

# **Opposition to State Legislation Mandating Labeling of Blood Products Based on Donor Vaccination Status for Autologous and Directed Donations:**

## **A Position Statement of the College of American Pathologists (CAP)**

### **Problem**

Since the COVID-19 pandemic, misinformation surrounding COVID-19 and mRNA vaccines has led to a growing number of patient requests for blood transfusions exclusively from unvaccinated donors.<sup>1,2</sup> In response, several states have proposed legislation requiring blood product labeling based on donor vaccination status or mandating hospitals and blood collectors to honor requests for directed and autologous donations. These legislative efforts do not offer any proven public health or individual benefit, and instead pose serious risks to the availability, safety, and sustainability of the blood supply while driving up costs and increasing waste.

### **Background**

#### **Labeling of Blood Products Based on Donor Vaccination Status**

Extensive research has shown no increased risk associated with transfusions from donors who have had COVID-19 or who have received a COVID-19 vaccine.<sup>3,4</sup> There is no evidence to suggest that SARS-CoV-2 can be transmitted through blood transfusion,<sup>1</sup> nor is there any medical reason to differentiate or exclude donations based on vaccination status.<sup>5</sup>

Blood products are a critical, time-sensitive medical resource. Platelets, for example, have a shelf life of only five days, making it *impossible* to reliably segregate or reserve vaccine-free platelet components. Any attempt to do so would severely limit availability and inevitably result in shortages, especially for patients requiring urgent care such as those undergoing chemotherapy, trauma surgery, or transplant.

With over 80% of the U.S. population having received at least one COVID-19 vaccine dose,<sup>6</sup> the national blood supply is dependent on the participation of all eligible donors. Blood donations are stringently regulated by the FDA, with oversight and accreditation from the Association for the Advancement of Blood and Biotherapies (AABB) and the College of American Pathologists (CAP). Blood products frequently cross state lines to meet clinical needs, especially during regional shortages or emergencies, and must comply with standardized federal labeling regulations.

Currently, there is no validated test to determine vaccine status from a blood donation. Reliance on self-reported history is neither accurate nor feasible as a basis for labeling. Any effort to label or restrict blood based on presumed vaccination status would be scientifically unjustified and operationally unmanageable.

Moreover, individualized labeling mandates by state would require costly infrastructure overhauls, including IT system changes, staff retraining, and the creation of entirely new inventory tracking mechanisms. These expenses would ultimately be borne by the healthcare system. Segregating blood products on non-scientific grounds would also increase storage complexity, strain supply chains, and lead to greater product expiration and waste.

### **Requiring Access to Directed and Autologous Donations**

Directed and autologous donations are important tools in specific medical scenarios, such as when a patient has rare antibodies, but they are resource-intensive and not suitable for routine use. The vast majority of patients receive life-saving transfusions from the community blood supply, which is exceptionally safe and must remain the primary focus of donor collection efforts. Less than 0.04% of transfusions each year involve autologous or directed blood. A widespread shift toward such requests—particularly for non-medical reasons such as donor vaccination status—would overwhelm collection centers and jeopardize timely care for all patients.

Directed donations can also pose greater risks. A family member may not be a compatible or safe donor, or may unintentionally introduce complications, such as alloimmunization. For example, a directed donation from husband to wife could increase the risk of Hemolytic Disease of the Fetus and Newborn in future pregnancies. Medical professionals must prioritize both donor and recipient safety when evaluating these requests.

### **Conclusion**

The U.S. blood supply is among the safest in the world.<sup>8</sup> Blood donated by individuals who have received a COVID-19 vaccine authorized for use in the U.S. is safe for transfusion. Legislation mandating the labeling of blood products based on donor vaccination status or requiring the routine availability of directed or autologous donations offers no proven benefit and could significantly destabilize the blood supply system. These proposals threaten to reduce availability, increase costs, introduce waste, and delay life-saving care—particularly for products like platelets, where availability is already time-critical. We urge policymakers to consider the overwhelming scientific and logistical evidence and to protect the integrity and safety of the national blood supply.

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