

Testimony of Hank Hanna, MD - May 6, 2015

Chair Monnes Anderson and members of the Senate Health Care Committee, I am Dr. Hank Hanna, Medical Director of the American Red Cross Pacific Northwest Blood Services Region.

Donor Safety and the Safety of the Blood Supply

House Bill 2541-A would not enhance donor safety or the safety of the blood supply, and it would place unnecessary constraints on blood collections in Oregon. The top priority of the Red Cross is the safety of blood donors and the recipients of blood and blood products.

First, all blood collection organizations are regulated by the Food and Drug Administration (FDA). The applicable regulations for donor suitability and blood collections are contained in Title 21 of the Code of Federal Regulations. All blood banks, including the Red Cross, are subject to regular inspections by the FDA and AABB. In addition, the Red Cross has its own internal auditors for all processes and procedures associated with blood collection – including Donor Complication management.

Second, the Red Cross extensively trains and assesses the competency of its workforce to ensure compliance with the regulatory requirements of the FDA as well as its own high standards of performance. Under our Standard Operating Procedures (SOPs) relating to Donor Suitability and Donor Complication management, Collections staff undergo extensive training, including both classroom and on-the-job training before being released to perform tasks independently. Competency assessment occurs during the initial training period, and continuing competency assessments occur at periodic intervals throughout each year of employment.

Moreover, each Red Cross Blood Services region has dedicated physicians available 24-hours-a-day to consult on any medical concerns relating to blood drives. Our Donor and Client Support Center (DCSC) is staffed 24-hours-a-day, seven-days-a-week with Donor Suitability specialists and Donor Complications specialists who are able to provide telephone consultation to Collections staff regarding any matters that may arise during blood drives. DCSC staff also provides toll-free telephone consultation to donors who may have questions or concerns after leaving the blood drive collection site. For donors who may

have contacted our DCSC, the staff remains in contact either by phone or written communication until the matter is resolved. Red Cross physicians are available to assist DCSC staff 24-hours-a-day as needed.

And finally, the Red Cross tracks donor complication data through the Red Cross Biomedical Headquarters Hemovigilance Program. There are some variations among Red Cross regions, with most donor complications being mild in nature, like lightheadedness, and brief in duration.

The chart submitted with my written testimony shows major donor complication rates across the national Red Cross system are low – ranging from 10 to 25 per every 10,000 blood collections in FY13. In fact, donor complication rates in California and the Pacific Northwest, where the Red Cross currently deploys licensed staff on blood drives, are near the upper end of that range.

While the rates vary from region to region, the data from the Red Cross Hemovigilance Program show that regions with unlicensed Collections staff have similar rates of donor complications or lesser rates of donor complications as those regions with a combination of unlicensed staff and licensed staff (Registered Nurses; Medical Technologists/Clinical Laboratory Specialists; Licensed Vocational Nurses/Licensed Practical Nurses). There is simply no evidence that supports the contention of enhanced safety by having licensed staff on hand at blood drives.

Therefore, the Red Cross opposes House Bill 2541-A as it would not enhance donor safety or the safety of the blood supply, and it would place unnecessary constraints on blood collections in Oregon.

Thank you for the opportunity to testify before you today.