My name is Brian Gannon, and I am the Chief Executive Officer of the Gulf Coast Regional Blood Center and the chair of the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (Task Force). I am pleased to provide this statement to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) in my capacity as the chair of the Task Force and on behalf of myself and the vice-chair of the Task Force, Leo Debandi. I will provide the Committee with background information about the Task Force, and will then address the following three questions related to the COVID-19 pandemic response, including:

1. WHAT WORKED WELL AND ARE STRENGTHS TO BUILD UPON FOR FUTURE PUBLIC HEALTH EMERGENCIES?

2. WHAT WEAKNESSES WERE IDENTIFIED THAT THREATENED OR COULD THREATEN THE SAFETY AND AVAILABILITY OF THE BLOOD SUPPLY AND PATIENT CARE?

3. WHAT ARE THE TOP THREE TO FIVE RECOMMENDATIONS TO ACHIEVE IN THE NEXT 2-4 YEARS TO INCREASE OUR PREPAREDNESS AND CARE FOR PATIENTS?

BACKGROUND

The Task Force was established in January 2002 to help ensure that blood collection efforts resulting from domestic disasters and acts of terrorism are managed properly and to deliver clear and consistent messages to the public regarding the status of America’s blood supply. The Task Force is composed of representatives from U.S. blood services, associations and commercial entities, as well as liaisons from governmental agencies, who work together in an effort to ensure that safe and adequate blood product inventories are in place at all times in preparation for disasters. In addition, the Task Force operates as a mechanism to assess the need for collections or transportation of blood should a disaster occur.
AABB serves at the designated coordinating entity for the Task Force. Members of the Task Force’s Critical Events Assessment Group (CEAG) include America’s Blood Centers, the American Red Cross, and Blood Centers of America as well as liaisons from the Armed Services Blood Program and the U.S. Department of Health and Human Services/Office of the Assistant Secretary for Health (OASH). Additional members of the Task Force include the American Hospital Association, the College of American Pathologists, AdvaMed, the National Marrow Donor Program and the Plasma Protein Therapeutics Association as well as liaisons from the Centers for Disease Control and Prevention and the Food and Drug Administration.

In the event of an emergency, AABB immediately convenes a meeting of a subgroup of the Task Force, including the CEAG, FDA and CDC. Local blood centers are responsible for ascertaining medical needs based on casualty estimates using pre-determined formulas, assessing available local supply, and communicating that information to the Task Force through a reporting organization. The subgroup of the Task Force determines the strategy and coordination efforts, including: (1) constructing a message to blood community and donors; (2) coordinating a broad public message in conjunction with HHS; (3) transporting and coordinating needed blood to the affected area; and (4) determining next steps until event has been resolved. They communicate these recommendations to the other members of the Task Force if needed.

1. WHAT WORKED WELL AND ARE STRENGTHS TO BUILD UPON FOR FUTURE PUBLIC HEALTH EMERGENCIES?

The Task Force enabled the exchange of timely information on the status of the blood supply and facilitated a rapid, organized response to the COVID-19 pandemic. Building on processes and procedures that have been established over nearly two decades, the Task Force rapidly mobilized at the beginning of the pandemic after a blood center in the initial hotspot, Washington state, reported that the blood supply was threatened. The blood center reported experiencing a sharp drop in blood donation and they were unable to meet the supply needs of their hospitals. The CEAG activated the Task Force after the blood center’s request could not be fulfilled through routine channels, thereby qualifying the event as a disaster. Individual members of the Task Force have significant expertise in helping the blood community prepare for and respond to public health emergencies, which was essential to developing a strategy to respond to the emerging crisis. The Task Force contacted and coordinated with blood centers across the nation and helped avoid a blood shortage in the impacted area by directing blood to the affected blood center.

At that same time, blood donation across the country began dropping as blood drives and blood donation appointments were cancelled due to social distancing policies and remote working arrangements quickly taking root. The Task Force’s unique public-private composition enabled the private sector and the government to quickly come together and use the resources of the different member organizations to identify opportunities to support the nation.
Additionally, the Task Force is uniquely positioned to provide a consistent message to the blood community and the public on the status of the blood supply during a disaster or public health emergency. The Task Force issued multiple public messages throughout the pandemic, which included appeals for blood donors and messages supporting the safety of blood donation during the pandemic. Additionally, individual member organizations of the Task Force mobilized and worked together to engage in a wide range of activities to support the continued adequacy of the blood supply. The coordinated messages, in conjunction with activities and consistent messages by individual blood centers, Task Force member organizations, national associations, the Surgeon General, several federal agencies, members of Congress and other federal, state and local policymakers, resonated with the public and helped ensure the continued adequacy of the blood supply.

Importantly, individual blood centers have been responsive throughout the pandemic, and should be commended for ensuring the continued safety and adequacy of the blood supply. Blood centers responded to the Task Force’s call to action by sending blood to areas with critically low supplies. They also worked tirelessly with their local communities and policymakers to raise awareness of blood donation, continue making blood available for patients throughout the country, and successfully manufacture COVID-19 convalescent plasma, a first line investigational treatment for patients with COVID-19.

2. WHAT WEAKNESSES WERE IDENTIFIED THAT THREATENED OR COULD THREATEN THE SAFETY AND AVAILABILITY OF THE BLOOD SUPPLY AND PATIENT CARE?

