AMERICA'S BLOOD SUPPLY IN THE AFTERMATH OF SEPTEMBER 11, 2001

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES

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AMERICA'S BLOOD SUPPLY IN THE AFTERMATH OF SEPTEMBER 11, 2001

TUESDAY, SEPTEMBER 10, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:07 a.m., in room 2123, Rayburn House Office Building, Hon. James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Burr, Bass, Fletcher, Deutsch, and Strickland.

Staff present: Alan Slobodin, majority counsel; Peter Spencer, majority professional staff; Will Carty, legislative clerk; Chris Knauer, minority counsel; and Nicole Kenner, research assistant.

Mr. GREENWOOD. The hearing will come to order.

Good morning, everyone, and welcome. Our hearing today will center on America's blood supply in the aftermath of the horrific events of September 11, 2001.

We recall the magnificent generosity of our friends and neighbors immediately following the terrible acts of September 11. As President Bush observed in his speech to Congress and the Nation just 10 days after that awful day, "We have seen the state of our union and the endurance of rescuers working past exhaustion. We have seen the unfurling of flags, the lighting of candles, the giving of blood."

We remember the stories and pictures of people from all walks of life donating their blood in New York, here in Washington, and around the country, often waiting in long lines to do so. Many of us here also stood in those lines in the days and weeks after the attacks.

The nationwide donations added up quickly. Upwards of a half million more units of blood were collected in the 2 months following the attacks than was normal for that time of year, almost half again more supply than was usually collected.

Sadly, this tremendous response to help others ran headlong into the limits of our blood supply system to store, maintain, and use donated blood. Thousands of donors were upset to read news reports that a large portion of the blood collected in this period had to be discarded. The system simply couldn't process and use all the blood safely before the value of this precious gift expired.

Many in the blood supply community were also disappointed with such apparent wastefulness. Unlike ordinary citizens, they quickly became aware that there would be few survivors from the

terrorist attacks, and thus only a limited need for emergency blood transfusions; yet, their mixed public responses led to a series of additional problems: strained resources, financial loss, donor confusion, and disenchantment with the system.

We will learn this morning about how actions surrounding the September 11 blood donation response affected future donations. At the time, however, no one could reasonably anticipate the degree of extraordinary public response to pleas for blood donations, nor could anyone be certain in the days and weeks immediately following 9/11 that there would not be further incidents of terrorism that would dramatically increase the demands on our blood supply reserves. So, in that sense, the surplus was a sign of disasters that did not come and lives that were not lost. But the fact remains, the tremendous response to donate blood at that time exposed aspects of the management of our blood supply system that require close scrutiny if we are to improve the system.

The need for and critical value of donated blood cannot be overemphasized. Every 3 seconds a patient in the U.S. requires blood, yet blood is a human tissue that cannot be manufactured, it can only be donated. Currently, only 5 percent of the eligible population donate, yet it is estimated that by the time we reach the age of 65, 60 percent of us will have relied on the use of another person's blood for our own survival. And since blood can be separated into such components as red blood cells, platelets, and plasma, the donation of just one pint of whole blood can help save four lives.

This hearing will provide the subcommittee with an overview of the state of America's blood supply in the context of lessons learned and fixes under way following September 11. Much is involved to ensure that our Nation has a safe and ample supply of blood available to people who need it when they need it. The witnesses before us today possess expert understanding about these matters, and their different perspectives will certainly improve our own understanding. Today's inquiry begins with a look at the preparations by the blood community, including the Federal Government, for future disasters, terrorist attacks, or wars.

By all accounts, the blood community has worked diligently to improve its ability to respond to future emergencies. After the attacks, the American Association of Blood Banks helped create the Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. This task force offers, as I understand it, a new and potentially very valuable level of coordination within the community, an encouraging development that may help prevent wasteful donations in the future. I look forward to learning about the task force's work and in particular its recommendations. This past February, these recommendations were endorsed by the Department of Health and Human Services advisory committee on blood safety and availability, which recommended, in turn, that the Secretary adopt them.

I look forward to learning the status of the efforts of the Department of Health and Human Services on this front, and in particular how it is deploying measures that respond to the advisory committee's recommendations. Our inquiry will also involve examining our preparedness in the broader context of the issues that

confront our Nation's system for maintaining an adequate donor base and blood supply for everyday needs.

As I noted earlier, the challenges of maintaining an adequate blood supply aren't just about emergencies. The tremendous surge in donations last fall did not last. On the contrary, while daily demands on the blood supply continue apace, donation levels this summer have reportedly been quite low, generating urgent appeals for people to give, something which I urge everyone in this hearing room to do. Maintaining a sufficient blood supply on the shelf is critical, but it is also critical that we maintain a safe supply of blood products; and that is why we will explore questions of safety and supply this morning, including recent concerns over the danger, if any, of the West Nile virus to our blood supply. How, for example, does the system respond to emerging risks and the related donor restrictions? What technologies and practices can help maintain adequate donation levels or help moderate increases in demand for blood?

Fortunately, the available blood supply monitoring data have improved over the past several years. We now can get a better picture of the various factors that affect supply and demand. I asked the General Accounting Office to draw on this information to review some of the key issues relating to the adequacy of the blood supply, trends, emergency preparedness, and new safety guidelines, the mad cow disease-related donor restrictions in particular.

The GAO's findings, which will be reported during the first panel, should help provide a framework for broader discussion of America's blood supply. There are many difficult challenges facing this portion of our public health system, but there is also, as the GAO report indicates, some encouraging news about the ability of the system to meet these challenges. Most importantly, we are blessed by the long history of Americans' generosity in donating their blood, a truly life-giving gift that is largely anonymous and intended for strangers. I hope through our hearing today we can help strengthen this foundation and strengthen public confidence in this system. I look forward to learning about the actions being taken by Federal Government and the rest of the blood community to strengthen America's blood supply system.

Let me welcome the panelists and thank you all for coming to talk about these important matters this morning; and I recognize the ranking member, Mr. Deutsch, for an opening statement.

Mr. DEUTSCH. Thank you, Mr. Chairman. And I appreciate the work of our committee and our staff on this issue over a very long period of time. In an effort really to hear the witnesses' testimony, I would yield back the balance of my time.

Mr. GREENWOOD. Dr. Fletcher, do you care to make an opening statement?

Mr. FLETCHER. Mr. Chairman, thank you for holding this hearing, and I will just submit an opening statement in the interest of time. Thank you.

Mr. GREENWOOD. The Chair thanks the gentleman. The Chair would ask unanimous consent that any opening statements submitted by members of the committee be included in the official record of the hearing.

Without objection, so it shall be.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you Chairman Greenwood. And, let me also commend you for putting together what promises to be a very valuable hearing this morning on America's blood supply.

The full Committee's jurisdiction covers many critical aspects of emergency and public health planning—from pipeline and port security to radiological and bioterror preparedness. And, we've been very busy this past year, especially since September 11, to help ensure we are better prepared for any future attacks or emergencies.

The safety and availability of blood, for life-saving transfusions after public health emergencies or after risky surgery, is a vital element of America's public health preparedness. And this Committee takes very seriously its responsibilities to ensure an adequate and safe blood supply.

Part of our responsibility involves maintaining confidence in the system. As you suggested, Mr. Chairman, the supply revolves around donors. The issue is very clear: lack of confidence can seriously reduce peoples' drive to donate. It can also affect the public's perception of the safety of the supply.

We saw how confidence can be harmed in the months after September 11 when an astounding amount of blood—more than 200,000 units, five times the normal rate I understand from the GAO—had to be discarded. Moreover, we'll learn today how the handling of the huge, heartfelt public response to donate had other potentially negative side effects.

I'm very eager to learn about the status and current trends in the blood supply—and find out just what is being done to improve the response of the blood community next time.

We all know there will be a "next time" whether it is a terrorist attack or natural disaster. So it is vital that we build on past lessons to be sure that this essential public health resource is not squandered. One lesson is very clear: That is that the best way to prepare for an emergency is to have safe blood, available already on the shelves of hospitals.

I would like to know how the blood community is working to improve public donation levels. I would also like to know what the Health and Human Services' Office of Public Health Emergency Preparedness is doing to prepare for emergencies, as well as to improve public understanding.

The General Accounting Office identifies some positive trends in donation levels—prior to September 11. While we still don't have a clear a picture about current trends, we certainly know not to let the responsible agency go too slow in taking corrective action to build on the gains of the past.

There are questions about the blood supply that I hope this hearing will address. At the top of my list is some needed perspective on emerging disease threats. The GAO reports on the Mad Cow-disease restrictions. And I know some of the other panelists have informative views on these restrictions.

We also have serious concerns about West Nile Virus, a topic of urgent interest to many of our constituents right now. In particular, I'd like to know HHS's—and FDA's—current assessment of the risks West Nile poses to the blood supply and the status of the development of diagnostic testing and screening methods. You should know, this Committee plans to monitor vigilantly the Department's progress here. We would like to be assured that the HHS will be capable of handling any emerging West Nile Virus threats before risks increase again with next spring's mosquito season.

Finally, I'm interested to learn about some of the new ways of approaching blood supply preparedness. We should encourage innovative technologies and management methods that can help reduce demand on the system, after an emergency or in day to day operations. Again, we have some experts today who can speak informatively on this topic.

Let me also welcome the witnesses, and thank you again, Mr. Chairman.

Mr. GREENWOOD. Let me introduce the first panel. We are delighted to have Mr. Jerome M. Hauer, Acting Assistant Secretary of Public Health Emergency Preparedness from the Department of Health and Human Services. Good morning, sir. He is accompanied by Dr. Jay Epstein, Director of the Office of Blood Research and Review, Center for Biological Evaluation and Research of the U.S. Food and Drug Administration. Thank you.

Colonel Glen Fitzpatrick, Director of the Armed Services Blood Program. Good morning, sir. And Dr. Janet Heinrich, Ph.D., Director of Health Care, Public Health Issues of General Accounting Office. Good morning. Good to have you with us, as usual.

You members of the panel are aware that the committee is holding an investigative hearing, and when doing so we have had the practice of taking testimony under oath. Do any of you have objection to giving your testimony under oath?

Seeing no such objection, I would advise you then that under the Rules of the House and the rules of the committee, you are entitled to be represented by counsel. Do any of you choose to be represented by counsel?

Okay, in that case, if you would please rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. GREENWOOD. You may be seated. You are under oath. And we will begin with you, Mr. Hauer. You are recognized for 5 minutes for your opening statement.

TESTIMONY OF JEROME M. HAUER, ACTING ASSISTANT SECRETARY, PUBLIC HEALTH EMERGENCY PREPAREDNESS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JAY EPSTEIN, DIRECTOR, OFFICE OF BLOOD RESEARCH AND REVIEW, CENTER FOR BIOLOGICAL EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION; COLONEL GLEN M. FITZPATRICK, DIRECTOR, ARMED SERVICES BLOOD PROGRAM; AND JANET HEINRICH, DIRECTOR, HEALTH CARE—PUBLIC HEALTH ISSUES, GENERAL ACCOUNTING OFFICE

Mr. HAUER. Thank you. Thank you, Mr. Chairman, and members of the committee, for the opportunity to be here today to comment on the newly released GAO report on the blood supply.

Secretary Thompson and I are pleased to note that the report finds the Nation's blood supply to be generally adequate, despite donor restrictions. This is a well-deserved tribute to the American Red Cross, the members of America's blood centers and the remaining collection services, such as the Armed Forces Blood Program, which together collect nearly 15 million units of blood each year. It is also an equally well-deserved tribute to the generosity of the American people and to our collective commitment to support each other in times of either individual or collective need.

This commitment was reaffirmed by the overwhelming number of Americans who came out to give blood in the hours and days after September 11. One year later, the most important lesson to be learned from the response of these donors is that the selflessness and heroism on the streets of New York City pervades this country, and that it is something of which we can all be very proud.

The other lesson is that we were not fully prepared to handle the large number of blood donations from so many generous Americans, which ended up exceeding the actual need. The blood community responded to this experience by joining together to form the American Association of Blood Banks Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. I am a member of this task force and represent the Department on that task force.

This task force met on December 11, 2001, and it has adopted a set of principles and an action plan for dealing with future events of this sort. The task force work product was publicly reviewed at the January 31, 2002, meeting of the Department's Advisory Committee on Blood Safety and Availability, and the Advisory Committee unanimously endorsed the task force's recommendations.

Other speakers before you today will discuss these recommendations and they will get into more detail. I will simply say here that the Department of Health and Human Services remains actively involved in the task force and its individual members, and that the Department is prepared to implement the task force plans if the need should ever arise.

Before leaving this subject, however, I want to point out that the Food and Drug Administration was exceptionally responsive to the needs of both public health and the blood industry during this difficult time, and I want to commend them publicly once again for their response. The FDA also conducted a comprehensive review of their capacity to address future demands of this sort on the blood supply, whether due to natural disasters or to terrorism. They too presented their plans to the Department's Advisory Committee on Blood Safety and Availability, and the advisory committee also unanimously endorsed their plans.

Today, there remains some concern about the impact in some parts of the country of new blood donor deferral policies that will go into effect in October 2002. These policies are intended to decrease the possible transmission by blood of new variant CJD. The policies will have particular impact on New York City, which for some time has imported a substantial amount of its blood from Europe.

The entire blood supply has anticipated this event, and plans have been made for other blood collection centers to provide blood to New York while its own facilities expand their operations. We will be monitoring the situation in New York very closely over the coming months. We anticipate that the Nation's blood suppliers will be able to meet this challenge, and we are pleased that the newly released GAO report concurs.

Let me also mention that our system of preparedness has already been tested three times since September 11. In October of last year, we were challenged by the anthrax disseminated through the postal system. Despite other public health concerns, CDC and FDA managed to work very rapidly to assess the risk to the blood system, and to issue appropriate guidance on reasonable precautions.

Second, in December of last year, at the time of the Winter Olympics in Salt Lake City, both industry and government mobilized fully and stayed on constant alert to ensure that any disruption or disaster that could have happened at the Olympics would be addressed with confidence in the safety of the blood and blood supply through the activation of existing plans.

And, finally, we are now in the midst of an emerging epidemic of West Nile virus. Again, the public health agencies in collaboration with the blood industry have mobilized rapidly and are acting aggressively to define any possible risk from transfusions and to identify feasible and effective intervention strategies. The Department of Health and Human Services remains interested in receiv-

ing suggestions from the blood industry on how we can support their efforts to assure that the blood supply remains both adequate and safe both in times of peace and in times of national emergency. In particular, we will be receiving the most recent recommendations of the Advisory Committee on Blood Safety and Availability, which met last week.

I appreciate the time, and I would be happy to answer any questions.

[The prepared statement of Jerome M. Hauer follows:]

PREPARED STATEMENT OF JEROME M. HAUER, ACTING ASSISTANT SECRETARY FOR PUBLIC HEALTH, EMERGENCY PREPAREDNESS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Thank you, Mr. Chairman and members of the Committee for the opportunity to be here today to comment on the newly released GAO report on the blood supply.

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Today, there remains some concern about the impact in some parts of the country of new blood donor deferral policies that will go into effect at the end of October 2002. These policies are intended to decrease the possible transmission by blood of new variant Cruetzfeldt-Jacob Disease, or vCJD. The policies will have particular impact on New York City, which for some time has imported a substantial amount of its blood from Europe.

The entire blood industry has anticipated this event, and plans have been made for other blood collection centers to provide blood to New York while its own facilities expand their operations. We will be monitoring the situation in New York very closely over the coming months. We anticipate that the nation's blood suppliers will be able to meet this challenge, and we are pleased that the newly released GAO report concurs.

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anthrax disseminated through the postal system. Despite other public health concerns, CDC and FDA managed to work very rapidly to assess the risk to the blood system and to issue appropriate guidance on reasonable precautions.

Second, in December 2001, at the time of the Winter Olympics in Salt Lake City, both industry and government mobilized fully and stayed on constant alert to ensure that any disruption or disaster could be addressed with confidence in the safety and availability of blood through the activation of existing plans.

And third, we are now in the midst of an emerging epidemic of West Nile Virus. Again, the public health agencies in collaboration with the blood industry have mobilized rapidly and are acting aggressively to define any possible risk from transfusions and to identify feasible and effective intervention strategies.

The Department of Health and Human Services remains interested in receiving suggestions from the blood industry on how we can support their efforts to assure that the blood supply remains both adequate and safe, in times of peace and in times of national emergency. In particular, we will be receiving the most recent recommendations of the Advisory Committee on Blood Safety and Availability which met last week.

I would be happy to answer any questions you may have.

Mr. GREENWOOD. Thank you, Mr. Hauer.

And I understand, Mr. Epstein, you are not making an opening statement but are there to assist in answering questions.

Mr. EPSTEIN. That's correct.

Mr. GREENWOOD. Okay. Thank you.

In that case, Colonel Fitzpatrick, you are recognized for your statement, please.

TESTIMONY OF COLONEL GLEN M. FITZPATRICK

Mr. FITZPATRICK. Chairman Greenwood, Mr. Deutsch, and members of the committee, thank you for the opportunity to address the issues regarding this blood supply in the United States—sorry. Thank you for the opportunity to address the issues regarding the blood supply in the United States since September 11, 2001. And I am thankful for the opportunity to inform you of the successful blood support provided to Operations Noble Eagle and Enduring Freedom.

The Armed Services Blood Program Office was established as a field operation agency of the War Department in 1953. The mission of my office is to ensure that the elements of the Armed Services Blood Program and the services are always available and ready to collect, transport, and deliver blood anywhere in the world.

During Desert Shield and Desert Storm, over 100,000 units of red blood cells were delivered and available for transfusion. The Department of Defense currently has over 59,000 units of frozen red blood cells stored aboard ships in the Pacific and European theaters because it could take 7 to 10 days to fully meet the needs of a major conflict in those theaters.

However, frozen blood has limitations. It is expensive; there is a large logistical support tail. One technician can produce only 2 units per hour, and it is difficult to ensure that new required tests are accomplished on a product with a 10-year shelf life. But, frozen red blood cells are currently the only alternative available when liquid red blood cells cannot be provided in sufficient quantity—that is, until the FDA finds a safe, and licenses a safe, blood substitute such as a hemoglobin-based oxygen carrier; and they are very engaged in that at this moment.

