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PUBLIC HEALTH

Maintaining an Adequate
Blood Supply Is Key to
Emergency Preparedness

Statement of Janet Heinrich
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Mr. Chairman and Members of the Subcommittee:

I am pleased to have the opportunity to testify as the Subcommittee considers the blood supply and its adequacy to meet the nation's emergency needs. The terrorist attacks of September 11, 2001, reminded the nation of the critical importance of a safe and adequate supply of blood for transfusions. In recent years, an average of about 8 million volunteers have donated more than 14 million units¹ of blood annually, and approximately 4.5 million patients per year have received life-saving blood transfusions, according to the American Association of Blood Banks (AABB).² About 90 percent of the U.S. blood supply is collected by two blood suppliers, the American National Red Cross and independent blood banks affiliated with America's Blood Centers (ABC). Within the federal government, the Food and Drug Administration (FDA) is responsible for overseeing the safety of the nation's blood supply. The surge in donations after the terrorist attacks added an estimated 500,000 units to annual collections in 2001. The experience illustrated that large numbers of Americans are willing to donate blood in response to disasters. However, because very few of the units donated immediately after September 11 were needed by the survivors, this experience has also raised concerns among blood suppliers and within the government about how best to manage and prepare the blood supply for emergencies.

Today we are releasing a report that summarizes several issues regarding blood safety and availability.³ My comments will focus on three of the topics addressed in our report: the adequacy of the blood supply, the response of the blood suppliers to the September 11 attacks, and their planning for future emergencies. Our report also describes recent changes in the price of blood and evaluates the potential impact of the new guidance from FDA that is aimed at reducing the risk of transmitting variant Creutzfeldt-Jakob disease, the human form of "mad cow" disease, through blood transfusions.

¹A unit equals 1 pint.

²AABB is the professional and accrediting organization for blood suppliers and transfusion services.

³U.S. General Accounting Office, *Public Health: Blood Supply Generally Adequate Despite New Donor Restrictions*, [GAO-02-754](#) (Washington, D.C.: July 22, 2002).

In brief, available data indicate that the blood supply has increased in the past 5 years and that it remains generally adequate. Blood collections increased 21 percent from 1997 to 2001, and collections in the first half of 2002 appear to have been roughly equivalent to the same period in 2001. There has been a corresponding rise in the number of transfusions from 1997 to 2001. Although local and temporary blood shortages occur from time to time, the inventory of blood in America's hospitals was at historically high levels before September 11 and has generally remained adequate through the first 8 months of 2002. In the weeks immediately following September 11, blood collections increased nearly 40 percent over collections earlier in 2001. Because only a small amount of blood was needed to treat survivors of the attacks, a nationwide surplus developed, which stressed the collection system. We estimate that about five times the usual proportion of units of blood became outdated and had to be discarded in the months following September 11. Monthly blood collections returned to preattack levels by November, following the pattern of collections after earlier emergencies. Blood suppliers and the federal government have begun to reevaluate how blood is collected during and after disasters to avoid repeating this experience and also to ensure that enough blood is available during emergencies. A task force including members from federal agencies and blood suppliers has been formed to coordinate the response in future emergencies to the need for blood. Insights from the experiences of September 11 and other disasters have led the task force to conclude that the need for blood in most emergencies can be best met by maintaining an adequate blood inventory at all times, rather than by increasing blood collections following a disaster.

Background

Sixty percent of the U.S. population is eligible to donate blood, but in any given year only about 5 percent of those who are eligible actually do so.⁴ Eighty percent of donors are repeat donors. A typical donor gives blood approximately 1.6 times per year, but donors may give 6 times per year, or every 8 weeks, which is the period the body needs to replenish red blood cells.

The two largest blood suppliers, the Red Cross and ABC, each collect about 45 percent of the nation's blood supply, and roughly 10 percent is supplied by other independent blood centers, the Department of Defense, and

⁴To be eligible to donate, a person must be at least 17 years of age, weigh at least 110 pounds, be in good physical health, and provide a medical history.

hospitals that have their own blood banks. Suppliers test, process, and store the blood they collect, and ultimately sell it to health care providers. Liquid red blood cells have a shelf life of 42 days, and a small proportion of the blood collected is not used during that period and is discarded. Most hospital transfusion services purchase blood and blood components under a contract with a local supplier, which describes the price and quantity of blood to be delivered. Blood suppliers use resource-sharing programs to help distribute blood from low-demand to high-demand areas. Taken together, the Red Cross, ABC, and AABB's National Blood Exchange redistributed about 1.4 million units of blood—over 10 percent of the nation's supply—among blood banks in 2000. In addition, the Red Cross has a nationwide inventory control system to facilitate the movement of its surplus blood.

