The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB’s highest priority has been to maintain and enhance the safety and availability of the nation’s blood supply.

As communities across the United States continue to face real and potential blood shortages, we believe it is critical that the Food and Drug Administration (FDA) and the blood community carefully evaluate the need for donor deferral policies affecting individuals with tattoos, body piercing, and a history of acupuncture. The impact of such policies on both blood safety and availability must be considered.

The AABB’s Standards for Blood Banks and Transfusion Services require a 12-month deferral of potential blood donors after application of body art. This includes tattoos and body piercing. The same deferral is required for acupuncture. The issue of recent tattoos and body piercing as cause for temporary deferral of otherwise qualified volunteer whole blood donors was referred to the CBER by the Transfusion Transmitted Diseases Committee of the AABB when we began to receive requests for variances from our Standards based upon the growth of state regulation of these activities.

The National Environmental Health Association developed its Body Art Model Code and Guideline in December 1997 to assist states in regulating body piercing, and it is being used by many jurisdictions as they promulgate codes.
The argument is that given current test performance, in jurisdictions where appropriate regulation of the sterility of equipment is combined with verifiable inspection regimes, there should be no concern about the transmission of blood borne infection, and donors with recent tattoos or decorative body piercing should be acceptable donors.

While there is no doubt that tattooing and body piercing can transmit hepatitis viruses, that is not the issue in this controversy. The current issue is whether this is a significant enough route of blood borne pathogen transmission in the United States to justify blood donor deferral? We are greatly reassured by past data from CDC, especially the Sentinel County Studies, suggesting these are not common routes of transmission of blood borne pathogens. Data to the contrary seem dated or subject to confounding by the stigma of admitting to the more important behavior, injection drug use. We look forward to the results of ongoing CDC studies of HCV prevalence and associated behaviors in college students.

We remain concerned about the level of certainty that licensed body art establishments would maintain acceptable hygienic practices between inspections, the effectiveness of enforcement of state promulgated licensing strategies, and the accuracy of the donor’s knowledge regarding the licensure status of an individual establishment. Without generally agreed upon criteria, quality assurance and compliance personnel will have to make arbitrary decisions concerning compliance.

In light of these concerns, the AABB has not granted variances from the Standards, and proposed that FDA sponsor a public discussion of these issues. We would rather not grant such variances, but instead would like some framework for their acceptance from CBER and the Office of Blood.

The number of potential donors impacted is not small. In a recent study, 25% of men and 33% of women at a small Midwest private college had at least one tattoo or body piercing (Forbes, GB. Psychol Rep 2001 Dec;89(3):774-86). Another study of university students in New York State found prevalences of 51% and 23% for body piercing and tattooing respectively (Mayers, LB et al. Mayo Clin Proc. 2002. 77:29-34). A survey of the member of America’s Blood Centers this year, if generalized to the entire blood supply, suggests there may be as many as 114,000 deferrals annually for application of body art.

Deferral for acupuncture raises many of these same issues, and the AABB has likewise received many letters requesting that acupuncture, particularly in a medical setting, not be a cause for deferral. Again, we would like some framework from CBER in order to effect that change.

Relaxing a Standard that seems to have served us well deserves broad public discussion and analysis of data to be followed by a commonly accepted and medically defensible policy

Thank you for your consideration of this matter.