I believe it is essential for this country to have reserves of liquid red blood cells immediately available for shipment. A national re-

cruitment program could increase the available blood supply, in essence creating a national blood reserve that could be made available for homeland defense, military operations, and natural or man-made disasters.

The attacks of 9/11 changed our perspective about many things, and as in many disasters brought blood donations, blood needs, and blood management to the forefront of the public and the media's minds. Just as people waited for hours to donate to civilian collection agencies, military donors turned out in record numbers. The Armed Services Blood Program Office supported Operation Noble Eagle by assessing blood needs in Washington, DC, and New York, and establishing an ad hoc blood management structure for the military logistic district of Washington.

The grounding of all civilian aircraft created a situation never before encountered. Our office assisted with the movement of civilian and military blood products, test samples, and reagents by military aircraft. Tripler Army Medical Center in Honolulu, Hawaii, performed infectious disease testing for the blood bank of Hawaii because they normally ship their specimens to Washington State, and many military facilities stored blood collected by civilian agencies when their inventories exceeded their storage capacity.

Support for Operation Enduring Freedom has required the collection by DOD and shipment of over 15,000 units of red blood cells to U.S. Central Command, European Command, Southern Command, and Pacific Command. This has truly demonstrated the ability of the elements of the Armed Services Blood Program to deliver blood products worldwide. These blood units have provided over 800 transfusions, and have been used by U.S. coalition and host military personnel. Should the operational tempo or the level of hostilities increase, it will be necessary to provide more blood worldwide as well as ensuring ample supplies here in case of another terrorist attack at home.

In October 2001, the DOD faced the additional challenge of replacing 18 percent of the active duty population who were to become ineligible to donate because of travel to or residency in Europe. These individuals are now deferred to prevent the theoretical transition of mad cow disease through blood transfusion. To offset these deferrals, we hired recruiters and established recruiting campaigns focused on our basic training and initial entry sites. The service blood program offices should be commended for their ability to not only maintain collections at previous levels, but actually increase them to support Operation Enduring Freedom in the face of 18 percent of the population they serve having become ineligible to donate.

You are probably aware of the critical appeals for blood donations that have occurred in many civilian communities this summer. The success of the DOD program in the face of these challenges and, sometimes, shortages in the civilian community makes it even more essential that the DOD maintain a vigorous collection program for readiness.

It is the mission of the Armed Services Blood Program to ensure that no lives are lost because blood is not available. I hope you are assured by this testimony that the combined efforts of the Army,

Navy, and Air Force blood collection and distribution facilities are accomplishing this mission.

Thank you again for the opportunity to speak.

[The prepared statement of Colonel Glen M. Fitzpatrick follows:]

PREPARED STATEMENT OF COL. GLEN M. FITZPATRICK, USA, DIRECTOR, ARMED SERVICES BLOOD PROGRAM

I want to thank the committee for the opportunity to address the issues regarding the blood supply in the United States since September 11, 2001. The Armed Services Blood Program Office (ASBPO) was established as a Field Operating Agency of the War Department in 1953 after the Korean War. The military had learned from WWI, WWII, and Korea that it takes time to organize a blood collection and distribution system that is capable of supplying a product that requires special handling, e.g., maintaining a cold chain throughout its distribution and dealing with its short life (21 days at that time). The mission of my office has been to make sure that the Armed Services Blood Program (ASBP) is always ready to collect, transport, and manage blood anywhere in the world. We have proven over a number of conflicts that the elements of the ASBP can safely collect, store, manage, deliver and transfuse blood anywhere. During Desert Shield/Desert Storm over 100,000 units of red blood cells were delivered and available for transfusion. The attacks of 9-11 changed our perspective about many things and, as in many disasters, brought blood donation, blood needs, and blood management to the forefront of the public and the press's minds. Any natural or man-made disaster has always elicited an overwhelming response from blood donors and 9-11 was no exception. Just as people waited for hours to donate to civilian collection agencies, military donors turned out in record numbers. If the towers had fallen differently, or there had been multiple attacks throughout the country, the blood needs could have been drastically different. As it turned out, precious little blood was needed, but on 9-12, 13 and 14 there were many unknowns. Future blood needs could not be immediately predicted and people wanted to help by donating blood. Blood centers did not know if they should or how they could turn donors away. I would like to focus on the actions of the Department of Defense.

The ASBPO responded just as other agencies did during and after 9-11. Blood inventories were determined, blood needs in Washington, D.C. and New York assessed, and an ad hoc management structure for the Military District of Washington was put in place so that blood needs from any further attacks could be met. The grounding of all civilian aircraft created a situation never planned for within the United States. The ASBPO assisted with the movement of civilian and military blood products, test samples, and reagents by military aircraft when needed. Tripler Army Medical Center (TAMC) performed infectious disease testing for the Blood Bank of Hawaii (BBH) because BBH normally sends its samples to Seattle, Washington for testing and TAMC performs testing on-island. Many military facilities stored the blood collected by civilian agencies whose inventory exceeded their storage capacity. While civilian and military organizations rose to these challenges and maintained ample blood inventories for any further needs, it became apparent that too much blood might be collected and it was time to develop a clear message to the public thanking them for their response and asking that they return and donate in the future.

Since the beginning of Operation Enduring Freedom (OEF), the DoD has shipped over 15,000 units of red blood cells in support of U.S. Central Command, U.S. European Command, U.S. Southern Command, and U.S. Pacific Command. This has truly been a global test of the ability of the Armed Services Blood Program to respond to military blood needs worldwide. These units have provided over 800 transfusions, and excess stocks have been transferred to coalition or host nation hospitals, or destroyed upon their expiration. While this may seem wasteful we know that it is essential to have a minimum inventory available at all casualty-receiving stations at all times. Should the operational tempo or the level of hostilities increase, it will be necessary to provide more blood overseas, as well as determine the most efficient means of meeting blood needs in case of another terrorist attack at home.

In October of 2001 the DoD began deferring donors who had traveled to or lived in Europe to prevent the theoretical transmission of mad cow disease through blood transfusion. Initial estimates indicated that 18 percent of the active duty population would be deferred for travel to Europe and United Kingdom, increasing the average deferral rate in DoD from 25% to 43%. To compensate for this, we hired recruiters and established recruiting campaigns focused on our basic training and initial entry

sites. As you can see by the graph displayed (attached), we have managed not only to maintain collections, but actually increased them to support OEF. You are probably aware of the critical appeals for blood donations that have occurred in many communities this summer. This makes it even more essential that the DoD maintain a vigorous blood collection program.

A year has passed and a number of changes have occurred in this country. An inter-organizational task force, including an ASBPO representative, has been formed to address blood management in the Federal Emergency Response Plan. House Resolution 3448 Section 121 calls for a Strategic National Stockpile and authorizes a national stockpile of drugs, vaccines, biological products, medical devices and supplies to meet the health security needs of the U.S. Blood is a biological product, and a strategic reserve is needed to be able to respond immediately to any disaster.

The DoD currently has over 59,000 units of frozen red blood cells stored on board ships and in the Pacific and European theaters because it could take 7 to 10 days to fully meet the needs of a conflict with liquid blood. However, frozen blood has a number of problems: it is expensive, there is a large logistical support tail, one technician can only produce two units per hour, and it is very difficult to insure that new required tests are performed on a product with a ten-year shelf life. Frozen red blood cells are the only alternative available when liquid red blood cells cannot be provided in sufficient quantity, until a safe blood substitute such as hemoglobin based oxygen carrier, is licensed by the FDA. If this nation had a national reserve of liquid red blood cells for use within the United States or in support of military actions overseas the need for large stockpiles of frozen red blood cells could be greatly reduced. Blood must be immediately available to have any impact on saving lives, and if a national reserve is to be created, the blood must be maintained at sites that could immediately package it for transport seven days a week 24 hours a day. The DoD already has two such sites, one at Travis Air Force Base in California, the other at McGuire Air Force Base in New Jersey. Each of these Armed Services Whole Blood Processing Laboratories (ASWBPL) can receive, test, store, and prepare for shipment 7,200 units of red blood cells daily.

A national recruitment campaign could be developed to encourage the population to donate to the nearest blood donor center regardless of its affiliation. The most difficult part of such a program, should it be adopted as a goal of the inter-organizational task force, would be to develop a strategy for funding not only the collection and shipping of these units but the management structure needed to maintain, rotate and distribute them. I have written the chairman of the inter-organizational task force proposing the establishment of a national blood reserve and requesting he form a work group of experts to determine the best approach to financing such an endeavor. I believe it is essential for this country to have reserves of liquid red blood cells immediately available for shipment, and stockpiles of frozen red blood cells at strategic locations that can be thawed and prepared for transfusion to supplement the local liquid inventory if necessary. Such a strategy will require the cooperation and coordination of multiple civil and government agencies, but most important of all will be the message to the public, asking for their support of a national blood reserve. To be successful, it will require the public to donate regularly in order to maintain the reserve of this short-lived product, which can only be used for 42 days and requires constant replenishment. If we come together to accomplish these goals, critical shortages and emergency appeals for blood should be the exception and a constant vital supply for homeland defense, military actions, and natural or man-made disasters will be available.

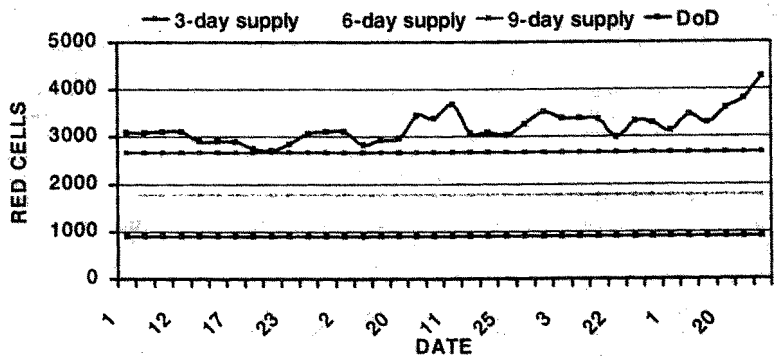
It is the mission of the Armed Services Blood Program Office to insure that no lives are lost because blood was not available. I hope you are assured by this testimony that the combined efforts of the Army, Navy and Air Force blood collection facilities are accomplishing this mission. The creation of a national blood reserve could provide the same support for homeland defense.

Thank you for the opportunity to address this committee.

MILITARY INVENTORY

AS OF 27 AUG 02

Military Medical Treatment Facility
(Continental U.S.) Inventory



ARMY – 2,462 **TOTAL – 4,263**

NAVY – 1,040

AIR FORCE – 761 **14.4 DOS**

Mr. GREENWOOD. Thank you, Dr. Fitzpatrick.
Dr. Heinrich.

TESTIMONY OF JANET HEINRICH

Ms. HEINRICH. Mr. Chairman and members of the subcommittee, I am pleased to have the opportunity to testify as you consider the blood supply and its adequacy to meet the Nation's needs.

The terrorist attacks 1 year ago reminded the Nation of the critical importance of a safe and adequate blood supply for all emergencies. Today, at your request, Mr. Chairman, we are releasing a report that summarizes several issues regarding blood safety and availability. My comments will focus on three of those topics: the adequacy of the blood supply, the response of blood suppliers to the September 11 attacks, and planning for future emergencies.

Although no one data source has tracked the Nation's blood supply in the past, all the sources we identified indicate that the national supply has grown in recent years and was at historically high levels before the surge in donations that occurred after September 11. Annual blood collections had increased substantially, 21 percent since 1997. These increased collections resulted in increased inventories of blood. For example, the New York Blood Center reported a 4 to 5 day supply in early September 2001. In hospitals that are part of the Department of Health and Human Services' Blood Sentinel Surveillance System reported 7 days of all

blood types on average and approximately 6 days for Type O-negative, the universal donor type.

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, a year ago, although local blood shortages, as we have heard, have occurred from time to time.

After the September 11 attacks, America's blood banks collected an unprecedented amount of blood in a short period. In response to the perception that blood would be needed to treat victims, Americans formed lines to give blood at hospitals and blood banks. HHS, America's Blood Centers, and the American Red Cross all issued requests for blood donations, although HHS and the American Blood Centers quickly stopped issuing requests when it became clear that there were few survivors of the attacks who needed transfusions.

Many blood suppliers were reluctant to turn away potential donors. Estimates of the number of units collected nationwide in September and October 2001 that were in excess of average collections ranged from 475,000 to 572,000 units. This surge of donors stressed the collection system. Long waiting lines developed and increased errors in the collection process were reported. Far more blood was collected immediately after September 11 than was needed by survivors or that ultimately could be absorbed in the Nation's blood banks. Fewer than 260 units were used to treat victims of the attacks, and of the roughly 572,000 additional units collected in response to September 11, we estimate that about 364,000 units or about two-thirds were utilized by the Nation's blood banks and approximately 208,000 units or about one-third expired and were discarded. All of these figures we consider to be underestimates of the total number of expired units because they do not capture units that expired in hospital inventories.

Following the pattern of responses to previous disasters, the sharp increase in blood collections did not last, and the number of units collected had returned to the usual level by November. Since September 11, as we have heard, Federal public health agencies and blood suppliers have been critical of their responses to prior disasters, and have begun to plan a more effective response to future emergencies through an interorganizational task force. Organized by the American Association of Blood Banks, the focus has begun to shift away from increasing blood collections in an emergency to maintaining an adequate inventory of blood at all times.

A recent report by the task force made recommendations for the emergency preparedness of the blood supply that were adopted by the HHS Advisory Committee on Blood Supply and Availability.

In conclusion, although local shortages of blood occur from time to time, America's blood supply is generally adequate. There is clearly a need for ongoing monitoring of the blood supply, both supply and demand, to ensure that we have an adequate supply in the future. Experts stress that an adequate inventory on a daily basis is the most important factor in the initial response to a disaster. It is people who donate blood on a regular basis before a disaster who save lives.

I would be happy to answer any questions.

[The prepared statement of Janet Heinrich follows:]

PREPARED STATEMENT OF JANET HEINRICH, DIRECTOR, HEALTH CARE—PUBLIC HEALTH ISSUES. U.S. GENERAL ACCOUNTING OFFICE

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 units [1] 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 the blood transfusions.

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 pre-attack 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.

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[1] A unit equals 1 pint.

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

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

[4] To 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.

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 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 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.)

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.

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

[6] The 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.

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, 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.)

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 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.

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

[8] Because 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.

[9] American 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).

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 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. 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.

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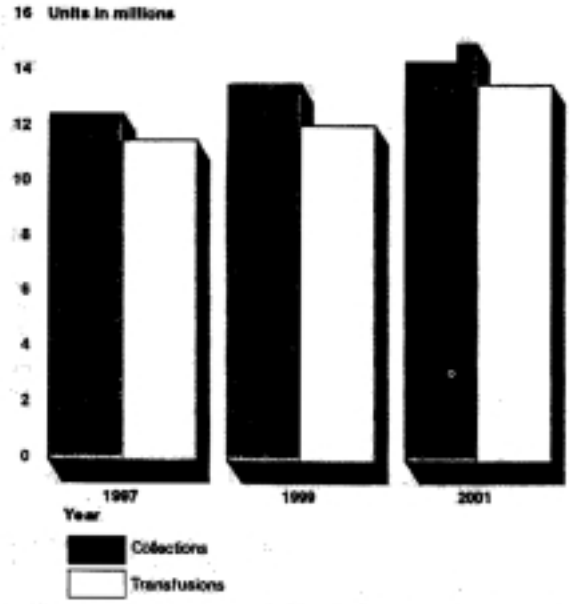
[10] The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. Members include the HHS Office of Public Health Preparedness, FDA, Department of Defense, Centers for Disease Control and Prevention, the Red Cross, and ABC.

[11] P.J. Schmidt, "Blood and Disaster—Supply and Demand," 617-20.

[12] In 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.

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.

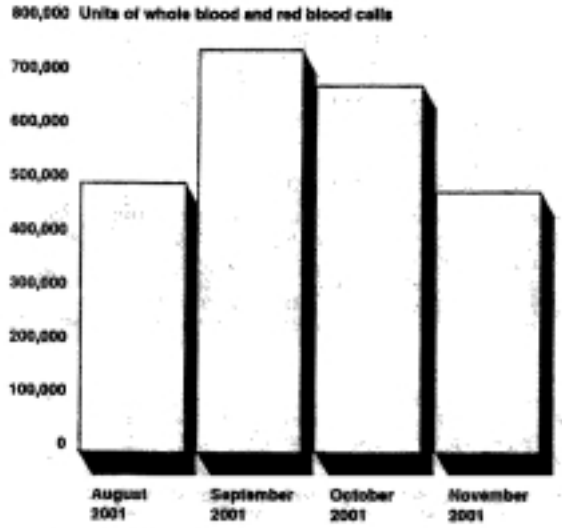
Figure 1: Units of Blood Collected and Transfused, 1997 to 2001



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.

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



Source: GAO calculation from Red Cross data.

Mr. GREENWOOD. Thank you, Dr. Heinrich, for your testimony.

The Chair recognizes himself for 10 minutes for questions, and let me address my first question to you, Mr. Hauer.

We note that the HHS Advisory Committee on Blood Safety and Availability advises the Assistant Secretary for Health, and you are the acting Assistant Secretary for Public Health Emergency Preparedness. In addition, the advisory committee on February 1, 2002, recommended that HHS should act to promote and coordinate a single consistent public message on blood issues, and that the ultimate spokesperson for the blood community should be the Assistant Secretary for Health or her designee.

Should the subcommittee construe your appearance today as meaning that Secretary Thompson has designated you as the ultimate Department spokesperson for blood issues? And, if not, who is?

Mr. HAUER. No. The Assistant Secretary For Health is coordinating the blood-related issues within the Department. I was asked to testify, one, because I came out of the blood banking community; and two, I am working on the task force and coordinating with the Assistant Secretary for Health to ensure that as we move forward we have a coordinated message with the blood community and the public.

Mr. GREENWOOD. Okay.

Has HHS updated its disaster plan for Emergency Support Function, Function 8 under FEMA, in light of September 11?