Under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act, FDA regulates and licenses blood and blood products to ensure that they are safe. FDA has no authority to determine the amount of blood that should be collected or to compel suppliers to make products available. However, it can make recommendations related to the availability of blood during public health emergencies.⁵ For example, after the September 11 attacks, FDA issued emergency guidelines to speed the delivery of blood to areas affected by the attacks. Also within the Department of Health and Human Services (HHS), the Advisory Committee on Blood Safety and Availability provides advice to the Secretary of HHS and to the Assistant Secretary for Health on various issues involving the blood supply, including economic factors affecting cost and supply, as well as public health, ethical, and legal issues related to blood safety.

The Blood Supply Has Increased and Remains Generally Adequate

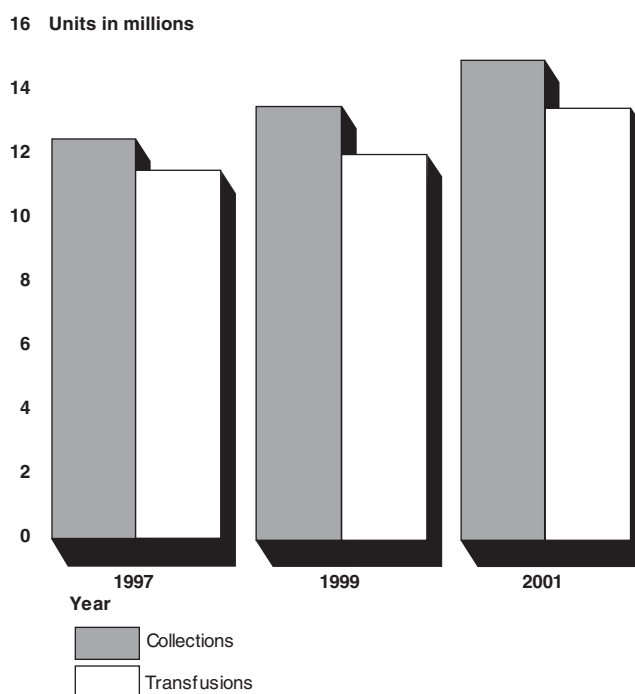
Available data indicate that the nation's blood supply has increased and remains generally adequate. Although local and temporary blood shortages occur from time to time, the inventory of blood in America's hospitals was at historically high levels before September 11 and has remained adequate through the first 8 months of 2002.

Although no one data source has comprehensively tracked the nation's blood supply in the past, all of the sources we identified indicated that the national supply has grown in recent years and was at historically high

⁵For example, see 42 U.S.C. §247d (1994).

levels before the surge in donations that occurred after September 11. Annual blood collections have increased substantially—21 percent—since 1997, according to National Blood Data Resource Center (NBDRC) measurements and estimates of annual blood collections by all blood centers. (See fig. 1.) The number of units of blood collected annually increased from 12.4 million in 1997 to an estimated 15 million in 2001. (NBDRC estimated that 2001 collections would have reached 14.5 million units, 17 percent higher than in 1997, without the post-September 11 surge.)

Figure 1: Units of Blood Collected and Transfused, 1997 to 2001



Note: Collection data do not include autologous donations (that is, donations in which the blood donor and transfusion recipient are the same) of whole blood and red blood cells.

Source: NBDRC.

The increase in the blood supply has been echoed by a corresponding increase in the amount of blood transfused. (See fig. 1.) For example, NBDRC data indicate that the number of red blood cell units transfused rose 17 percent from 1997 to 2001, from 11.5 million to 13.5 million units.

The annual number of units that were available but not transfused remained at about 1 million units.

Blood inventories were generally adequate just prior to the September 11 attacks. The Red Cross reported that its total red blood cell inventory was 33 percent higher in August 2001 than it was in August 2000 and that its type O inventory was 83 percent higher than it was in August 2000. The New York Blood Center (NYBC) reported that it had a 4- to 5-day supply of blood on hand in early September 2001. On September 10, 2001, the median inventory for the hospitals in HHS's Blood Sentinel Surveillance System for all blood types stood at approximately 7 days, and for type O Rh-negative blood, at 6 days.⁶

The limited information available to us indicates that blood collections to date in 2002 have been roughly comparable to the levels immediately prior to September 11. According to NBDRC data, collections for the first half of 2002 have been similar to the same period in 2001. The hospital inventories measured by HHS's Blood Sentinel Surveillance System in mid-August 2002 were similar to those levels measured just prior to September 11, 2001.

