America's Blood Centers
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1717 K Street NW, Suite 900, Washington, DC 20006
Tel: 202-393-5725 | Fax: 202-899-2621
www.AmericasBlood.org

Comments: FDA Roundtable: Strengthening the Supply Chain for Blood Manufacturing

Kate Fry, MBA
Chief Executive Officer
America's Blood Centers
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Good afternoon. America's Blood Centers appreciates the opportunity to comment as part of this roundtable discussion. We also thank the FDA for convening industry, government, and blood community stakeholders on this issue, and for FDA's ongoing work to harmonize data standards and advance innovative product approvals that benefit patients and donors.

My name is Kate Fry, and I serve as CEO of America's Blood Centers (ABC). ABC is the national organization representing community-based, independent, nonprofit blood centers that collect close to 60 percent of the nation's blood supply across more than 1,100 communities, supporting some 3,500 hospitals. We offer these comments to ensure that community blood centers are fully represented in federal supply chain policy decisions, as our members are responsible for managing the effects of disruptions on the supply chain to ensure a safe and reliable blood supply. Today, my comments address three main topics: (1) redundancy, (2) a comprehensive ecosystem view, and (3) an early-warning system.

First is redundancy to support business continuity. As you have heard repeatedly today, the blood community has extremely limited suppliers for essential products and services critical to a robust blood supply, with market economics and regulatory complexity creating significant challenges for new entrants to the market. Lean, just-in-time manufacturing has made this worse, not better. As recommended by the ACBTSA in 2020, we ask FDA, ASPR, and HHS to map existing alternative manufacturing sites and identify the specific product codes, such as plastics, testing reagents, and ancillary supplies, that could be cross manufactured at those sites, and to preserve FDA's flexibility to authorize alternate sites quickly when disruption hits. Additionally, Recommendation 4.2 of HHS' Report to Congress on the Adequacy of the National Blood Supply recommends the creation and funding of a public-private task force to "develop and maintain industry-wide business continuity plan that incorporates all necessary supplies for blood collection and storage." Once established, simulation exercises should be conducted to test and refine the plans.

Second, to build resilience, we must examine the vein-to-vein ecosystem of the blood community. Solutions focused narrowly on incentivizing a single input, such as blood

bags, will not produce long-term resilience. ABC conducted work in 2022 that found the supply chain breaks down at only 10 to 20 percent above base production levels, underscoring how little margin exists. Therefore, we ask HHS and ASPR to promote policies for the blood ecosystem as a whole, including donors, workforce, reagents, computer systems, and cold chain together.

Third, we must strengthen the early-warning system for supply chain disruptions. Today, we rely on manufacturers notifying FDA, FDA publishing, and manufacturers separately notifying their clients. While blood and blood components are covered under Section 506C of the FD&C Act, the collection and manufacturing supplies blood centers depend on are largely regulated as devices, and mandatory notification under Section 506J applies only during or in advance of a declared public health emergency, so the gradual supplier exits that most threaten supply in ordinary times often trigger no required notice at all. Additionally, while the Section 506J device list includes certain blood transfusion and collection-related devices, it does not include many of the critical devices used for blood collection and blood-component manufacturing that ABC specifically requested FDA to add in 2024. Therefore, we request that FDA include blood collection and manufacturing supplies, by product code, on the Section 506J device shortage-notification list and support extending mandatory notification beyond declared public health emergencies.

Our core ask that ties all of the aforementioned requests together includes the following: ensure blood and blood products and their critical manufacturing inputs are incorporated into the essential medicines supply-chain resilience framework that CMS and other federal agencies rely on, the ASPR-sponsored Essential Medicines Supply Chain and Manufacturing Resilience Assessment (2022), from which blood and blood products were expressly excluded. This will allow blood and blood products to qualify for the same supply chain protection as other essential medicines.

Resilience is not built during a crisis; it is funded before one occurs. The U.S. blood supply is a public necessity that underpins trauma care, surgery, cancer treatment, maternal health, emergency response, and military readiness. America's Blood Centers stands ready to partner with FDA, HHS, and industry to strengthen the supply chain that makes lifesaving blood available when patients need it most. We appreciate the agency's attention to these comments and welcome the opportunity to provide further details.

Respectfully submitted,

Kate Fry, MBA
Chief Executive Officer
America's Blood Centers