Mr. HAUER. We have gotten some recommendations from the blood community which we are completely in agreement with. We have sent those over to FEMA to be incorporated when a new ESF-8 supplement to the Federal response plan comes out.

Mr. GREENWOOD. Is that recommendation in writing? Is that a formal document?

Mr. HAUER. I believe it is, but I would have to check and get back to you.

Mr. GREENWOOD. Let me turn to Dr. Epstein. Do you know whether any advances are being made in developing a reliable diagnostic test for screening mad cow disease?

Mr. EPSTEIN. Technical scientific progress is being made, but at the present time there is no test anywhere close to being practical. The existing methods are sensitive for detecting the abnormal prions in tissues, but they are not sufficiently sensitive to detect that infectivity in blood.

Mr. GREENWOOD. So what are the measures that this country is taking to protect receivers of blood donations from potential harmful effects of mad cow disease?

Mr. EPSTEIN. Basically, we do two things. We protect our population by keeping the bovine form of the disease out of our country, and we restrict donations by individuals who may have been exposed to mad cow disease by eating contaminated beef in locations abroad.

Mr. GREENWOOD. So how do you do that? For instance, I have been—I have traveled to Europe once in the last several months. Am I excluded from donating?

Mr. EPSTEIN. No. That would not be a sufficient exposure to exclude you. At the present time, based on a guidance that became

effective in January of this year, we defer persons who have been exposed in the United Kingdom for 3 months or more between 1980 through 1996, when food safety controls became adequate.

Mr. GREENWOOD. Let me interrupt you for a second. So just having been there for a 3-month duration is sufficient to be deferred?

Mr. EPSTEIN. Yes, it is.

Mr. GREENWOOD. Okay. Go ahead. Continue.

Mr. EPSTEIN. Additionally, we call for a deferral of persons who lived in France for 5 or more years from 1980 to the present time, because there is less confidence that their foodborne epidemic is controlled.

We defer persons in the military or their dependents who lived for 6 months or more on military bases in Europe. We distinguish time periods either north of the Alps 1980 through 1990, or other locations, basically south of the Alps 1980 through 1996. The reason for these deferrals is that there was a program within Department of Defense specifically to procure beef products from the United Kingdom during these periods.

We additionally recommend deferring persons who have received a blood transfusion in the United Kingdom since 1980 to the present. And, effective October 31 of this year, we additionally recommend implementation of a deferral for persons who have lived 5 or more years in any part of Europe, including the UK, between 1980 and the present.

Mr. GREENWOOD. Is there indication—have there been indications in those countries that, in fact, mad cow disease has been transmitted through transfusion?

Mr. EPSTEIN. No. There is no documented case of transfusion anywhere in the world. However, the suspicion is quite real, based on evidence from experimental models in animals. Transmission of transmissible spongiform encephalopathies has been shown in mice, in hamsters, and most recently, with the bovine agent, it was shown from sheep to sheep. These experiments have raised concern because they have demonstrated infectivity in the blood and they have also demonstrated actual transmission by transfusions.

Mr. GREENWOOD. I see.

Mr. EPSTEIN. But again, there is no human case that has ever been proven. But we haven't had that long to experience the human form of mad cow disease, and that creates a degree of uncertainty.

Mr. GREENWOOD. So you are erring pretty much on the side of caution.

Why does the duration of one's visit—is there a cumulative issue here, or is it just a question of the odds over time of consuming contaminated meat?

Mr. EPSTEIN. Well, that is not known to science, unfortunately. However, the model that we applied to assess risk was that it would be linearly related to exposure time. And we don't really know whether that is because it is cumulative or just, the longer you are there, the bigger your chance of a one-time hit. But it is a reasonable model because we do know that the cases that have appeared have been in people with fairly prolonged exposure. We also estimated the risk differentially based on the amount of contaminated beef, reckoning the highest levels to be in the UK; and

then, on a sliding scale, we created risk-based adjustment for France, which is second highest, and then Europe in general.

Mr. GREENWOOD. Is the NIH or anyone else actively funding and pursuing research for developing a diagnostic test for mad cow disease?

Mr. EPSTEIN. I know that within the FDA we have our own program on development of diagnostic tests. I am not prepared to speak to NIH in general. I apologize.

Mr. GREENWOOD. All right. The New York Times—this is also for you, Dr. Epstein.

The New York Times reported on Friday, September 6, that the Federal estimate of West Nile cases is one or two per 10,000 transfusions, and suggested that was high. Do you know how that was estimated?

Mr. EPSTEIN. Yes. There was a recent publication by scientists at the Centers for Disease Control who studied the epidemic in 1999 in Queens, New York. And based on the frequency of detection of positives, they estimated the frequency with which a donor might be acutely infected and have the virus in the blood. And that was then used to estimate the risk of a contaminated unit being given to a recipient.

That risk was placed on average at about 1 to 2 per 10,000, or, in ball park figures, 1 in 5,000. There was of course a confidence range. It was also noted in that paper, and consistent with previous publications, that the risk of actually developing disease after infection with that virus is less than 1 percent. However, we do have to recognize that blood recipients have a larger proportion of immune-compromised and older individuals than the population in general. So, that figure perhaps should be—may need to be reconfirmed. But, that was the basis of the estimate, namely the 1999 sero asurvey in Queens, New York.

Mr. GREENWOOD. So what are the precautions that are being taken right now, or—and/or contemplated so as to protect the blood supply from the adverse potential adverse impacts from West Nile?

Mr. EPSTEIN. At the present time we are limited because there are no practical tests to screen for the infection in a donor. What we have recommended is as follows: on August 17, we alerted the blood bank organizations to be vigilant in excluding individuals who might have early symptoms of illness consistent with West Nile virus, which would exclude an individual with flu-like syndrome or fever or severe headache as already stated in existing regulations and guidance.

Additionally, we have taken prudent precautions; in cases where there have been investigations of a possible transmission, we have advised the blood centers to retrieve any unused blood components that were on the shelf from those donors who may potentially have transmitted to a recipient. So that is where we stand now.

Unfortunately, additional deferrals based on donor screening are not feasible; 80 percent of the infections that are community-acquired are asymptomatic, and so there would be no way to sort them out.

Mr. GREENWOOD. Let me quickly pose a question to you, Colonel Fitzpatrick. What has the Department of Defense learned from its hemoglobin based—its program about boosting blood supply, such

as the use of artificial—use of artificial blood or hemoglobin-based oxygen carriers for extending the shelf life for blood from 42 days to 70 days? What is the—what have we learned from your program of research?

Mr. FITZPATRICK. Mr. Greenwood, the research has been conducted at Walter Reed Army Institute of Research. And I could speak generally, but for specific questions, I would have to come back to you on that.

We have learned that it is possible to extend the shelf life to 70 days with in vivo studies. The hemoglobin-based oxygen research is primarily being done in the civilian sector. And while we are maintaining our knowledge of what is going on there, we aren't actively doing research in that area at this point.

Mr. GREENWOOD. Okay. My time has expired.

The Chair recognizes the gentleman from Florida for 10 minutes.

Mr. DEUTSCH. Thank you, Mr. Chairman. If everyone who is not—I guess besides Dr. Heinrich—the other members of the panel who are not with the GAO, the GAO conclusion that the blood supply is generally adequate, would you agree or disagree with that statement?

Each of you can respond.

Mr. HAUER. We would agree with that statement.

Mr. DEUTSCH. And Mr. Epstein?

Mr. EPSTEIN. Yes, we generally agree. What we recognize is that there have been significant reports of spot shortages, and so the problem here is a relatively low inventory and transient dislocations. What we also see, consistent with the GAO report, is that the long-term trend has been a consistent increase in the blood supply meeting need.

And so the challenge is how to smooth out these peaks and valleys, and move the system toward a better steady state. But that is not inconsistent with the conclusion of the report. We think that there are enough donors out there and that there is the ability within the system to make adequate collections.

But we do need to make improvements, figuring out how to bring the donors in as needed.

Mr. DEUTSCH. Colonel Fitzpatrick?

Mr. FITZPATRICK. Mr. Deutsch, I can speak to the adequacy of the military blood supply. As you can see by the statement, we have been able to provide the blood needed for Department of Defense needs.

As for the civilian sector, when we were provided the report, we agreed that it was adequate; however, the definition of adequacy varies from individual to individual, and there is adequate blood to meet the patients' needs. I would agree with Dr. Epstein that it is a matter of making sure the distribution is appropriate to meet all the patients' needs and the determination by the interorganizational task force based on current circumstances of what is a not merely adequate supply, but a recommended supply within the country.

Mr. DEUTSCH. Dr. Heinrich, would you want to respond to either one of those critiques?

Ms. HEINRICH. Thank you for the opportunity to respond.

The message, I think, is quite consistent; if you look nationally, overall, and you look at the trends, we have a better supply now than we did, say, in 1997. But we are also saying that we recognize that there are these spot shortages, and we also recognize that the movement of excess blood in one region to another region is a very important aspect of the adequate supply.

Mr. DEUTSCH. Thank you. The two or three major lessons that can be applied to the overall health of U.S. blood supply as a result on the experience of 9/11, what would you point out as the major lessons?

Mr. HAUER. I think that, you know, as we see during any major incident, Oklahoma City—even in local types of events, when a police officer is shot in a community, we see enormous spikes in the number of people that want to give blood.

I think that we have to look at the type of event, assess the needs, and determine whether or not we are going to need significant quantities of blood. There are types of incidents that do require significant quantities of blood and some that don't. Biological incidents, chemical incidents tend not to need that much blood. Bombings, the type of incidents we saw last September, tend to require more blood. But, you know, unfortunately in New York City most of the victims succumbed to the collapse.

We need to get a message out, and we need to have a consistent message among the blood community and with HHS so that when there is a need for blood, we get out there and ask for it; when there is not a need for blood, we don't get out and ask for it. And I don't think that happened last year.

As a result of the mixed messages last year, one of the things we have done is invited all the members of the blood banking community to be part of our command structure at HHS so that in the event of a terrorist attack or other major incident, we have representatives from the various organizations in our command center so that if they are having difficulty with blood, moving blood, with regional shortages of blood; or if, in fact, they don't need blood and people are—you know, it's the way our country responds to these kind of incidents.

People are wonderful in that they want to try and do something, but sometimes we need to delay those donations and get people to donate on a more scheduled basis down the road as opposed to everybody doing it right after the incident. We are ensuring that we have a consistent message to the public. And finally, we are looking at the whole issue of having some kind of strategic reserve as a part of this, and we are trying to sort through that issue as well.

Mr. DEUTSCH. Dr. Epstein? Any lessons from 9/11?

Mr. EPSTEIN. No. I think that's a complete description.

Mr. DEUTSCH. Colonel?

Mr. FITZPATRICK. Congressman Deutsch, I think the basic lesson from the military aspect was the wisdom of my predecessors in creating our program. We know that blood has to be on the shelf and available in order to immediately impact survival of patients and casualties, and as a result of that, we have a command and control and organizational structure to meet that need outside of our borders. We learned that it is a requirement now to meet that need within our borders, and the interorganizational task force that's

been formed I think is addressing that, and it will meet that need once they have provided all their recommendations.

Mr. DEUTSCH. Dr. Heinrich? Lessons of 9/11?

Ms. HEINRICH. I think that the unified message is a very important lesson, and to do that well, I think HHS and the blood suppliers have to find new ways of working with the media. Coordination certainly was something that was needed and that people have been critical about. An adequate supply on a daily basis I think is the—well, one aspect that from GAO's perspective we find very interesting, and the part of that that I think has not been focused on enough is the need for data on what that supply is. And we are concerned actually that the current efforts to have good data on the supply are not adequate.

Mr. DEUTSCH. If I could follow up—I want to have a chance.

Mr. Hauer, I think you pointed out great lessons. If you could follow up on what is HHS doing to implement the shelf life, the—really scheduling, you know, of donations. I mean, what is actually being done to follow up on those lessons?

Mr. HAUER. Part of that has to occur during—following an incident. Following an incident, we need to stem the tide of donors early on because, again depending on the nature of the incident, people want to feel like they are doing something, and giving blood is one way that they respond. Unfortunately, they overwhelm the blood centers. The—and much of that blood, as we saw following September 11, is not needed.

What we need to do is, again, as you just heard, have a consistent message with the media so we get people to defer media donations, and defer over time—and donate over time to augment the blood supply. If, in fact, we have a catastrophic event where we do need blood, then we will have to address it and get people in immediately to augment the blood supply that is immediate—needed immediately.

But, you know, I think that the basic issue comes down to getting people to donate blood on a regular basis and getting people to donate blood during these times when we see these spot shortages. And, you know, those occur at various times of the year. Around the Christmas holidays we see that the blood supply tends to drop off.

When I worked with Dr. Page, in Boston, we saw that during the summer we had a terrible time getting blood because 30 percent of our donor population left town when the students left town, so we see a decrease in the blood supply. It is a matter of making sure that people give blood on a regular basis and not just during those——

Mr. DEUTSCH. Again, if I can try to just focus a little bit. I mean, you have articulated the problem extraordinarily well.

What about the solution? I mean, you keep saying we are going to try to do something.

Mr. HAUER. Well, we are working with the various blood organizations to, one, ensure that we have a coordinated message following an incident, because that, I believe, is what your question is. Your question is—was, what do we do following an incident to ensure that we have a scheduled——

Mr. DEUTSCH. So you basically have a plan for the next incident; is that the——

Mr. HAUER. Well, we are working on a plan and we are talking with the blood organizations. I have personally met with the various blood organizations to ensure that they are part of our process and in our command center following an incident so that we can coordinate when we need blood and when we don't need blood, and have a consistent and coordinated message.

Mr. DEUTSCH. Thank you. My time has expired.

Mr. GREENWOOD. The Chair thanks the gentleman. Before I recognize the gentleman from New Hampshire, just one quick follow-up question.

If next week or next month we had an event where we had thousands and thousands of Americans going to donate blood, and it looked like we were going to have this oversupply problem where we would have blood discarded, who would—who opens the book and says, okay, it is now time for me, the Secretary or someone else, to launch our communication efforts so we communicate with the donating public, as well as the—all of the blood centers, that we have more than a sufficiency of supply?

Is that—whose responsibility is that?

Mr. HAUER. That would be done between myself, the FDA, and the ASH. And the three of us would coordinate, look at where we are with the type of incident, the needs of the incident, and the current blood supply. We would be talking with the blood community. And if, in fact, there was an overdonation at that point in time or we anticipated there would be an overdonation, we would make a recommendation to the Secretary.

Mr. GREENWOOD. And so you have a system whereby you know how to measure that, you know how to immediately, or in a timely fashion, get the word to the blood centers and then get the word to the public? Somebody has a notebook that says, here is how we do our media program to inform the public that they don't need to get in line any longer?

Mr. HAUER. We would ask the Secretary or recommend to the Secretary at that point in time that he get out and communicate with the public. We would have the various blood organizations doing that. And again, part of our goal is to work with the blood organizations. HHS historically during these types of incidents has not had the blood organizations as part of the strategy at the headquarters level, and I think that is where one of the disconnects has been. And we have now fixed that issue.

Mr. GREENWOOD. Okay.

The Chair recognizes the gentleman from New Hampshire, Mr. Bass, for 10 minutes for inquiry.

Mr. BASS. Thank you very much, Mr. Chairman. And I love the GAO, because they produce reports that you get the whole report in the title. Blood Supply Generally Adequate Despite New Donor Restrictions. It's the whole thing. And then you read more if you want to turn and look a little bit more.

But, Dr. Heinrich, I was wondering if you could review, please, the nature or level at which the Federal Government has been involved in monitoring the Nation's blood supply.

Ms. HEINRICH. There was a longstanding effort to fund the monitoring of the adequacy of the blood supply up until about a year and a half ago, a couple of years ago. And that funding then stopped. They actually funded the American Association of Blood Banks and their data center to do that work.

Then, recently, within the Office of the Secretary there was an effort to monitor the demand for blood; so they developed a sample of hospitals that they routinely collected information on in terms of how much blood they had on hand and how much they were using.

What the future of that program is, I can't say. Maybe others here from the Department could speak to that. We have heard that the future of that may be uncertain.

So we have heard that there may be efforts by the Food and Drug Administration to develop some type of monitoring program. Again, I don't have specifics on that. Maybe the others could speak to that. But in essence—well, and certainly the Department of Defense has their efforts to monitor the blood that they collect and that they use, but here, there isn't an overall national data collection system.

Mr. BASS. Do any of you other witnesses have any comments about that?

Mr. HAUER. Yes. Dr. Epstein and I were just talking about that.

One of the things that we are going to be doing, because it is an issue, there is no centrally coordinated national data system for looking at the blood supply. And that is one of the things we are going to have to address, and we are going to have to address that very quickly. And Dr. Epstein and I were just addressing setting up a meeting with the blood organizations, AABB and the Red Cross, relatively quickly to look at how we would put a system like that in place. There are some disjointed systems out there, but there is not one central system.

Mr. BASS. Is the monitoring of the Nation's blood supply part or relevant in terms of the issue of homeland security? And, if so, is there anything in that legislation that makes—that affects in any way this challenge?

Mr. HAUER. I don't know that there is anything in the legislation about the blood supply or the monitoring of the blood supply, but HHS does monitor components and has sentinel blood sites that are monitored to look at generally where the blood supply is at. But as much as we are doing—Secretary Thompson has got an enormous initiative to connect hospitals and public health agencies so that we have a better understanding of surveillance of disease. There is certainly the infrastructure in place, and I think there is an opportunity here to do the same type of thing with the blood supply.

Mr. BASS. So the conclusion is there is no—there is no monitoring or inventorying at this point, but you're planning to meet——

Mr. HAUER. No, there is monitoring, and there is inventorying. It's not done centrally, and it's not done as comprehensively as I think the GAO is talking about, and that's one of the things we need to address.

Mr. BASS. Okay. Mr. Hauer, GAO reported, as have others, that the emergency response of September 11 led to large amounts of blood being discarded. What actions is the Department taking to avoid this problem in future emergencies?