Blood Collected in Response to September 11 Stressed Collection System and Resulted in Surplus

The high volume of blood donations by volunteers immediately after September 11 stressed the collection system and resulted in a national surplus. Monthly blood collections increased nearly 40 percent over collections earlier in 2001 in the weeks immediately following September 11, but there was little additional need of blood for transfusions. The nationwide blood supply was substantially greater than needed for transfusions. Consequently, the proportion of units that expired and were discarded in October and November 2001 was five times higher than the proportion that expired in an average 2-month period earlier in 2001.

America's blood banks collected an unprecedented amount of blood in a short period after the September 11 attacks. In response to the perception that blood would be needed to treat victims, Americans formed lines to give blood at hospitals and blood banks even before a call for blood went out. HHS, ABC, and the Red Cross all issued requests for blood donations,

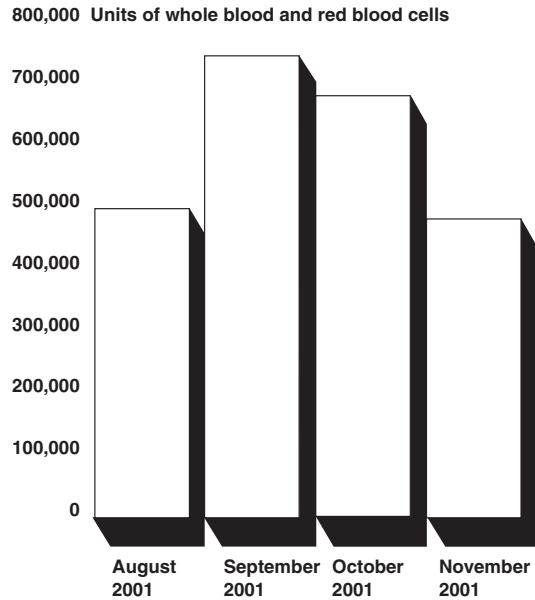
⁶The hospitals in HHS's surveillance system are not a statistically representative sample of the nation's transfusion centers. However, collectively they account for about 10 percent of the blood transfused nationally, and hospitals throughout the country are included in the sample.

although HHS and ABC quickly stopped issuing requests when it became clear that there were few survivors of the attacks and therefore little need for additional blood for transfusions. Many blood suppliers were reluctant to turn away potential donors, however, and some hospitals that did not have their own blood banks responded to the surge in volunteers by collecting blood anyway. NBDRC estimated that total blood collections in the United States were 38 percent higher in September 2001 than average monthly collections earlier in 2001. The Red Cross reported that its national blood collections during the week of September 11 more than doubled compared with the preceding weeks. Estimates of the number of additional units collected nationwide in September and October 2001 in response to the September 11 attacks range from 475,000 to 572,000.⁷ Following the pattern of responses to previous disasters, the sharp increase in blood collections did not last. While higher than usual blood collections continued for several weeks after September 11, the number of units collected had returned to the baseline level or slightly below it by the beginning of November.⁸ (See fig. 2.)

⁷P.J. Schmidt, "Blood and Disaster—Supply and Demand," *New England Journal of Medicine*, vol. 346, no. 8 (2002), 617-20.

⁸Because donors can give blood only every 8 weeks, large numbers of regular donors who give immediately after a disaster may skip their next planned donation, thus causing postdisaster inventory to dip below normal levels.

Figure 2: Volume of Red Cross Collections before and after the September 11 Attacks



Source: GAO calculation from Red Cross data.

This surge of donors stressed the collection system. Shortages in blood collecting supplies, phlebotomists (technicians trained to collect blood), and storage capacity occurred as more potential donors arrived. Long waiting lines developed because there was insufficient staff to draw blood. Increased errors in the collection process at some blood banks accompanied the surge in donations. As much as 20 percent of some blood banks' donations was collected improperly and had to be discarded, primarily because individuals had not completed the donor questionnaire correctly.⁹

Far more blood was collected immediately after September 11 than was needed by survivors or than ultimately could be absorbed by the nation's blood banks. Fewer than 260 units were used to treat victims of the

⁹American Association of Blood Banks: Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, *Report and Recommendations* (Bethesda, Md.: Jan. 31, 2000) http://www.aabb.org/Pressroom/In_the_News/idfddat013002.htm (downloaded on Feb. 5, 2002).

attacks. A portion of the surplus went unused, expired, and was discarded. NBDRC surveyed a nationally representative sample of 26 blood suppliers and found that about 10 percent of the units collected in September and October 2001 by the suppliers it surveyed expired and were discarded. This was nearly a fivefold increase in the proportion of units these suppliers discarded because they had expired in the first 8 months of 2001. Of the roughly 572,000 additional units collected in response to September 11, we estimate that about 364,000 units, or about two-thirds, entered the nation's blood inventory and that approximately 208,000 units, or about one-third, expired and were discarded. All of these figures underestimate the total number of expired units because they represent expirations at blood suppliers only and do not capture units that expired in hospital inventories.

