) met in Washington, D.C. on August 22 and 23, 2007. At that meeting, The Committee heard presentations and public comments regarding recent Centers for Medicare and Medicaid Services' (CMS) ruling related to the use of Erythropoiesis Stimulating Agents (ESA) and the elasticity of the blood supply to meet potential disasters.

After deliberating, the Committee developed and unanimously accepted the following two recommendations on ESA therapy for your consideration.

The Committee believes that there is inadequate information to accurately assess the impact of CMS's National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESA) on the management of anemia in the general patient population and in cancer patients.

1. Whereas, the revised position on ESA coverage may increase blood demand, ACBSA recommends HHS perform an analysis of the impact of ESA NCD on blood demand in affected patient populations. The information needed should be derived from prospective data collection.
2. Whereas current demand for transfusion in various patient groups is not well characterized and varies with local practices, including adherence or non adherence with available transfusion guidelines, the ACBSA recommends HHS support studies to identify and characterize transfusion practices in relation to clinical outcomes in patient groups affected by the NCD, e.g., survival, quality of life (using validated instruments), adverse events, including cardiovascular events.

The Committee also heard from speakers on the status of the Nation's blood inventory system including readiness for meeting emergencies. It is clear to the Committee that while we have the beginnings of a system for assessing and maintaining blood inventories, further refinement is needed to improve our ability to respond to potential challenges. The Committee offered the following resolution regarding blood inventory.

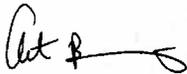
Whereas the blood supply is a critical part of the Nation's healthcare infrastructure, the HHS ACBSA believes that knowledge of real-time national blood and blood product inventory and its dynamics is essential for emergency preparedness and response. The committee finds that blood center data are extensive, but not comprehensively aggregated nor available to HHS; hospital data reporting is essential, but limited. Although the blood supply is elastic, it is unclear whether it is sufficiently elastic to address potential disasters.

The Committee recommends that:

1. HHS establish sufficient hospital and blood center participation in inventory reporting to allow accurate determination of national blood and blood product inventory as a trigger for efficient local, state, and federal responses.
2. HHS develop comprehensive models to address and respond to needs for blood and related critical materials in a variety of surge, donor depletion and other threat conditions to accurately cover blood needs.
3. HHS work with the blood community to define shortage scenarios that would require implementation of alternative strategies for blood collection, distribution, and use.
4. HHS support operations research to characterize and recruit potential donors who do not now routinely donate.

We feel that the recommendations made above will be important in ensuring providing optimal patient care and safeguarding the Nation's blood resources. If you need more information on this issue, please let me know.

Sincerely,



Arthur W. Bracey, M.D.
Chair, HHS ACBSA