Mr. HAUER. Well, I believe that my comments to—earlier on alluded to that. We—the amount of blood that was discarded was because we had this overwhelming number of people show up at blood banks who wanted to do something. They wanted to help. But blood has a finite shelf life, and they all showed up at once within a short period of time, and much of that blood outdated. What we need to do is let people know that blood is needed over a period of time following an emergency and not just in the immediate aftermath of the emergency and get people to defer their donations for periods of time following an incident or donate at times distant from the emergency, which is sometimes frustrating.

But the reality is getting everybody in to donate. You would predict in an event like the World Trade Center, where most of the people succumb to the incident rather than being injured, that there would be a less of a demand for blood than you would have thought; and you know, unfortunately, it is a very frustrating issue for us because people want to help. Donating blood is a very tangible way to help, and they feel like they're contributing, and that's just, you know, it's human nature. And it's a wonderful thing. But we have seen this over and over again following major incidents where much of the blood winds up outdating.

Mr. BASS. What's the shelf life of blood?

Mr. HAUER. Forty-two days.

Mr. BASS. Forty-two days. Does freezing it—or is there any other way to extend that shelf life?

Mr. HAUER. Yeah. You can freeze blood, but there are obstacles to taking blood that's donated and freezing it. First of all, some centers don't do a lot of freezing; and, you know, it's expensive. I mean, there's a number of issues with taking all this blood before it outdates.

Jay, did you want to——

Mr. EPSTEIN. Sure. There are several technical issues. You basically want to assure two things. You want to insure integrity of the red cells after they're thawed, and you want to insure that they're sterile so that you don't transmit bacterial and fungal infections. And the current systems are largely manual. FDA has approved an automated system that provides for sterile freezing and thawing that extends shelf life from the current 24 hours for the manual system to 14 days. Those have not been widely implemented yet and they have a narrow set of constraints. People would like to validate different volumes, different preservative solutions, different rejuvenation solutions.

Another issue is that you have to act quickly. If you don't revitalize the red cells, you have to freeze them within 6 days. That opportunity is not always available. So there are a lot of safety validation issues that have to be addressed.

Above and beyond that, although the frozen red cell has a 10-year shelf life under licensing, the standards for donor suitability do evolve over that time period. So you may have frozen the blood safely, but, 3 or 5 years later there may be a different standard for

what's considered an acceptable donation. That's one problem. And then, in addition to the cost issue, which is very significant, as mentioned by Colonel Fitzpatrick, there's the problem that it's a very labor intensive procedure and you can only produce units at a very slow rate.

So all of these factors conspire against rapid use of a frozen inventory.

Now, whether frozen inventories would have a benefit as a back-up for rapid release of liquid inventories has yet to be really thought through by the system as a whole. So basically FDA's point of view is we're supportive of the concept of developing blood reserves. We are focused on the concept that it has to be done safely and fully consistent with all applicable standards and we are cooperative with the initiatives both by Department of Defense and the civilian blood organizations to try to come up with a coherent plan for how to create usable liquid and frozen reserves.

Mr. BASS. Thanks. One last question, Mr. Hauer, and if you've already answered this, you know, just a one-sentence summary is fine. But does the Department have an effective emergency response plan for providing massive amounts of blood in cases of—there's—you know, if there's some huge national disaster and there are many survivors needing blood.

Mr. HAUER. We rely on the Red Cross and the blood centers to do that.

Mr. BASS. Okay. Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

Finally, Mr. Hauer, could you just remind us or make sure that we are clear on what is the status of the advisory committee's recommendations being adopted formally by the Department.

Mr. HAUER. Jay, did you—do you want to—let me let Dr. Epstein address that.

Mr. EPSTEIN. Yes. There are two sets of recommendations, first from February 2002, and then we just had a meeting September 5 of last week where the recommendations are not yet formally made to the Department, so they are not yet under consideration by the Department. I believe that the Department has responded to the February recommendations: As Mr. Hauer stated, there is Department support for modification of the Emergency Support Function number 8 under the FEMA emergency plan; and Mr. Hauer's own participation in the interorganizational task force on disasters and supply bespeaks the response to the recommendation to make the role of that coordinating body primary in regard to preparedness. So I think that's the general thrust.

Mr. GREENWOOD. Thank you. I thank you. The Chair thanks each of the witnesses, and you are excused.

For the benefit of the next panel, as you can tell, we have three votes on the floor, so we will recess now for about 20 minutes and should be back here just a little bit before 11:30. The committee is in recess.

[Brief recess.]

Mr. GREENWOOD. The Chair apologizes to our panel for the length of the wait, but it took a little while longer than I thought to get those votes concluded. We should have time now to get all of your testimony in before the next series of votes.

I welcome our next panel consisting of Ms. Karen Shoos Lipton, Chief Executive Officer of the American Association of Blood Banks; Mr. Allan S. Ross, Vice President for Technical Operations and Biomedical Services, the American Red Cross; Ms. Jean Dariotis, is that correct?

Ms. DARIOTIS. Correct.

Mr. GREENWOOD. President of America's Blood Centers here in Washington. She is accompanied by Dr. Robert Jones, the President and Chief Executive Officer of the New York Blood Center.

On behalf of the Society for the Advancement of Blood Management, Dr. Lawrence Goodnough—is that pronounced correctly?

Mr. GOODNOUGH. Yes, sir.

Mr. GREENWOOD. Goodnough—Professor of Medicine, Pathology and Immunology at the Washington University School of Medicine.

We thank all of you for your help this morning and look forward to your testimony. As you heard from the—me say to the last panel, we are holding an investigative hearing, and it's our practice when doing so to take testimony under oath. Do any of you have any objections to offering your testimony under oath?

I should advise you then that under the rules of this committee and the House of Representatives you are entitled to be represented by counsel. Do any of you wish to be represented by counsel? I didn't think so.

Okay. Then if you would rise and raise your right hand.

[Witnesses sworn.]

Mr. GREENWOOD. You are under oath.

Ms. Lipton, you are recognized for 5 minutes to give your statement, please.

TESTIMONY OF KAREN SHOOS LIPTON, CHIEF EXECUTIVE OFFICER, AMERICAN ASSOCIATION OF BLOOD BANKS; ALLAN S. ROSS, VICE PRESIDENT FOR TECHNICAL OPERATIONS AND BIOMEDICAL SERVICES, AMERICAN RED CROSS, NATIONAL HEADQUARTERS; JEANNE DARIOTIS, PRESIDENT, AMERICA'S BLOOD CENTERS; ROBERT L. JONES, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NEW YORK BLOOD CENTER; AND LAWRENCE T. GOODNOUGH, PROFESSOR OF MEDICINE, PATHOLOGY AND IMMUNOLOGY, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE, ON BEHALF OF THE SOCIETY FOR THE ADVANCEMENT OF BLOOD MANAGEMENT

Ms. LIPTON. Thank you very much.

Mr. Chairman and members of the subcommittee, thanks for the opportunity to testify today. I am the Chief Executive Officer of the American Association of Blood Banks, the professional association representing approximately 1,800 institutions, blood centers and transfusion services and 8,000 individuals involved in all aspects of blood banking and transfusion medicine. AABB's members are responsible for virtually all the blood that's collected in the United States and approximately 70 percent of the blood that's transfused in the United States.

I am going to begin by focusing on the blood community's effort to insure that there's an adequate blood—that there's adequate blood available to treat all patients in need in the event of a disaster, and then I will briefly touch upon steps the government

should take to insure patients have access to an adequate supply at all times.

Based on lessons learned from the September 11 attacks, the blood community recognized the need to develop a response plan to future disasters and acts of terrorism. The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism was formed in December 2001, to help insure that, in the event of a disaster, blood collection and distribution efforts are managed properly, with the public receiving clear and consistent messages regarding the status of America's blood supply.

The AABB serves as the coordinating entity for the task force, and other task force members include America's Blood Centers, the American Red Cross, Blood Centers of America, the American Hospital Association and a number of government agencies, including the Department of Health and Human Services Department of Defense, the Centers for Disease Control and Prevention and the FDA. I would particularly like to acknowledge the involvement and active participation of the FDA and Mr. Jerome Hauer in the task force deliberations.

The task force has identified three primary lessons that we learned from the September 11 disaster. The first is the need to control collections in excess of actual medical need, the second is the need to insure that facilities maintain adequate inventories to prepare for disasters at all times in all locations, and the third is the need for overall inventory management within the United States.

In order to mitigate the problems created by collection in excess of actual need and to insure that the blood community can respond effectively in future disasters the task force has developed a plan of action. In the event of a disaster, the AABB will immediately convene a meeting of task force representatives and establish contact with the blood centers affected. Affected blood centers—those are the blood centers that serve the affected disaster area—will be responsible for communicating with their customer hospitals to ascertain medical need that's based on casualty estimates; and the blood centers are also responsible for assessing the available local supply and for communicating that information immediately to the task force. If applicable, the task force will identify sites with existing excess blood inventory and determine, along with the affected blood centers, the need, if any, for blood shipment and the logistics of such shipments.

In addition, the task force will be responsible for helping to develop a single, consistent public message and will work with HHS to disseminate this message to the public.

This plan of action is detailed in an operations handbook that the task force has drafted to help blood collectors and hospitals prepare for and respond to potential disasters. The handbook has been distributed in draft form to blood centers nationwide, and a final version will be widely distributed this fall. We have also sent letters under the logos of all of the blood organizations to all of our members and to hospitals alerting them to the existence of this task force, their activities and the operations handbook.

The task force recognizes that the provision of blood in response to a disaster requires that an adequate supply be available in every

community, every day. The blood on the shelf of the blood centers and hospitals in the affected area is the single biggest determinant of the success of the blood communities' first response in a disaster.

Persistent seasonal and regional shortages of blood are the major barrier to responding to immediate medical need in any community. The task force strongly believes that any planning for future disasters should include the recommendation that all blood centers have available a 7-day supply of blood at all times.

Information that's just released from the 2001 National Blood Collection and Utilization Survey conducted by our subsidiary, the National Blood Data Resource Center, reveals that 2002 collections and inventory totals remain unchanged in comparison with pre-September 11, 2001, measurements and that fully 12.8 percent of responding hospitals—that is 139 out of 1,086 hospitals—reported cancellation of elective surgeries in 2001. That's nearly two times as many as reported cancellations in 1999.

The government must play a role in insuring the ongoing availability of blood. First, the government must support public awareness campaigns that are designed to highlight the importance of blood donations in the American public and the role of blood donation in disasters. Currently, the AABB is working with the American Red Cross and America's Blood Centers to develop a multi-year, unbranded blood donation public education and awareness campaign, which we hope will be launched in the not-too-distant future. The Federal Government has funded public awareness campaigns about other public health issues such as organ tissue and marrow donations. Blood donation, which touches millions of lives each year, clearly merits a similar commitment.

In addition, in order for us to accurately gauge whether the supply on the shelf will be adequate to meet patients' future blood needs, it's crucial that the government support collection of long-term, quantitative blood supply and utilization data. Unfortunately, the government has not made any long-term commitments to collecting this data; and unless the government financially supports the collection of quantitative data sufficient to forecast future blood supply trends and predict shortages, we will continue to operate with only today in mind and without any reliable picture of what the Nation's blood needs will be in the future.

Last, when making any blood-related policies, including donor deferral policies, the Federal Government must carefully consider the potential impact on the blood supply, both national and regional. For epidemiologic and demographic reasons, different deferral policies may affect certain regions of the country more than others. And although the blood supply may be generally adequate, if there is a supply problem in any part of the country, in any blood type, on any day, there's a shortage.

AABB thanks the subcommittee for holding this hearing and hopes that you will act to insure the Federal Government steps forward in supporting these critical initiatives. Thank you.

[The prepared statement of Karen Shoos Lipton follows:]

PREPARED STATEMENT OF KAREN SHOOS LIPTON, AMERICAN ASSOCIATION OF BLOOD BANKS

Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today regarding issues affecting the nation's blood supply, and in particular

the blood community's efforts to ensure there is adequate blood available to treat all patients in need in the event of a domestic disaster. Today, I am speaking to you as Chief Executive Officer of the American Association of Blood Banks (AABB), the professional association representing approximately 1,800 institutions—including blood centers as well as hospital transfusion services—and 8,000 individuals involved in all aspects of blood banking and transfusion medicine. AABB's members are responsible for virtually all of the blood collected and approximately 70 percent of the blood transfused in the United States.

DISASTER PREPAREDNESS

Based on lessons learned from the September 11 attacks, the blood community recognized the need to develop a response plan to future domestic disasters and acts of terrorism. The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism was formed in December 2001 to help ensure that (in the event of a national disaster (blood collection efforts run smoothly and are managed properly, with the public receiving clear and consistent messages regarding the status of America's blood supply.

The AABB is serving as the coordinating entity for the task force. Other task force members include: America's Blood Centers (ABC), American Red Cross (ARC), Blood Centers of America/hemerica (BCA), Armed Services Blood Program Office (ASBPO), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), Food and Drug Administration (FDA), American Hospital Association, Advanced Medical Technology Association (AdvaMed), the Plasma Protein Therapeutics Association (PPTA), and the American Association of Tissue Banks.

The Task Force has identified three primary lessons learned from the September 11 disaster: 1) the need to control collections in excess of actual medical need, 2) the need to ensure that facilities maintain adequate inventories to prepare for disasters at all times in all locations across the country, and 3) the need for overall inventory management within the United States. Specifically, the Task Force recommends a minimum seven-day supply of red blood cells be maintained in order to prepare for a disaster. The Task Force is in the process of defining what constitutes a seven-day inventory.

In order to mitigate the problems created by collection in excess of actual medical need and to ensure the capability of the blood community to respond effectively in future disasters, the Task Force has developed a plan of action. In the event of a disaster, the AABB will immediately convene a meeting of task force representatives and establish contact with the local blood center(s) affected. Local blood center(s) will be responsible for ascertaining medical need based on casualty estimates, assessing available local supply and communicating that information to the Interorganizational Task Force. If applicable, the task force will identify sites with existing excess blood inventory and determine, along with the affected blood center(s), the need, if any, for blood shipment and the logistics of such shipments. In addition, the task force will be responsible for developing a single, consistent public message and will work with the Department of Health and Human Services (HHS) to disseminate this message to the blood community.

This plan of action is detailed in an Operations Handbook the Task Force has drafted to help blood collectors and hospitals prepare for and respond to potential disasters. The Handbook, which has been distributed in draft form to blood centers nationwide, contains information on preparation steps, activation (i.e., step-by-step response), training materials and reference materials (e.g., important phone numbers, etc.). The Handbook also contains a hospital supplement focusing on hospital transfusion services. In addition, the Handbook distinguishes between "traditional' disasters and biological events, which are likely to affect donor suitability more than demand for blood. The Task Force will incorporate comments on the draft into a final version of the Operations Handbook, which will be widely distributed this fall.

The Task Force also has been busy this year working on other related projects. This past winter, the Task Force created a test pilot to operate during the winter Olympics in Salt Lake City. Before the Olympics began, representatives of the Task Force met with the two blood suppliers for Salt Lake City. Both suppliers agreed to work together to assess medical need should a disaster occur and to work with the Task Force on a coordinated national response. Redundant lines of communication among the Task Force and the blood centers were established. In addition, since the major supplier in that area, the American Red Cross, already had an extensive disaster plan in place in Salt Lake, the Task Force plan was integrated into their plan through the creation and distribution of a shared document with specific instructions and defined communication lines should an event occur. Fortunately,

our efforts were not needed, but this served as a valuable pilot in establishing a coordinated approach to disaster preparedness.

In addition, the Task Force has served as an effective mechanism for bringing together the blood community to discuss and develop positions regarding individual disaster-related issues that could affect the blood supply. For example, the Task Force wrote to the Department of Health and Human Services about a variety of issues relating to the blood supply that it felt should be carefully considered before the Department developed any new policies calling for widespread smallpox immunization. Immunization against or exposure to individual biological agents could adversely affect the blood supply by expanding, at least temporarily, the population of unsuitable donors. Because we are already faced with persistent, regional blood shortages, it is critical that the government carefully address the effects any bioterrorism policies could have on blood availability. Whenever possible, the AABB believes it is most effective and efficient for the entire blood banking community to speak with one voice on such important policy matters, and the Task Force enables us to do just that.

IMPORTANCE OF BLOOD ON THE SHELVES

The AABB and the Interorganizational Task Force recognize that the provision of blood in response to a disaster requires that an adequate supply of blood be available in every community, every day. The blood on the shelf of the blood centers and hospitals in the affected area is the single biggest determinant of the success of the blood community's first response to a disaster. Persistent seasonal and regional shortages of blood are the major barrier to responding to immediate medical need in any community. For that reason, the Task Force strongly believes that any planning for future disasters should include the recommendation that all blood centers have available a seven-day supply of blood at all times. Continuing and effective communication to the public through multi-year public education and awareness programs, of this real need is of critical importance to the public health of this country.

The government must play a role in ensuring the ongoing availability of blood. *First, the government needs to support needed public awareness campaigns designed to highlight the importance of blood donations to the American public.* Currently, the AABB is working with the American Red Cross and America's Blood Centers to develop a multi-year, unbranded blood donation public awareness campaign, which we hope will be launched in the not-too-distant future. The federal government has funded public awareness campaigns about other public health issues, such as the currently funded program for organ, tissue and marrow donations. Blood donation, which touches millions of lives each year, clearly merits a similar commitment.

In addition, in order for us to accurately gauge whether the supply on the shelf will be adequate to meet patients' blood needs in the future, it is crucial that the government support collection of long-term, quantitative blood supply and utilization data. Unfortunately, the government has not made any long-term commitment to collecting this necessary, representative data. Unless such a commitment is made and the government financially supports the collection of quantitative data sufficient to forecast future blood supply trends, we will continue to operate with only today in mind, and without any reliable picture of what the nation's blood needs will be in the future.

Lastly, when making any blood related policies, including donor deferral policies, the federal government must carefully consider their potential impact on the blood supply, both national and regional. For epidemiologic and demographic reasons, different deferral policies may affect certain regions of the country more than others. If there is a supply problem in any part of the country, in any blood type, there is a shortage. Patient access to an available blood supply is clearly a safety issue as well as a public health priority.