Some blood banks also suffered serious financial losses, as they incurred the costs of collecting and processing units of blood they could not sell. For example, the New York Blood Center claimed it lost from \$4 million to \$5 million and suffered a nearly threefold increase in the number of units it had to discard when blood donated in response to the attack expired.

Blood Suppliers Are Focusing Emergency Planning on Maintaining Adequate Inventory

Incorporating the lessons learned from past disasters, blood suppliers and the federal government are reevaluating how blood is collected during and after disasters and are focusing on maintaining a consistently adequate inventory in local blood banks in preparation for disasters and not collecting more blood after a disaster than is medically necessary.

Since September 11, federal public health agencies and blood suppliers have been critical of their responses to prior disasters and have begun to plan for a more effective response to future emergencies. Through an interorganizational task force organized by AABB in late 2001, the focus has begun to shift away from increasing blood collections in an emergency to maintaining an adequate inventory of blood at all times.¹⁰ This shift was prompted by the realization that a surge in blood collections following a disaster does not help victims because disaster victims rarely require many units of blood and because newly collected blood cannot be used

¹⁰The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. Members include the HHS Office of Public Health Preparedness, FDA, Department of Defense, Centers for Disease Control and Prevention, the Red Cross, and ABC.

immediately.¹¹ For example, as with September 11, only a small percentage of the additional blood collected after the Oklahoma City bombing was transfused into victims (131 units of more than 9,000 units collected). Moreover, the units used to treat victims in the hours after a disaster are those already on hand at the treating hospital or local blood bank.¹² It takes 2 days to completely process and test a unit of newly donated blood, so existing stores of blood must be used to treat disaster casualties. Finally, military experts and blood industry officials told us that it is unlikely a discrete disaster would require more blood than is normally stored in the nation's blood inventory. They noted that large amounts of blood have not been needed in building collapses (like the September 11 attacks and the Oklahoma City bombing), nor would blood transfusions be a likely treatment for illnesses caused by a bioterrorism attack. Nonetheless, disaster scenarios that have not yet been identified may require more blood than is currently envisioned.

A report by the AABB task force made recommendations for the emergency preparedness of the blood supply that were adopted by the HHS Advisory Committee on Blood Safety and Availability. The recommendations are aimed at having federal and other organizations that are involved in the collection or use of blood coordinate their actions in an emergency. For example, the task force recommended that all blood banks—not just the Red Cross as is now the case—be designated as suppliers of blood in an emergency and that the Assistant Secretary for Health serve as the spokesperson for all organizations involved in managing and transporting blood in an emergency. Recognizing that an adequate blood inventory in an affected area is the most important factor in the initial response to a disaster, the task force also recommended that blood banks maintain a 7-day supply of all blood types at all times.

Both the Red Cross and ABC are independently pursuing their own plans to meet emergency and long-term needs. The Red Cross expects to increase annual collections by 9 percent during each of the next 5 years. The Red Cross also plans to implement a “strategic blood reserve” within the next 5 years using preregistered donors and a limited stock of frozen blood cells.

¹¹P.J. Schmidt, “Blood and Disaster—Supply and Demand,” 617-20.

¹²In an emergency, blood that has not been fully tested may be used in lifesaving circumstances. In such circumstances, the requesting physician must sign a statement indicating that the clinical situation is sufficiently urgent to require the release and use of blood before the completion of testing.

ABC has established a “national strategic donor reserve” through which it can call on the donors it has registered, if needed.

Concluding Observations

Although local and temporary blood shortages occur from time to time, America’s blood supply is generally adequate. The blood community’s response to disasters can be improved, and the community is beginning to take the necessary steps to learn from past experiences. The interorganizational task force organized by AABB has involved the blood community in efforts to more effectively plan for future disasters. In addition, the Red Cross and ABC are independently taking steps to meet emergency requirements.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have at this time.

Contact and Acknowledgments

For further information about this testimony, please contact me at (202) 512-7119. Martin T. Gahart, Sharif Idris, and Roseanne Price also made key contributions to this statement.

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