The most significant challenge the Task Force faced while responding to the COVID-19 pandemic was the absence of accurate, comprehensive, and timely data on the blood supply. While the current process provides a benchmark for the Task Force, there are limitations with the data. Daily reporting by blood centers is manual and is not uniform across the industry. Not every center reports its inventory daily, organizations report inventories differently, and an old formula – developed over 15 years ago – is used to estimate the inventory levels and ABO distribution of blood on the shelf. Additionally, the Task Force does not have data that reflects hospitals’ inventories, which is significant because hospitals hold most of the nation’s blood.

Thus, the Task Force does not have access to detailed, complete national level blood product inventory data beyond macro-trends and is limited in its ability to continuously assess the status of the blood supply in real time. During the COVID-19 pandemic, FEMA requested a single-line assessment of the blood inventory daily and the Task Force was limited in what it was able to provide. While the Task Force provided FEMA with estimates based on the available information, the limitations with the current data made it impossible to precisely reflect the available blood supply at national or regional levels.
The Task Force was also challenged by the lack of real time data on blood utilization and inconsistent coordination between hospitals and blood centers on the evolving changes in the blood supply and utilization. Around the same time as the initial drop in the blood supply and significant outreach efforts previously described, hospitals stopped performing non-emergent procedures and services leading to a sharp decline in blood utilization. After a few months, non-emergent procedures and services resumed, and there was an increase in utilization. The absence of real time data on blood utilization and inconsistent coordination between hospitals and blood centers on the status of non-emergent procedures and services made it impossible to continuously and accurately assess whether the available blood supply was capable of meeting demand.

The blood community experiences ongoing challenges with effectively communicating the status of the blood supply to the public. While harmonious national donor awareness messaging was generally a strength of the response to the pandemic, some inconsistent messaging in local communities had the potential to negatively impact the status of the blood supply by causing donor confusion or fatigue. Additionally, the Task Force’s press releases do not always generate the needed media or public attention and are not intended to address systemic challenges with collections and donor recruitment. The Task Force continues to work with organizations throughout the blood community to ensure consistent, effective messaging on the status of the blood supply during disasters.

The COVID-19 pandemic highlighted vulnerabilities throughout the blood supply chain that have the potential to threaten blood safety and availability as well as patient care, such as:

- Challenges with the continuous recruitment of eligible donors, and the need for public awareness efforts to promote a robust donor base and encourage young and minority donors;
- Not prioritizing blood centers for supplies, such as PPE, saline, reagents and vaccines;
- Challenges with transportation of blood products and testing samples if commercial flights and courier services are disrupted and by local couriers in disaster zones; and
- Blood centers’ reliance on sole-sourced products, such as the Fresenius-Kabi blood bag. Fresenius-Kabi has excellent business continuity plans, but if their manufacturing operation in Puerto Rico/Dominican Republic is compromised there is very little inventory in the system to prevent supply disruptions.

3. WHAT ARE THE TOP THREE TO FIVE RECOMMENDATIONS TO ACHIEVE IN THE NEXT 2-4 YEARS TO INCREASE OUR PREPAREDNESS AND CARE FOR PATIENTS?

I recommend that the Department of Health and Human Services (HHS) increase the nation’s preparedness and care for patients by establishing a system that makes available real-time,
comprehensive data on the blood supply, strengthening the resiliency of the blood supply chain and dedicating funding to support the infrastructure of the Task Force.

**HHS should dedicate funding to modernize the system used to report the available blood supply, and maintain an automated system that includes real-time, comprehensive, accurate data on blood inventories.** A data infrastructure to monitor the status of the blood supply would inform the Task Force’s operations and significantly improve our ability to ensure that blood is continuously available to meet patients’ needs. The system should include both blood centers’ and hospitals’ inventory data to provide a comprehensive understanding of blood availability. Additionally, data on platelets would be beneficial, as platelet availability is often a challenge during disasters.

Importantly, many blood centers and hospitals consider their blood inventories to be proprietary and confidential. Therefore, it is essential that a national level blood inventory system ensures the confidentiality of reporting entities’ inventories and protects the security of the data.

**HHS should develop policies and invest resources to strengthen the resiliency of the entire blood supply chain.** HHS should ensure the continuity of blood centers’ operations during disasters and public health emergencies by updating policies to prioritize blood centers’ access to PPE, blood bags, saline, reagents, vaccines and other critical supplies. Additionally, HHS should consider establishing a national stockpile of PPE, whole blood bags, and other key supplies that are hard to get during crises, critical to continuing safe blood collection, or have the potential to disrupt the entire blood supply if manufacturing facilities are compromised. HHS also should ensure that blood centers have priority access to transportation so that blood continues to be available to patients.

Donors are the irreplaceable beginning of the blood supply chain. HHS should dedicate funding to support national blood donor awareness efforts, which can be amplified if the blood supply is challenged due to a disaster or emergency.

**Additionally, HHS should dedicate funding to support the Task Force’s infrastructure, which would enable innovation and potential automation of some of the Task Force’s activities.** Similar to all organizations throughout the blood community and healthcare system, the COVID-19 pandemic response helped highlight strengths of the blood system and the Task Force as well as opportunities for improvement. The Task Force was formed after 9/11, and over the past two decades the entire healthcare industry, including the blood sector, has radically changed.

In the aftermath of the pandemic, we look forward to working with our public partners as well as blood centers, hospitals, device and testing manufacturers and other organizations throughout the blood community to thoroughly review and evolve the Task Force to ensure that it continues to meet the needs of the blood community and the nation.