The AABB thanks the Subcommittee for holding this hearing and hopes that you will act to ensure the federal government steps forward in supporting these critical initiatives aimed at promoting a safe, available blood supply.

Mr. GREENWOOD. Thank you.

Now Mr. Ross.

TESTIMONY OF ALLAN S. ROSS

Mr. ROSS. Chairman Greenwood, Ranking Member Deutsch and members of the subcommittee, my name is Allan Ross; and I'm Vice President of Technical Operations for Biomedical Services at

American Red Cross. Thank you for inviting me to discuss the work of the Red Cross following the September 11 attacks and to insure blood products are available should another attack occur, or a major natural disaster occur.

In the year following September 11, the most important lessons learned in the blood banking community have been an understanding that we must work collaboratively and a consensus that the daily inventory of blood components must be substantially increased. As we face the new reality of terrorist attacks on American soil that may result in mass casualties, the blood banking community and public health officials must work together to address the long-standing challenge to build a stable and sustained blood supply.

Today I'd like to highlight for the subcommittee our strategies related to blood preparedness, including: our collaboration with our blood banking and public health colleagues to prepare for future disasters; the consensus that is evolving as to what truly constitutes an adequate inventory and our measures to effectively manage existing and projected patient needs; and our efforts to increase blood donation through market research, public awareness and outreach programs.

Blood preparedness is comprised of a readily available supply of blood components matching projected patient needs, effective management of current inventory and healthy blood donors close at hand when needed. You have just heard from the AABB about the recently established task force. This is a major step forward in our preparedness efforts. Now we have an effective means for the blood banking organizations and Federal Government officials to coordinate efforts before and after disaster strikes. The Red Cross is pleased to be part of this important initiative.

Another example of increased collaboration between the blood banking and health care communities was the unprecedented joint national blood appeal in June of this year to immediately bolster blood inventories. The Red Cross worked closely with government officials, the AABB, America's Blood Centers, the American Hospital Association and the American Public Health Association to issue a joint appeal for blood donors to enhance blood supplies this past summer.

Although this effort increased blood availability for a portion of the summer, our current inventory level is just slightly above what we classify as critical and that's about 50,000 units on hand. That's just over 2 days supply, which brings me to the important issue of what constitutes an adequate blood supply. Maintaining a 3-day inventory is not sufficient to handle normal usage and be prepared for a catastrophic event. There is a growing consensus that an optimal supply is more in the range of 7 days.

The Red Cross has enhanced its inventory management system to insure that blood products are available where they are needed. This system is comprised of three components: planning the balance between units collected and units distributed among our 36 blood regions, managing the units and inventory at our 36 blood regions, and working with hospitals to balance their inventory levels.

As we move toward an increasing inventory of 7 days, there is a cost to preparedness that we must recognize. We need to work

together to educate the public that blood, like pharmaceuticals, must be stockpiled in order to be readily available to respond to any event. It is important that the public understands that some blood may eventually outdate and not be used. This is the cost of preparedness, our insurance policy to cover us in the event of disaster.

Public awareness of the need for blood is key to insuring a new generation of donors. Within the past year we have begun to share research on donor motivations with our blood banking colleagues. Working together, the blood banking community is examining ways to identify those segments of the population most likely to donate and better use scarce resources to target them. In addition, paid advertising is a more effective tool to recruit and retain blood donors than PSAs. However, our ability to use paid advertising on a regular basis has been limited due to cost constraints.

We are trying to recruit new donors and buildupon our relationships with existing donors through the Internet, especially youth. Approximately 20 percent of first-time donors who gave immediately following the September 11 attacks were high school and college age, 25 years or younger. The Internet provides an effective way to encourage these individuals to become regular blood donors.

At the beginning of this month the American Red Cross launched a public awareness and education campaign called Together We Can Save a Life. This is supported by Microsoft, Yahoo and America Online; and those of you here today are in a unique position to educate the public about the need for blood and the importance of blood preparedness.

We are grateful for the leadership many in Congress have shown through regular blood donations in your home districts or here on Capitol Hill and your support in getting the message out to the public. Special thanks to Congressman Bass for his leadership and the New Hampshire congressional delegation and their promotion of the importance of donating blood.

In summary, the horrific events of September 11 challenged the blood banking community and made all of us look at ways we could better support the country's preparedness efforts. Through collaboration, management of inventories and increased public outreach, we are working toward ending the cylical shortages we have faced for more than 50 years. Of course, none of this will be easy. Success will require that all involved, the blood banking community, hospitals and the Federal Government work collaboratively. Together we can buildupon the renewed spirit of civic engagement in this country and recruit a new generation of altruistic blood donors committed to give regularly to benefit fellow citizens.

Thank you.

[The prepared statement of Allan S. Ross follows:]

PREPARED STATEMENT OF ALLAN ROSS, VICE PRESIDENT, TECHNICAL OPERATIONS, BIOMEDICAL SERVICES, AMERICAN RED CROSS

Chairman Greenwood, Ranking Member Deutsch and members of the subcommittee, my name is Allan Ross and I am the Vice President of Technical Operations for Biomedical Services at the American Red Cross. I am pleased to be here today to discuss the work of the Red Cross in the aftermath of the September 11 attacks on our country to ensure that we are prepared to support the need for blood products following another terrorist attack or a major natural disaster. In the year

following September 11, the most important "lessons learned" in the blood banking community have been:

- An understanding that we must work collaboratively; and
- A consensus among government and blood suppliers that we must significantly increase the daily inventory of blood components if we are to be adequately prepared.

Blood is one of the cornerstones of medicine. It is a precious public health resource made available only through volunteers who generously give part of themselves to help patients in need. The Red Cross supports almost one-half of the nation's blood supply through our system of 36 blood regions across the country, serving more than 3,000 hospitals. Last year, we collected more than 6 million units of whole blood through the generous donations of approximately 4.5 million donors.

As a single organization with a nationwide presence, Red Cross is able to move products where they are needed. This is especially important in the current environment where the nation must now be prepared for both natural disasters and acts of terrorism. The Red Cross is committed to meeting the challenge of developing a stable and sustained blood supply to prepare for everyday needs and for the new reality of terrorist attacks on American soil that may result in mass casualties.

Today I would like to highlight for the Subcommittee Red Cross' strategies related to blood preparedness, including:

- Collaboration with our blood banking and public health colleagues to prepare for future disasters;
- Consensus as to what constitutes an adequate inventory and measures to effectively manage the inventory to meet existing and projected patient needs; and
- Efforts to increase blood donation through market research, public awareness and outreach programs.

BUILDING PREPAREDNESS THROUGH COLLABORATION

Blood preparedness is a readily available supply of blood components matching projected patient need, effective management of current inventory and healthy blood donors close at hand when needed. Representatives from the American Association of Blood Banks have briefed the Committee on the recently established Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism. The Task Force provides an effective means for the blood banking organizations and federal government officials responsible for disaster preparedness and public health to coordinate efforts before and after disaster strikes. The Red Cross is pleased to be part of this important initiative to ensure that we are prepared for any and all hazards, by maintaining an adequate inventory at all times. For the first time, through the Task Force, the entire blood banking community and public health officials will have an effective means of:

- Assessing the need for blood donations following a mass casualty event;
- Coordinating public messaging of the need for blood donations; and
- Coordinating the transportation of blood components where needed.

Another example of the increased collaboration between the blood banking and healthcare communities was the unprecedented joint national blood appeal issued on June 25, 2002, to immediately bolster blood inventories and educate Americans about the everyday need for blood. Red Cross worked closely with government officials, the American Association of Blood Banks, America's Blood Centers, the American Hospital Association, and the American Public Health Association, to issue a joint appeal for blood donors to enhance blood supplies this summer and throughout the year. By leveraging each organization's relationships with the media, we were able to reach the public in more than 60 major media markets, including New York, Philadelphia, Chicago, Detroit, Boston, Miami, Atlanta and Los Angeles. It is our understanding each of our organizations saw an increase in presenting donors, and specific to the Red Cross, our projected collections for the July 4th holiday week increased by 8,000 units, and scheduled appointments increased by 6,000 to 9,000 per week for several weeks after the holiday. Although this effort increased blood availability for a portion of the summer, our inventory level as of August 30 was just slightly above what we classify as "critical", or 50,000 units on hand equaling a two-day supply.

A STABLE, SUSTAINED BLOOD SUPPLY " FOUNDATION OF PREPAREDNESS

Our nation has suffered from seasonal and cyclical blood shortages for more than 50 years. Prior to September 11, the need to develop a stable and sustained blood supply to meet increasing patient needs and hospital demand for these life-saving products was readily apparent. In the summer of 2001, as the Department of Health

and Human Services and the blood banking organizations wrestled with the issues surrounding an expansion of the donor deferral criteria related to new variant Cruetzfeld-Jakob disease (vCJD), the discussion centered on the fragile state of the blood supply. Traditionally, we have struggled to maintain an inventory ranging from one to three days. Donated units of blood can be processed into three primary components: red blood cells, platelets and plasma. One donation can yield platelets for cancer patients; red cells for surgery, anemia and accident victims; and plasma for burn patients. The challenge is to constantly replenish our inventories as the shelf life for red blood cells is 42 days, and only 5 days for platelets.

Maintaining a three-day inventory is not sufficient to handle normal usage and be prepared for a catastrophic event. There is a growing consensus among policymakers and the blood banking organizations that an optimal supply is more in the range of 7 days.

The Red Cross blood services system collects, processes, and distributes blood components through our 36 blood service regions. In order to ensure an adequate supply of blood products for these regions, we have established an inventory management system that provides a mechanism to ensure blood products are available where they are needed. This system is comprised of three components:

- Planning the balance between units collected and units distributed among the regions
- Managing the units in inventory at the regions
- And working with hospitals to balance their inventories.

Through this integrated approach, the Red Cross determines, on a quarterly basis, an 18-month demand forecast. We do this by analyzing the requirements of our hospital customers and our collections forecasts. To determine the optimal inventory level, the Red Cross must balance:

- The total demand requirements provided by hospital customers;
- The lead time to increase collections, processing of units and distribution to hospitals;
- Customer service levels;
- The day to day volatility of demand;
- The shelf life and expiration cycle for each blood component; and
- The right mix of blood types matched to blood usage (with particular emphasis on the need to collect proportionately more blood group O units).

Through this analysis we are able to balance the needs among the regions and forecast the collections we will need to ensure an adequate blood supply.

On a monthly basis we measure the forecasts and compare them to our actual collections. We are then able to determine the causes for the differences between forecasts and our actual collections and make needed adjustments to the 18-month forecast. We also conduct a daily analysis of our forecasted inventory levels with the requirements of each region, and are then able to identify excess blood in our system and move it to hospitals in areas of the country where additional products are needed. These quarterly, monthly, and daily analyses are performed so as to provide the most efficient use of blood donated to the Red Cross by generous Americans throughout our country.

There is a cost to blood preparedness that must be recognized. Despite our best efforts, there will continue to be a certain percentage of units that will outdate before they can be transfused. Currently, between 1 to 2 percent of blood products nationwide expire before a hospital can use them. As the inventory is increased to 7 days in order to meet increased demand and prepare for a possible mass casualty event, the number of units outdating will increase. The Red Cross and our blood banking colleagues are careful stewards of the units voluntarily donated to us by altruistic individuals. As we move forward in our preparedness efforts, the public needs to be educated that blood, like pharmaceuticals, must be "stockpiled" in order to be readily available to respond to any event. It is important that the public understands that some blood may eventually outdate and not be used. This is the cost of preparedness " our insurance policy to cover us in the event of disaster. If the Red Cross is to achieve and maintain an optimal inventory, we need 25,000 donors to visit one of over 400 Red Cross fixed donation sites, or one of hundreds of our mobile donation sites each day.

NEW INITIATIVES TO INCREASE BLOOD AVAILABILITY

Over the past decade, the Red Cross has invested over $335 million in technologies and systems to improve the safety of the blood supply. In comparison, during the same period, we have had only a small fraction of that amount available to invest in the availability of the blood supply. Despite our extensive efforts to build public awareness of the need for blood, significant challenges remain. As a

group, Americans over the age of 65 tend to require more blood than other age groups. In addition, as these individuals age, we lose our most dedicated, repeat blood donors. The challenge to the blood banking community, the federal government, and the American public is to ensure these dedicated donors are replaced with a new generation of donors ready, willing, and able to provide a life-saving resource

The Red Cross is working on a number of initiatives to help make that happen. I would like to outline a few these programs in order to highlight the breadth of work we are undertaking to ensure an adequate supply of blood.

Research Sharing

The Red Cross and our blood banking colleagues have begun to share the research we have performed individually on donor motivations. In research performed several years ago, we found that our most loyal donors also volunteer their time with non-blood organizations. With the hectic pace of today's society these individuals are finding less time to donate blood. Working together, the blood banking community is examining ways to overcome these problems by undertaking studies to help identify those segments of the population most likely to donate. Through this market segmentation, we will then be able to better utilize scarce resources to target those individuals most likely to donate and donate frequently.

One of the important issues that collaborative research efforts can address is the true size of the population that is eligible to donate. The estimate that only 5% of the population eligible to donate do so, is based upon research that is relatively dated.

Public Awareness and Education Efforts

In a recent public opinion poll conducted by the Red Cross of more than 1,000 Americans, we learned that a majority of respondents *underestimated* the everyday need for blood and *overestimated* the availability of the blood supply. Through this and other information, the blood banking community has been working on a non-branded, multi-year joint campaign to increase public awareness on the need for blood. As part of this effort, the blood banking community will: provide information to the general public on the need for a new generation of donors; produce and execute national media campaigns; perform market research; and, collaborate on other activities to raise the awareness of the vital need for Americans to donate blood.

E-marketing strategies

While it is vital that we attract new donors, it is equally important that we retain them after their initial experience. The Red Cross is leveraging the power of the Internet to recruit new donors and build upon relationships with existing donors to ensure that we continue to grow the blood supply. Previously we have relied upon traditional media and other channels to reach the public, i.e. direct mail, television and radio ads, many of them public service announcements. The Red Cross has found the use of paid advertising to be an effective tool to recruit and retain blood donors. However, our ability to use paid advertising on a regular basis has been limited due to cost constraints. We are now exploring the use of regular emails to potential and existing members of the Red Cross as an education tool.

This is a medium that is particularly attractive to youth, our next generation of blood donors. Approximately 20% of first-time blood donors who gave immediately following the September 11 attacks were high school and college-age (25 or younger). The Internet provides an effective way to encourage these individuals to become regular donors. At the beginning of this month, the American Red Cross launched a public awareness and education campaign—"Together, We Can Save a Life"—with the support of Microsoft, Yahoo! and America Online. The campaign will educate Americans about the importance of giving blood on a regular basis and for a lifetime. Americans can now learn more about the crucial need for blood donations and how to schedule appointments through online features (such as http://blood.givelife.org and AOL Keyword: Gift of Life), links and PSAs running throughout MSN, Yahoo! and AOL properties. The participating technology companies estimate that millions of people will view the four-week campaign from the participating companies' sites alone. With the help from these leading technology companies, the American Red Cross is leveraging the power of the Internet to increase blood donations and ensure a safe and stable blood supply in support of our nation's public health and security.

Role of Congress and Federal Government

Elected officials at all levels of government are in a unique position to educate their constituents and target audiences about the need for blood and the importance of blood preparedness.

We have worked extensively with Members of Congress to promote public awareness of the need for blood. Members of Congress have provided vital leadership to help ensure an adequate blood inventory is available throughout the country. This support has come in the form of regular blood donations at home and at the seven Red Cross blood drives held annually on Capitol Hill; public service announcements; newspaper editorials; and speeches on the floors of the House and Senate and at home in their districts.

As you have heard today, HHS is focused on this public health issue as well, and has highlighted the need for federal government support of public awareness and the monitoring of blood availability through the HHS Advisory Committee on Blood Safety and Availability and the FDA. Red Cross has also worked with HHS on the "Gift of Life" donation initiative to increase awareness and promote donation of organs, and the corresponding need for blood for transplantation procedures.

CONCLUSION

The horrific events of September 11 challenged the blood banking community and made all of us look at ways we could better support the country's preparedness efforts for future natural disasters or acts of terrorism. Through the work of the AABB Inter-organizational Task Force on Domestic Disasters and Acts of Terrorism, the Red Cross and our colleagues have taken major steps to ensure a coordinated response to such events in the future. The continued refinement of the Red Cross inventory management system will provide us with a means to ensure the most efficient use of blood that is donated by generous Americans throughout our country. New initiatives to increase public awareness for the need for blood and activities to recruit and retain a new generation of dedicated blood donors will hopefully move us away from the cyclical shortages the community has faced for over 50 years.

Of course, none of this will be easy. The events of September 11 taught all of us that we must be prepared. Success will require that all involved " the blood banking community, hospitals, HHS, FDA, and CDC " work collaboratively. Together, we can build upon the renewed spirit of civic engagement in this country, and engage a new generation of altruistic blood donors, committed to give regularly to benefit their fellow citizens. We have no option on this matter and the Red Cross is committed to doing all we can to provide this life-saving resource wherever and whenever it is needed.

Mr. GREENWOOD. Thank you, Mr. Ross.

Ms. Dariotis.

TESTIMONY OF JEANNE DARIOTIS

Ms. DARIOTIS. Thank you.

Mr. Greenwood and the honorable members of this oversight committee, I am Jeanne—is that better? My name is Jeanne Dariotis. I'm the President of America's Blood Centers, and I'm the Chief Executive Officer of the Southeastern Community Blood Center located in Tallahassee, Florida. On behalf of ABC members nationwide, I thank the committee for the opportunity to testify and comment on the availability and safety of blood and blood products in the United States. I'm here to ask you for support and acknowledgment that our fragile blood supply is an important public health and safety issue.

America's Blood Centers, or ABC, is the national network of 75 not-for-profit community-based blood centers which provide nearly half of the U.S. And one-quarter of Canada's blood supply to over 3,300 hospitals. In the United States, America's Blood Centers members are located in 45 States and serve more than 140 million people from over 500 blood donationsites. ABC members have been committed to serving the needs of their local communities since the 1940's. Indeed, one of ABC's founding members is the Blood Bank of Hawaii, which was formed in the days following the attack on Pearl Harbor. ABC members save over 2 million lives each year by providing volunteer blood donations. Our members were also the

first to respond to national tragedies like the Oklahoma City bombing, the Columbine shootings and the September 11 attacks.

It's important to note the remarkable safety of the U.S. blood supply today. Twenty years ago, some blood transfusions were infecting thousands of transfusion recipients with HIV and hepatitis. Today, an HIV transmission from blood is a rare event, estimated at less than one in 2 million transfusions, so rare it makes national headlines. Even transfusion related hepatitis is now equally rare. Many other viruses have been eliminated from transfusions, and today the U.S. Blood supply has never been safer.

The reasons for this increased safety are twofold. First, new leading-edge technology for testing blood has been introduced to blood screened almost yearly. Second, individuals are deferred as would be donors if they have identifiable risk factors for an infection, such as the new donor deferral for Mad Cow Disease that eliminates potential donors based on travel or living in Europe.

Unfortunately, these precautionary deferrals also eliminate millions of perfectly safe and willing donors. It is these deferrals such as the recent Mad Cow deferrals, along with the aging population that is donating less but using more blood, which are the leading causes of increased blood shortages.

The new Mad Cow deferrals could cause a crisis in New York City in the coming weeks as New York City, which has been dependent on blood from Europe for over 25 years, will no longer be able to import blood because of the New FDA requirements. ABC members and others are sending unprecedented amounts of blood to New York, primarily to the New York Blood Center, one of our members. We are all working hard to prevent a crisis in New York, but there's no guarantee that one can be averted.

Blood shortages also exist all over America, as we all are aware. Indeed, blood shortages are in the news more than ever in history. Are patients dying from these shortages? We have no way to tell for sure. Hospitals and blood centers have become very skillful at managing meager blood supplies and preventing tragedies from occurring. But reports of wasted organs are increasing, and each day necessary surgeries are canceled or postponed for the lack of an adequate supply in the hospital.

As we know from experience in responding to major disasters, it is the blood on the shelves that saves lives, not the blood collected from those who line up when a tragedy strikes. It takes well over 24 hours from the time of a donation until blood is ready to be used by a patient. Today there is less than a 3-day supply nationwide. Never in modern times have our reserves been lower.

In these days of heightened concern for attack, our blood supply is inadequate to deal with a major disaster because, as I said before, it's the blood on the shelves that saves lives. We must respectfully disagree with the GAO report that today's blood supply is adequate. One year ago today, September 10, most communities around the United States had a 3 to 5-day blood supply and thus were prepared to deal with a local or national emergency requiring massive amounts of blood. Today, many communities have a 2 day or less supply and are not prepared to meet even a local emergency, much less a disaster or national emergency.

As I said, shortages are worsening because demand is growing and the eligible donor base is shrinking. Demand continues to increase because of the aging patient population and the increased use of blood for medical procedures such as organ and marrow transplants and more aggressive chemotherapy. Our volunteer donor base is also aging as the population ages. We must now resort to emergency blood appeals during the time of the year that used to be periods of abundance. We cannot continue to rely on urgent appeals to solve our problems because they're only a temporary fix. And at some point the media and public stop listening. Needless to say, the fragility of the blood supply is an urgent public health issue.

What's the answer? Blood centers are pouring millions more dollars into marketing research and advertising to persuade millions of eligible people to give blood and to give it routinely, not just when a tragedy occurs. Blood saves more than 4 million Americans every year, and we are struggling to meet the demand.

We need help. We can't do it alone. Both Congress and the administration have key roles in assuring readiness in America's blood supply.

Last year, America's Blood Centers met with Secretary Thompson about the issue of shortages and its effect on the public health. At the Secretary's request, ABC developed and submitted a blood action plan that HHS could use to help increase donations for blood. A copy of that plan has been attached. Despite the Secretary's pledge and numerous attempts in follow-up, no action has been seen from HHS to help bolster supply.

While HHS has rightly placed a emphasis on blood safety, they have not focused on the adequacy of the supply. We need a designated person inside HHS that focuses on blood availability and coordinates this very important public health issue with the private sector. We suggest that, as they do for organs, tissue and marrow, the Health Resources and Services Administration be charged to work with the private sector on helping to assure an adequate blood supply.

HHS could also do simple things such as credibly reinforcing the need for Americans to give blood through the sponsorship of an advertising campaign, by asking celebrities to donate their time, and by having high officials regularly donate on camera.

Congress, too, can help by assuring funding for new public health educational initiatives and blood donations, by encouraging every Congressman and Senator who can to give blood publicly and frequently, and by working with their local blood suppliers to participate in public events that would help create a culture of donation in the United States.

If merely 1 percent of the public—only 2 million more Americans—would give blood, shortages would end and reserve supplies would swell. But even 2 million donations today won't meet tomorrow's needs. We need HHS's help to work in partnership with the private sector to help assure tomorrow's blood supply.

I thank the committee for the opportunity to speak on these very important issues. I would like to introduce Dr. Robert Jones of the New York Blood Center, and he will speak about some of the unique blood supply problems of his center.

[The prepared statement of Jeanne Dariotis follows:]

PREPARED STATEMENT OF JEANNE DARIOTIS, PRESIDENT, AMERICA'S BLOOD CENTERS

Mr. Greenwood and honorable members of this Oversight Committee, I am Jeanne Dariotis, president of America's Blood Centers and CEO of the Southeastern Community Blood Center in Tallahassee Florida. On behalf of ABC members nationwide, I thank the Committee for the opportunity to testify and comment on the availability and safety of blood and blood products in the United States. I am here to ask for support and acknowledgement that our fragile blood supply is an important public health and safety issue.

America's Blood Centers, or ABC, is the national network of 75 not-for-profit community-based blood centers, which provide nearly half the US and one-quarter of Canada's blood supply to over 3,300 hospitals. In the US, America's Blood Centers' members are located in 45 states and serve more than 140 million people from over 500 blood donation sites. ABC members have been committed to serving the needs of their local communities since the 1940s. Indeed, one of ABC's founding members is the Blood Bank of Hawaii, which was formed in the days following the attack on Pearl Harbor. ABC members save over 2 million lives each year by providing volunteer blood donations. Our members were also the first to respond to national tragedies like the Oklahoma City bombing, Columbine shootings and September 11th attacks.

It is important to note the remarkable safety of the US blood supply today. Twenty years ago, some blood transfusions were infecting thousands of transfusion recipients with HIV and hepatitis. Today, an HIV transmission from blood is a rare event—estimated at less than one in 2 million transfusions—so rare it makes national headlines. Even transfusion-related hepatitis is now an equally rare event. Many other viruses have been eliminated from transfusions and today the US blood supply has never been safer. The reasons for this increased safety are two-fold. First, new leading edge technology for testing blood has been introduced to blood screening almost yearly. Second, individuals are deferred as would-be donors if they have identifiable risk factors for an infection, such as the new donor deferral criteria for Mad Cow Disease that eliminates potential donors based on travel or living in Europe.

Unfortunately, these precautionary deferrals also eliminate millions of perfectly safe and willing donors. It is these deferrals, such as the recent Mad Cow deferrals, along with an aging population that is donating less and using more blood, which are the leading causes of increased blood shortages.

The new Mad Cow deferrals could cause a crisis in New York City in the coming weeks as New York City, which has been dependent on blood from Europe for over 25 years, will no longer be able to import blood because of new FDA requirements. ABC members and others are sending unprecedented amounts of blood to New York, primarily to the New York Blood Center, an ABC member. We all are working hard to prevent a crisis in New York, but there is no guarantee that one can be averted.

Blood shortages also exist all over America, as we are all aware. Indeed, blood shortages are in the news more than ever in history. Are patients dying from these shortages? We have no way to tell for sure. Hospitals and blood centers have become very skillful at managing meager blood supplies and preventing tragedies from occurring. But reports of wasted organs are increasing and each day necessary surgeries are cancelled or postponed for lack of an adequate blood supply in the hospital. As we know from experience in responding to major disasters, it is the blood on the shelves that saves lives—not the blood collected from those who line up when a tragedy strikes. It takes over 24 hours from the time of donation until blood is ready to be used by a patient.

Today there is less than a three-day supply nationwide. Never in modern times have our reserves been lower. In these days of heightened concerns for attacks, our blood supply is inadequate to deal with a major disaster.

As I said, shortages are worsening because demand is growing and the eligible donor base is shrinking. Demand continues to increase because of the aging of the patient population and increased use of blood for medical procedures such as organ and marrow transplants and more aggressive chemotherapy. Our volunteer donor base is also aging as the population ages. We must now resort to emergency blood appeals during times of the year that used to be periods of abundance. We cannot continue to rely on urgent appeals to solve our problems because it's only a temporary fix, and at some point the media and public stop listening. Needless to say, the fragility of the blood supply is an urgent public health issue.

What's the answer? Blood centers are pouring millions more dollars into marketing research and advertising to persuade millions of eligible people to give blood

and give it routinely, not just when a tragedy occurs. Blood helps save more than 4 millions Americans every year and we are struggling to meet that demand.

We need help. We can't do it alone. Both Congress and the Administration have key roles in assuring readiness in America's blood supply.

Last year, America's Blood Centers met with Secretary Thompson about the issue of shortages and its affect on the public health. At the Secretary's request, America's Blood Centers developed and submitted a Blood Action Plan that HHS could use to help increase donations for blood. A copy of that plan is attached to my testimony. Despite the Secretary's pledge and numerous attempts in follow-up, no action has been seen from HHS to help bolster supply.

While HHS has rightly placed a heavy emphasis on blood safety, they have not focused on the adequacy of the supply. We need a designated person inside HHS that focuses on blood availability and coordinates this very important public health issue with the private sector. We suggest that, as they do for organs, tissue and marrow, the Health Resources and Services Administration be charged to work with the private sector on helping to assure an adequate blood supply.

HHS could also do simple things such as credibly reinforcing the need for Americans to give blood through sponsorship of an advertising campaign, by asking celebrities to donate their time to this worthy cause, and by having high officials regularly donate on camera.

Congress, too, can help by assuring funding for new public educational initiatives on blood donation, by encouraging every Congressman and Senator who can to give blood publicly and frequently, and by working with their local blood suppliers to participate in public events that would help create a culture of donation in the US.

If merely one percent more of the public—only 2 million more Americans—would give blood, shortages would end for the time being and reserve supplies would swell to safe levels. But even 2 million more donations today won't meet tomorrow's needs. We need HHS's help to work in partnership with the private sector to help assure tomorrow's blood supply.

I thank the Committee for the opportunity to speak on this issue.

Mr. GREENWOOD. Dr. Jones, you are recognized.

TESTIMONY OF ROBERT L. JONES

Mr. JONES. Mr. Chairman and members of the committee, thank you and America's Blood Centers for the opportunity to briefly share our experience and views. I'm Dr. Robert Jones, President and CEO of the New York Blood Center, which supplies blood to 200 hospitals in the New York and New Jersey area.

I ask that my complete written statement be included in the record and please refer to it for the details of my brief oral statement.

The aftermath of the attack on our country, in combination with the implementation of new blood donor deferrals for the human form of Mad Cow disease, have seriously reduced the ability of the Nation's blood collectors to supply our hospitals adequately with life-saving blood. No part of the country has been impacted more by both events than the New York/New Jersey metropolitan area. Blood donations are down by 20 to 25 percent from necessary levels since implementing FDA's vCJD donor deferral guidance in June, and please refer to graphs in my written statement.

We urge immediate Federal funding for our national blood donor awareness campaign. At the same time and as importantly, we urge immediate examination of the value of blood safety—some blood safety measures, such as the vCJD deferrals, which may inadvertently cause patient safety problems that arise because blood supplies are not adequate for hospital care or emergency preparedness needs.

Thank you.

[The prepared statement of Robert L. Jones follows:]

PREPARED STATEMENT OF ROBERT L. JONES, PRESIDENT AND CEO, NEW YORK BLOOD CENTER

Mr. Chairman and Members of the Committee, I am Dr. Robert Jones, President and CEO of the New York Blood Center. My career spans a spectrum of medical practice, medical research, hospital administration, health care regulation and now blood center administration. I appreciate the opportunity to participate in today's hearing on the safety and availability of the nation's blood supply.

The New York Blood Center (NYBC) is the nation's largest independent community-based blood collection and distribution organization in the country, serving the New York and New Jersey area for nearly 40 years. Today we supply over 200 hospitals and serve 20 million people in New York, New Jersey, and Connecticut with life-saving transfusion products. NYBC is also home to the Lindsley F. Kimball Research Institute, one of the world's leading centers for basic and applied research in hematology and transfusion medicine.

NYBC provides blood and blood products for more than one million transfusions annually, nearly ten percent of the national supply. Close to 2,000 donations are needed daily in the metropolitan area that we serve, an area with one of the most diverse populations in the world.

Blood Supply Safety and Availability after September 11:

One year ago our lives changed forever as we experienced the terrible attack on our country and our way of life. In our world of blood collections and transfusion medicine the world changed dramatically as well.

Prior to September 11, the blood world was intensively involved in debate over new Food and Drug Administration blood donor criteria limiting the eligibility of blood donors who had traveled to countries where there are cases of bovine spongiform encephalopathy (BSE), also known as mad cow disease. The FDA guidelines were based on the theoretical risk of transmission of variant Creutzfeldt-Jakob Disease (vCJD, Mad Cow Disease) in humans by blood transfusion; there are no documented cases to date where this has actually occurred.

The impact of the vCJD guidance deferring blood donors was predicted to be substantial, and preparations were already underway to deal with the loss of blood donors along with the elimination of the Red Blood Cell (RBC) supply that was routinely imported from Europe for New York Blood Center.

As the disaster of September 11 unfolded, an unprecedented surge of blood donations brought a new set of problems of oversupply that none of us would have predicted. Our immediate reaction was to assume, at least hope, that the problems of lagging blood donations and short supply, with which we have struggled for years, would no longer be with us. But in the months after 9/11, we began dealing with the unfortunate circumstance of discarding thousands of red blood cell units for which there were no transfusion recipients. This began precisely 42 days after the disaster (the shelf life of these products) and continued for months afterward as donations continued to be strong through December and January.

Since we believed that this phenomenon of rising donation levels would not be sustained, we continued our preparations for the implementation of vCJD donor deferrals, the first phase of which was scheduled for May 31, 2002. We made major investments in new donor recruitment and collections capacity and new agreements for sharing surplus RBC supply from other U.S. blood collection agencies such as members of America's Blood Centers (ABC centers), Blood Centers of America (BCA), and the American Red Cross (ARC).

Our instincts about the donations trend were correct as we saw the surge of last September and October return to our baseline in November and descend into a trough that continued into May of this year (see figure one). We now calculate a net loss to our available supply of over 21,000 units or about 5% of our annual whole blood collections, which occurred as a result of the 9/11 disaster.

FDA Guidance and vCJD Deferrals:

Last summer, when estimating the impact of the proposed FDA guidance on our blood donor base, we surveyed our donors and found that the percentage of donors that fit the vCJD criteria would be 7-8%, which translates into a loss of about 10% of our donations in the New York metropolitan area. Since June 1, 2002, when the first phase of FDA's vCJD deferral criteria was implemented, we have experienced a surprising and catastrophic loss of donations, however: 20-25% below our expected blood collection levels.

The current loss of eligible donors is compounded by the self-deferrals of those who perceive that they fit the deferral criteria plus a difficult to quantify donor apathy. As we interview donors and donor group leaders, we believe that the apathy is due to anger with blood collectors over discarding units, the poor understanding

of blood perishability, and the economic impact of the disaster which has left many of our corporate donor partners downsizing and with low company morale. We are now urgently extending our efforts at trying new donor recruitment strategies and finding new donor groups to make up for this shortfall in donations.

Although we remain optimistic, if donation rates do not improve, our supply assumptions that rely on obtaining other U.S. supply will not be sufficient to provide an adequate supply of RBCs to metropolitan New York/ New Jersey area hospitals. It will also raise the difficult financial issue of whether we can sustain our capacity to collect blood that we have so deliberately built up over the years at the cost of substantial community resources.

As previously mentioned, our RBC supply status since 9/11 was remarkably high through the first few months after the disaster (see figure two). In the first months of this year, the fall off in donations was compensated for by new supply coming from other U.S. suppliers plus the continuance of the European supply—the majority of which was lost after May 31 due to the new FDA guidance. After a peak in the spring, our supply has progressively deteriorated this summer to levels that are now below what we experienced prior to 9/11.

Our overall supply curve does not depict the type-specific donation problem experienced by all blood collectors. Because Rh-negative donations fall below transfusion demand, during these shortages we have had to reduce our supply to our hospitals of type O-negative and type A-negative units for almost the entire summer. Therefore we have been in short supply of these RBC types in spite of having the overall RBC supply that appears to be adequate. Given the surprising donation deficits we are now encountering, the efforts we made to build a cushion of supply for the loss of Euroblood may now prove to be insufficient for patient care and emergency preparedness needs.

Considering the problems with donations that NYBC and most other blood collection agencies that we know have experienced in recent months, it appears that the impact of the FDA vCJD guidance is greater than anticipated and threatens to severely weaken our national ability to provide for patients who need transfusion, not to mention our needs for emergency preparedness. Although our supply issues have been limited to Rh-negative RBCs so far, we understand that many other parts of the country have experienced blood supply shortages for the entire summer.

It appears that the convergence of several factors—post 9/11 apathy, the reaction to negative publicity about blood donations being discarded, and the new vCJD deferrals—have produced a situation that rivals historic blood shortages of similar severity.

These acute and chronic blood shortages are causing disruption and problems in patient care in our nation's hospitals. Delay of surgical procedures, loss of organs for transplantation due to low blood availability, and patients being diverted from emergency rooms with inadequate blood supplies are becoming more frequent during these shortages. Increasingly transfusion specialists must substitute type-mismatched blood (Rh-positive for Rh-negative) because there is not enough type-specific blood available. These practices carry measurable risk that should be incorporated into the total risk assessment for blood safety. Such low blood supplies also present a significant vulnerability for our nation's newly identified needs for emergency preparedness.

As we survey this medical landscape, the question should arise as to whether we are introducing greater risk to patients by restricting the blood donor base than we are by protecting patients from the theoretical or remote risk of transmission of infectious disease. The problem, in our view, is that risk assessment is done only in the isolation of a specific issue and not examined against the background of supply losses all along the supply chain. All subtractions from the blood supply due to donor deferrals, blood testing, processing, distribution, inventory management, etc. are cumulative, and take away from the total available units for transfusion.

In fairness to the regulators who make the difficult decisions that protect the safety of blood, the public perceptual and political logic behind these policies is understandable. They view these decisions as public health policy and the blood supply as an elastic resource that can expand to meet public need. What we have learned in the past few years is that the supply is not as elastic as necessary to adapt to policies of this impact without the danger of jeopardizing patient care. In our estimation as a medical care provider, and from my own experience as a physician and hospital administrator, this is where the medical logic of these policies falls short. All of the transfusion specialists with whom I have spoken agree with this view.

NYBC Recommendations:

Given the fragile state of the national blood supply, some current regulatory policies may be producing greater patient danger than blood safety protection. In addi-

tion to a nationwide federally sponsored program of blood donor awareness and recruitment, we urge the immediate review of the vCJD deferral policy against the realities of the total risk of transfusion to patients including those cited above. This review should be performed as a collaboration of federal regulators and transfusion medicine practitioners, who are closest to patient care. We also urge FDA to examine its blood safety policies—historic, current and future—on a regular basis against the risk of short supply.

The events of last September 11th bring new meaning to emergency preparedness and the importance of an immediately available blood supply. We were fortunate last year that we had adequate blood on the shelf for the events of 9/11, even though tragically not much blood was needed. However, blood donor restrictions that continue to erode the nation's blood donor base do not prepare us for another terrorist attack that could require a blood supply that is not on the shelf. This is another unfortunate but, in today's world, necessary example of how medical logic must be incorporated into decisions that impact on the safety and availability of the nation's blood supply.

FIGURE ONE

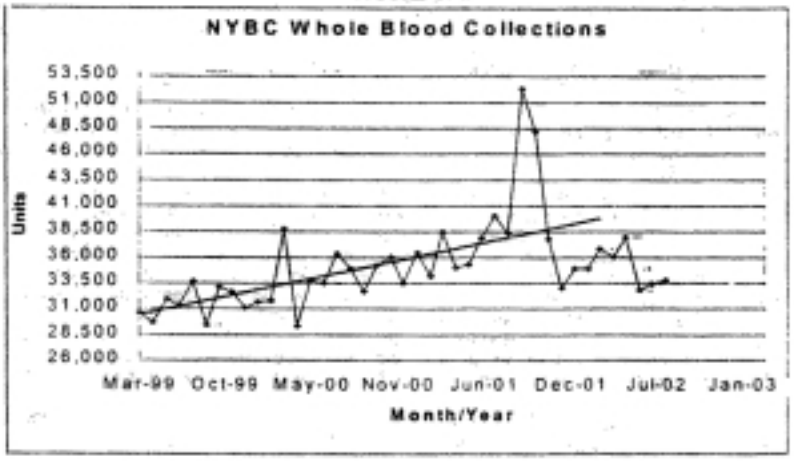
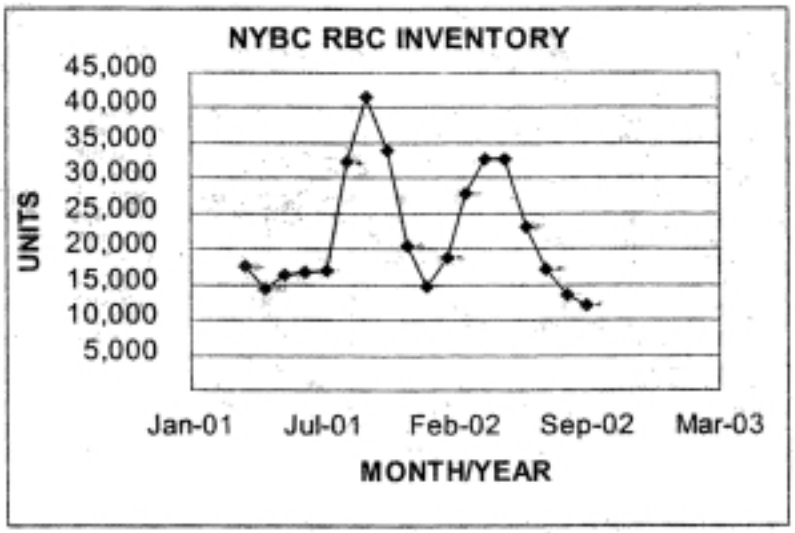


FIGURE TWO



Mr. GREENWOOD. Thank you, Dr. Jones.
Dr. Goodnough.

TESTIMONY OF LAWRENCE T. GOODNOUGH

Mr. GOODNOUGH. Mr. Chairman and members of the committee, I am Vice President of the Society for the Advancement of Blood Management, or SABM, and Director of Transfusion Services at Barnes Jewish Hospital, a 1,200 bed hospital complex in St. Louis. Thank you for the opportunity to present the role of SABM in the preservation of the national blood inventory.

We are a nonprofit, multi-disciplinary organization of medical professionals who are dedicated to the promotion of blood conservation and appropriate utilization of blood and blood components. These two goals have significant implications for the successful management and preservation of the national blood inventory.

First, one mission of SABM is to make blood conservation the standard of care so that blood transfusions are reserved for those patients who must depend on the national blood inventory because of their urgent or emergent needs. To this end, SABM has supported more than 40 symposia and continuing medical education events since 9/11.

Second, we have initiated a collaboration with the military services and the trauma program of the Medical College of Pennsylvania in the development of STORMACT. That is, Strategies to Reduce Military and Civilian Transfusions. A series of seven symposia has resulted in the development of a consensus statement, along with an algorithm for guiding resuscitation of the trauma victim. We believe this will help use more efficiently and effectively the estimated 2 million blood units transfused yearly, representing 18 percent of all blood transfused in the United States for trauma resuscitations.

Blood conservation with bloodless management refers to medical care with minimal or no use of allogenic blood transfusion. This goal can be considered in four clinical settings: when patients are Jehovah's witnesses, when blood may not be available, when safe blood is not available, or when blood is medically contraindicated. Trauma and massive blood loss settings are examples of the need for bloodless management when blood may not be available or is in short supply. Additionally, an estimated 13 million units donated worldwide are not tested for the human immunodeficiency virus or hepatitis viruses, settings in which safe blood is not available. Finally, blood transfusion can be regarded as medically contraindicated in certain clinical settings such as autoimmune hemolytic anemias. Blood conservation with bloodless management is properly a goal in each of these instances.

Furthermore, the surplus of available blood—that is, the difference between blood collected and blood tranfused—has declined in the U.S. From an estimated 7.4 percent surplus in 1997 to 4.8 percent in 2000, as detailed in table 3 in the supplemental materials, due to a combination of increased demand for blood coupled with loss of blood donors. Strategies that exploit appropriate combinations of drugs, technologic devices and medical or surgical techniques, along with interdisciplinary team approaches that combine specialists who share a commitment to minimizing use of blood

products are therefore important to the preservation of the national blood inventory.

Preoperative autologous donation is one such strategy. Patients who predonate their own autologous blood before elective surgery essentially help preserve the national blood inventory by providing their own blood needs. However, this activity has declined substantially since 1992 when autologous blood represented 5 percent of all blood transfused to an estimated 3 percent of blood transfused in 2000, again in table 3 of the supplemental materials.

Patients scheduled for elective surgical procedures such as total joint replacement or radical prostatectomy together comprise approximately a half a million surgical procedures yearly that are particularly suitable for patients to undergo pre-donation of their own blood.

Pharmacologic interventions are a second approach. Agents that stimulate red blood cell production such as erythropoietin therapy and iron therapy are useful in restoring hemoglobin levels in patients who are anemic. Artificial oxygen carriers are under development.

Acute normovolemic hemodilution, or ANH, is a third option. ANH is a low-cost and effective blood conservation technique that can significantly reduce loss of red cell volume in surgical patients with high expected blood losses. During ANH several units of blood are collected from a patient immediately before or after the induction of anesthesia and replaced with either a crystalloid or colloid solution or both. Although blood loss during surgery remains essentially unchanged, fewer red blood cells are lost during the surgical procedure because the patient's own blood has been diluted. At the conclusion of surgery or at a transfusion trigger the collected blood is returned to the patient.

Blood recovery and reinfusion is a fourth strategy. Autologic blood salvage involves the recovery of the patient's shed blood from a surgical wound, washed or filtered and reinfused into the patient. Reinfusion can be performed continuously during surgery or after surgery. Autotransfusion is an effective blood conservation option for surgical procedures characterized by massive blood loss.

In conclusion, there are a number of safe and cost-effective therapeutic options for the management of patients without blood transfusion. Improved education regarding transfusion alternatives, along with commitment and collaboration from all involved disciplines, would help achieve a goal of blood conservation and bloodless management.

I would be happy to answer any questions that you might have. Thank you.

[The prepared statement of Lawrence T. Goodnough follows:]

PREPARED STATEMENT OF LAWRENCE T. GOODNOUGH, VICE PRESIDENT, SOCIETY FOR THE ADVANCEMENT OF BLOOD MANAGEMENT

PREFACE

The Society for the Advancement of Blood Management (SABM) is a non-profit, organization of multi-disciplinary medical professionals who are dedicated to the promotion of blood conservation in the use of blood-sparing technologies and appropriate utilization of blood and blood components. These two goals have significant implications for the successful management and preservation of the national blood inventory.

INTRODUCTION

Blood conservation with bloodless management refers to medical care with minimal or no use of allogeneic blood transfusion. This goal can be considered in four clinical settings: when patients are Jehovah's Witnesses; when blood may not be available; when safe blood is not available; and when blood is medically contraindicated. Trauma and massive transfusion settings are examples of the need for bloodless medicine when blood may not be available or is in short supply. Additionally, an estimated 13 million units of donated blood worldwide are not tested for the human immunodeficiency virus or hepatitis viruses, settings in which safe blood is not available. Finally, blood transfusion can be regarded as medically contraindicated in autoimmune hemolytic anemias. Blood conservation with bloodless management is properly a goal in each of these instances.

Exposure of patients to allogeneic transfusion can be minimized or avoided by the systematic use of multiple blood conservation techniques. Such strategies exploit appropriate *combinations* of drugs, technological devices, and surgical/medical techniques. It also demands an interdisciplinary team approach, combining medical, surgical, and other specialists who share a commitment to avoiding the use of allogeneic blood transfusion. An overview of the general principles of medical and surgical care to minimize or prevent allogeneic transfusion is presented in Table 1.

Current utilization of technologies or techniques to reduce allogeneic blood transfusion is variable. 1,000 U.S. hospitals reported that preoperative autologous blood donation (PAD) and cell salvage programs were widely (>80%) available.[1] However, while pharmaceutical agents such as aprotinin and erythropoietin (EPO) were available in 61% and 43% of hospital respondents, these two agents were "never" or "almost never" utilized at 81% and 91% of the sites, respectively. Despite its worldwide approval in the surgical setting beginning in 1993, acceptance of EPO therapy as an alternative to blood transfusion has been slow.[2]

Notwithstanding recent improvements in blood safety, a finite risk of transfusion-transmitted infections remains,[3] along with risks from new and unknown pathogens. Minimizing blood transfusion has therefore become a desirable goal in surgical procedures for all patients.[4] Furthermore, the fractional margin of available allogeneic blood (the difference between blood collected and blood transfused) has declined from an estimated 7.4% in 19973 to 4.8% in 2000,[5] due to increased demand for blood coupled with loss of blood donors. Strategies that exploit appropriate combinations of drugs, technological devices, and surgical/medical techniques,[6,7] along with an interdisciplinary team approach that combines specialists who share a commitment to minimizing use of blood products, are therefore important to the preservation of the national blood inventory.

BLOOD MANAGEMENT DURING THE PREOPERATIVE PERIOD

Thorough preoperative planning is essential to reducing or avoiding perioperative allogeneic transfusion. Preoperative assessment requires accurate history taking and physical examination. Attention should be paid to any personal or family history of bleeding disorders. In patients requesting transfusion-free care who require major cardiac and orthopedic surgical procedures, aggressive preoperative workups have yielded excellent results.[8,9] Table 2 summarizes presurgical assessment and planning.

Optimize Preoperative Hemoglobin Level

Patients with low hemoglobin levels prior to surgery are at higher risk of receiving allogeneic transfusion. To minimize this risk, patients should have their red cell mass increased preoperatively. The use of recombinant human erythropoietin (EPO) and/or iron therapy has been effective for this purpose (see pharmacologic strategies).

Preoperative Blood Conservation

A simple measure to conserve the patient's own blood consists of restricted diagnostic phlebotomy (reducing the number of tests and the volume of blood withdrawn).[10] Another measure is careful management of anticoagulation, including discontinuation or substitution of agents that could adversely affect clotting in the perioperative period (e.g., ASA and medication containing aspirin, NSAIDs, antiplatelet agents, anticoagulants).

Preoperative Autologous Donation (PAD)

Patients who predonate their own (autologous) blood before elective surgery essentially help preserve the national blood inventory by providing their own blood needs. However, this activity has declined substantially since 1992, when autologous blood

represented 5.0% of all blood transfused, [3,11] to an estimated 3.0% of blood transfused in 20005,[12] (Table 3).

INTRAOPERATIVE MANAGEMENT

Surgical Approaches to Reducing Blood Loss

The principles of surgical and anesthetic bloodless management are summarized in Table 4. The sine qua non of reducing transfusion need in surgical patients is to prevent blood loss. Surgeons are trained in the art of gentle tissue handling, recognition and avoidance of potential bleeding sources and rapid control of unexpected hemorrhage to accomplish this goal. Traditionally, this has been accomplished with electrocautery, utilizing either monopolar or bipolar instruments.[13] Newer modifications to electrocautery include the use of an argon beam-enhanced device that produces a stream of argon gas around the cautery tip that can coagulate vessels up to 3 mm in diameter while minimizing tissue trauma.[14]

Anesthetic Techniques

The use of controlled hypotensive anesthesia, maintenance of normothermia, blood cell salvage, and tolerance of normovolemic anemia are all associated with reduced surgical blood loss. Data suggest that each can contribute to reduction of bleeding.[15] Surgical and anesthetic blood management and conservation methods are summarized in Table 5.

Acute Normovolemic Hemodilution (ANH)

Acute normovolemic hemodilution (ANH) is a low-cost and effective blood conservation technique that can significantly reduce loss of red cell mass in surgical cases with a high-expected blood loss.[16] During ANH, several units of blood are collected from a patient immediately before or after the induction of anesthesia and replaced with either a crystalloid or colloid solution or both. Although bleeding during surgery remains essentially unchanged, blood lost during the surgical procedure contains fewer red cells and clotting factors because the patient's blood has been diluted. At the conclusion of surgery or transfusion trigger, collected blood may be returned to the patient.

ANH offers several practical advantages over PAD. Minimal preoperative preparation and negligible patient inconvenience makes it suitable for both urgent and elective procedures. Moreover, ANH units are collected and stored at room temperature at the patient's bedside, thus reducing the administrative costs associated with collection, storage and testing of PAD units as well as the risk of human error.[17]

Blood Recovery and Reinfusion

Autologous blood cell salvage (intraoperative autotransfusion) involves recovery of the patient's shed blood from a surgical wound, washing or filtering, and reinfusion of the blood into the patient. Reinfusion can be performed continuously during surgery. Autotransfusion is an effective blood conservation option for surgical procedures characterized by massive blood loss or where religious objections exclude the use of allogeneic blood. Technological advances have increased system automation. Furthermore, newer devices can process very small blood volumes (30 mL or less), require low priming volumes, and offer higher processing speed and better end product quality.

Cell recovery devices have been used extensively in surgery and have found their place in cardiac, orthopedic, vascular and trauma procedures. Evidence suggests that blood recovery is cost effective when there is a high-expected surgical blood loss or when hospital stay can be reduced.[18,19] Table 6 provides estimates of the blood sparing potential of several blood conservation techniques available for bloodless management.

POSTOPERATIVE PERIOD

Methods relevant to the immediate postoperative period include close surveillance for bleeding, adequate oxygenation, restricted phlebotomy for diagnostic tests, postoperative cell salvage, pharmacologic enhancement of hemostasis, avoidance of hypertension, tolerance of normovolemic anemia and meticulous management of anticoagulants and antiplatelet agents.

Tolerance of Anemia

Although hemoglobin level as a transfusion trigger has been drifting downward over the years, reproducible criteria for RBC transfusions are lacking. Historically, an arbitrary hemoglobin level of 100 g/L has been used as a trigger to transfuse. This practice continues despite recent studies indicating that patients are able to tolerate lower hemoglobin levels than previously believed.[20] A recent randomized,

controlled trial involving 838 normovolemic critically ill patients demonstrated that a restrictive red cell transfusion strategy (hemoglobin level between 70 and 90 g/L) was as safe as a liberal transfusion strategy (hemoglobin level between 100 and 120 g/L) in critically ill patients,[21] with the exception of patients with ischemic cardiovascular disease.[22]

Erythropoietin Therapy

A review recently summarized knowledge gained regarding the relationship between erythropoietin, iron, and erythropoiesis in patients undergoing PAD (as a model for blood loss anemia), with or without EPO therapy.[23] Endogenous erythropoietin-mediated erythropoiesis in response to PAD under standard conditions of one blood unit donated weekly, in this setting generates 397 to 568 ml RBC, or the equivalent of two-to-three units of blood. Exogenous erythropoietin (EPO) therapy in patients undergoing PAD generates 358 to 1102 ml, or the equivalent of two-to-five units of blood. Red blood cell expansion is seen with an increase in reticulocyte count by day three of treatment in non-anemic patients treated with EPO who are iron-replete.[24] The equivalent of one blood unit is produced by day seven and the equivalent of five blood units produced over 28 days.[25] If three to five blood units are necessary in order to minimize allogeneic blood exposure in patients undergoing complex procedures such as orthopedic joint replacement surgery, the preoperative interval necessary for EPO-stimulated erythropoiesis can be estimated to be three to four weeks.

Iron Therapy

In circumstances with significant ongoing iron losses, oral iron does not provide enough iron to correct the iron-deficient erythropoiesis, and intravenous iron therapy should be considered. Renal dialysis patients have such blood losses, and the role of intravenous iron therapy has been best defined in clinical trials achieving target hematocrit levels in this setting. Addressing iron deficiency with intravenous iron therapy allows correction of anemia along with utilization of lower erythropoietin dosage.[26] Other common clinical settings include pregnancy[27] and patients with dysfunctional uterine bleeding who are scheduled for hysterectomy.[28]

FUTURE DEVELOPMENTS

Artificial Oxygen Carriers

There has been accelerated progress in the development of artificial oxygen carriers (AOC).[29,30] Potential advantages for cell-free hemoglobin solutions and perflurocarbon emulsions include the absence of immunogenic cell membranes and prolonged shelf life at room temperature storage. Possible disadvantages of such products include interference with some laboratory tests, a relatively short time in circulation (24-48 h),[32] nitric oxide mediated vasoconstriction, and gastrointestinal discomfort.[33-36]

The principal clinical investigations for the AOC's currently are in patients with trauma[37] and in patients who are undergoing surgery, with or without acute normovolemic hemodilution. The rationale for the use of AOC with hemodilution is threefold: (i) the cellular hemoglobin collected during hemodilution would be used to replace the hemoglobin solution or other synthetic oxygen carrier as it is eliminated; (ii) the use of AOC would permit more aggressive hemodilution with lower targeted cellular hemoglobin levels than would otherwise be tolerated and (iii) an AOC could serve as a replacement fluid during blood loss.[38] If approved, they would most likely be applied in surgical settings including military casualties, civilian trauma patients, and massive surgical blood loss settings. Potential applications for medical settings include autoimmune hemolytic anemias[39,40] and in patients with sickle cell vaso-occlusive crises.[41] Enhanced oxygen delivery to the microcirculation by these carriers may also lead to applications in other patients with acute organ ischemia, such as myocardial infarction or cerebrovascular accidents.

THE SOCIETY FOR THE ADVANCEMENT OF BLOOD MANAGEMENT

For many years, the need for an organization dedicated to optimizing the field of blood management has been recognized from different fields within medicine. Recently several organizations have emerged, some run by blood center coordinators, some by nurses, some from overseas, but none by physicians who are both thought leaders and who recognize a need not being met by national and international blood organizations. These visionary individuals have provided the beginnings for a structural solution to the problem of blood management.

The vision for this solution is embodied by the mission statement and founding principles set out by the Society for the Advancement of Blood Management:

Need for New Ways of Thinking:

- Evolve overall thinking so that blood management initiatives will become the universal standard of care. Transfusions will become the last indication instead of the first resort. We want transfusions to be viewed as the alternative.
- Advance the principles of blood management due to: (1) low inventory of blood; (2) high cost of blood transfusions and; (3) risk associated with blood transfusions; and (4) consumer demand

Need for Information Dissemination:

- Lack of knowledge (not lack of alternatives to blood transfusion), is the main limitation of current inadequate application of blood management strategies.

Need for Commitment to Total Blood Management Care:

- Build partnerships with organizations representing all facets of blood management care (ie. ARC, AABB, ASHE).

Need for Physician Advocates:

- Successful adoption of blood management strategies needs to be driven by clinically-active, well recognized physicians at each medical center.

Need for Optimizing Perioperative Status (restoring red blood cell mass):

- Need pre-operative use of alternatives (i.e., increasing red blood cell mass), so that post-operative transfusions occur less often.

Need for Universal Guidelines:

- Evidence-based: Limit exposure to allogeneic blood.
- Incorporate rationale transfusion guidelines: Document physiological need.

Need for Universal Registry Tracking Patient Outcomes:

- Helps to move the concept from individual specialty to standard or "best practice"
- Facilitate cooperation among centers to share data.

Lack of algorithm-based guidelines that are evidence based, Inconsistent Guidelines

- Lead to different criteria and therefore cause lack of universal approach to blood management (e.g., anesthesia directs transfusion in Europe but not in the US).

Physician Behavior

- Many do not perceive problems (i.e., risk, cost, conservation) with use of allogeneic blood.

Competitive Environment

- Requires a coalition of multiple organizations which may have conflicting opinions/agendas.
- Many do not realize that promoting optimal blood management will benefit all bloodless programs/centers not undermine them.

Perception of High Cost

- There is a perception that blood management strategies come at a high cost. The reality is that alternatives may be less costly than obtaining and maintaining blood.

The major goals of SABM were established to:

- Provide physician-led initiatives into rationale approaches to blood management. The current ways of looking at alternatives to transfusions needed to be changed.
- A data registry modeled after successful outcomes-oriented registries (e.g., Northern New England Cardiovascular Disease Registry) will allow proper examination of clinical issues raised by controlled clinical trials indicating avoidance of blood transfusions results in improved outcomes in several studies examining this specific question.
- Therefore, as one of its charters, SABM will incorporate what is now and has been called "alternatives to transfusion" to become an INTEGRAL PART OF MODERN ANEMIA & TRANSFUSION ALGORITHMS incorporating blood product sparing modalities of treatment, i.e. change the practice of "*give a transfusion first*" to "*give a transfusion last*".

The Society looks to establish relationships with all professional societies concerned with blood and blood management, with physicians in academia and private practice, with industry and government in order to incorporate rationale blood management resulting in coherent "best practice" algorithms and guidelines. The Society

has taken its mission to be concerned primarily with issues surrounding ACUTE ANEMIAS.

After the consensus meeting in August, 2001, a Board of Directors, a set of Society Bylaws, a non-profit incorporation, a Membership policy and application, a Web site (www.SABM.org) and funding outreach were developed.

Funding efforts are ongoing; a new educational outreach program is being established during September, 2002 to incorporate Web-based tutorials and world-wide recruitment of student members.

Our presence has already been instrumental in the US military revising resuscitation algorithms by the STORMACT series of meetings (see below). These invitations to present modern blood management strategies resulted in immediate implementation of revised battlefield resuscitation methods. STORMACT (Strategies TO Reduce Military And Civilian Transfusions) continues to bring modern blood management to military physicians.

CONCLUSION

In conclusion, there are a number of safe and cost-effective therapeutic options for the management of surgery patients without allogeneic blood transfusion. Future developments in the field are summarized in Table 7 and examples of biotechnology products that can serve as alternatives to blood products are listed in Table 8. Improved education regarding transfusion alternatives , along with commitment and collaboration from all involved disciplines, will help achieve the goal for bloodless medicine.

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Table 1. General Principles of Blood Conservation with Bloodless Management

1. Formulate a plan of care for avoiding and controlling blood loss tailored to the clinical management of individual patients, including anticipated and potential procedures.
2. Employ a multidisciplinary treatment approach to blood conservation using a combination of interventions.
3. Proactive management by the lead clinician: anticipate and be prepared to address potential complications.
4. Promptly investigate and treat anemia, preferably preoperatively.
5. Decisive intervention, including surgery, should not be delayed in the actively bleeding patient. In general, avoid a "watch and wait" approach to the bleeding patient.
6. Exercising clinical judgment, be prepared to modify routine practice when appropriate.
7. Consult promptly with senior specialists experienced in blood conservation at an early stage if there is physiological deterioration or if complications arise.
8. Transfer a stabilized patient, if necessary, to a major center before the patient's condition deteriorates.
9. Restrict blood drawing for laboratory tests.
10. Decrease or avoid the perioperative use of anticoagulants and antiplatelet agents.
11. Emergencies: establish in advance a management plan for rapid location and arrest of hemorrhage, as well as for transfer to an appropriate center. Avoid delay.

Table 2. Preoperative Assessment and Planning

Methodical history taking, physical examination, supplemented by judicious laboratory tests
Identify appropriate combinations of strategies for prevention and treatment of anemia and/or bleeding
Optimize preoperative hemoglobin level with erythropoietin, iron, folate, vitamin B12Avoid pharmacologic coagulopathies
Manage anticoagulation
Restrict diagnostic phlebotomy

Table 3. Collection and transfusion of autologous blood in the USA*

Source	1980	1986	1989	1992	1994	1997	1999	2000 (est)
Transfused:								
Total	9,934	12,159	12,059	11,307	11,107	11,476	12,389	12,540
Autologous	NA	NA	369	566	482	421	367	390
(% of total)			(3.1%)	(5.0%)	(4.3%)	(3.7%)	(3.0%)	(3.0%)
Collected:								
Total	11,174	13,807	13,554	13,169	12,908	12,550	13,649	13,140
Autologous	28	206	655	1,117	1,013	611	651	640
(% of total)	(0.25%)	(1.5%)	(4.8%)	(8.5%)	(7.8%)	(4.9%)	(4.7%)	(4.9%)

NA, not available. From Goodnough LT et al. N Engl J Med 1999;340:439–47 and the National Blood Data Resource Center.

Table 4. Surgical and Anesthetic Principles of Blood Conservation with Bloodless Management

1. Preoperative Assessment/Planning: management of anemia, management of anticoagulation and congenital and drug-induced coagulopathies, prophylactic interventional radiology/embolization, prescribing/scheduling of cell salvage apparatus, restricted diagnostic phlebotomy.
2. Intraoperative Blood Conservation: meticulous surgical hemostasis, blood salvage, hemodilution, pharmaceutical enhancement of hemostasis, maintenance of normothermia, surgical positioning to minimize blood loss and hypertension.
3. Postoperative Blood Conservation: blood salvage, tolerance of anemia, optimum fluid and volume management, restricted diagnostic phlebotomy, adequate analgesia, maintenance of normothermia.
4. Maintain appropriate fluid resuscitation. Significant normovolemic anemia is well tolerated in hemodynamically stable patients.
5. In actively bleeding patients, the first management priority must be to stop the bleeding. Avoid attempts to normalize blood pressure until hemorrhage is controlled.
6. Prevent or treat coagulation disorders promptly.
7. Oral or parenteral iron may be used to improve iron stores. Recombinant (synthetic) human erythropoietin (rHuEPO) effectively increases red cell mass.
8. Hematology/oncology: aggressive rHuEPO and iron therapy for prophylaxis of anemia, individualized chemotherapy protocols to minimize hematologic toxicity, pharmacologic prophylaxis and treatment of bleeding, tolerance of anemia, and restricted diagnostic phlebotomy.

Table 5. Anesthetic and Surgical Blood Management Methods

Rigorous hemostasis and surgical technique
Surgical positioning of patient
Tourniquets
  Hemostatic surgical devices
  Electrocautery
  Electrosurgery (diathermy)
  Ultrasonic scalpels
Local vasoconstrictors
Preoperative (prophylactic) and therapeutic angiographic embolization
Mechanical occlusion of bleeding vessels
Topical hemostatic agents and tissue adhesives/sealants
  Fibrin glue
  Tissue adhesives
  Collagen, oxidized cellulose
Autologous Techiques
  Blood cell salvage devices (intraoperative and postoperative)

Hemodiluution
Pharmacologic prophylaxis of bleeding
Antifibrinolytics (tranexamic acid, aminocaproic acid)
Aprotinin
Desmopressin
Control of intraoperative and postoperative hypertension
Controlled hypotensive anesthesia
Maintenance of normothermia
Tolerance of normovolemic anemia
Fluid and volume management
Colloids
Crystalloids
Oxygen Therapeutics (Red-Cell Substitutes)
Synthetic oxygen-carrying fluids
Modified hemoglobin-based solutions

Table 6. Approximate Contributions of Selected Modalities to Blood Conservation in the Surgical Patient

	Blood Units
Preoperative Options	
Tolerance of anemia (reduce transfusion trigger)	1-2 units
Increase preoperative RBC mass	2 units
Preoperative autologous donation	1-2 units
Intraoperative Options	
Meticulous hemostasis and operative technique	1 or more units
Acute normovolemic hemodilution	1-2 units
Blood salvage	1 or more units
Postoperative Options	
Restricted phlebotomy	1 unit
Blood salvage	1 unit

Table 7. Future Developments

- There is a need to develop educational curricula focused on clinical aspects of transfusion practice and the use of transfusion alternatives.
- The safety and effectiveness of lowering transfusion triggers and acceptance of anemia as reasonable blood conservation options needs reassessment.
- Red-cell and platelet "substitutes," now in various stages of clinical trials, hold out new therapeutic options.
- Wider use of hematopoietic agents, including new products now in clinical trials (e.g., new forms of recombinant erythropoietin, recombinant thrombopoietin), will reduce dependence on allogeneic blood

Table 8: Examples of biotechnology products that can serve as alternatives to blood products

Erythropoiesis stimulants
erythropoietin
novel erythropoietin stimulating factor
Hemostasis
recombinant factor VIIa
recombinant factor VIII
recombinant factor IX
Artificial oxygen carriers
hemoglobin solutions
perfluorocarbons
Anticoagulants
antithrombin III
activated protein C
Modified Blood Components (under development)
Platelet membrane preparations
Enzyme-treated red cells devoid of blood group antigens
Ex-VIVO stem cell expansion
Dendritic cell vaccines

Mr. GREENWOOD. Thank you, Dr. Goodnough.
The Chair recognizes himself for 10 minutes for questions.

Let me ask this question of the blood banks. If the New York Blood Center runs short on blood, can you or other blood banks help them out?

Mr. ROSS. As I mentioned in my testimony, the American Red Cross is at about 2 days supply, which is much less than optimal for us. We are helping New York with whatever we can, but we do not have the supplies right now to help them.

Mr. GREENWOOD. Anybody else want to comment on that?

Ms. DARIOTIS. Yes. The America's Blood Centers have been shipping blood to New York on a regular basis starting in the spring of this year, but it is just helping them tread water, so to speak. We do not have the reserves, much like the Red Cross, to meet a national crisis should that happen for them.

Mr. GREENWOOD. Did you, in your testimony, identify what it would take in terms of an increased number of Americans donating blood to—we have 60 percent are eligible and only 5 percent of them—so that's 3 percent of America's population is donating the blood that 60 percent of us are going to end up using in our lives. What would it take in order to—what percentage of Americans would need to give blood so that we would be out of the water treading stage?

Ms. DARIOTIS. I think we estimated that an additional 1 percent, or approximately 2 million more donors, would help us all.

Mr. GREENWOOD. That's not very much, is it?

Ms. DARIOTIS. It doesn't seem like a lot, does it?

Mr. GREENWOOD. No.

I wanted to follow up. I might make a concrete suggestion that the blood banks get in touch with me. We will have a meeting afterwards. I think it would be a good idea if we marked a day on the calendar and get every Member of Congress to see if he and she can do an event in their district on the same day and invite much of the public to come in and donate blood on that day as possible; and maybe we will get some celebrities to join us or something like that and try to have some fun with it. But it would be a suggestion that you make. It's one that I had thought about before when I visited my own blood bank in Philadelphia, and we should follow up on that.

Ms. DARIOTIS. Thank you. We would welcome that support.

Mr. GREENWOOD. Let me ask another question. The blood experts tell us that we need more of certain blood types such as O and less of others such as AB and A. The equipment exists to take double units for O donors, plasma from ABs and only the platelets from As, but according to Douglas Starr in the July 29, 2002, issue of the New Republic, most blood centers still use the take-it-all approach. Is this true?

Ms. DARIOTIS. Well, it sounds good in theory. I'll start. But talking your donor into being that A that wants to donate only platelets or that AB that only wants to give plasma is a tricky operation. We do all of those things. We do do double red cells. We do try to draw only Os. But the ideal is difficult when you get down to a volunteer blood donor and convincing them that you have the right idea for how they should donate their blood.

Mr. GREENWOOD. Well, how does it change the experience for the donor?

Ms. DARIOTIS. Most of the donors, if you do an automated procedure, it will take longer. Some donors are leery of an automated procedure. Some relish it and think it's wonderful. But that's the main difference, that it usually the extends the time of their donation.

Mr. GREENWOOD. It's just the time factor? They don't have to get jabbed more frequently or——

Ms. DARIOTIS. Well, no. It's just one jab. And sometimes they will experience a little discomfort from some of the anticoagulants that we might be using. We can manage that quite well. Usually, it's a time commitment to the donor or just the fact that it's different.

Mr. GREENWOOD. Okay. Anybody else want to comment on that?

Mr. ROSS. Yes. Another limiting factor is about 65 percent of our blood is collected on mobile blood drives throughout the country in rural areas. Transporting these very expensive, highly complex pieces of equipment that actually perform the automated collections can be problematic and you end up having to revalidate them. Sometimes they get damaged in transport, and it's just not an optimal situation. But the automated technology is something that we are all implementing as quickly as we can, and it will help us as we move forward.

Mr. JONES. Mr. Chairman, I wonder if I could make a comment on an earlier statement you made. There is this lore that 60 percent of the population is eligible and only 5 percent donate. Those are old figures and most people, certainly at this table, think that those need to be updated; and we are actually launching a study. So, for example, if you study the 60 percent, there are about a third of those people, if you do market research, who would say they would never donate, no matter what you did. You can't count those people as eligible donors. So we need to get more sophisticated about that donor base to find out really how big the real donor base really might be.

Mr. GREENWOOD. Yes, Ms. Lipton.

Ms. LIPTON. Yes. I also might add I think one of the concerns that we are all trying to deal with is understanding the demographics. As we look at it in the year 2012 I think we are going to have—2020—12 million people moving into the population who are most at risk for transfusion. And if you look at the most recent census data we do not have a group of younger people underneath that that are in a pyramid structure. We are unique throughout the world in terms of our demographics. But we have an older population that's living longer, and we don't have a group of younger donors coming up underneath it. So I think we really need to think long and hard, you know, about the future strategies for blood supply; and I think it's going to become very critical.

Mr. GREENWOOD. All right. Back in January the task force found that there are no currently identified scenarios in which the need for blood and/or blood components would be beyond the capabilities of the blood community to provide. Is this still the blood community's position?

Ms. LIPTON. Perhaps I could respond to that. I think the answer is yes. One thing that we would be concerned about, not in terms of blood supply to the patient but really the effect on the donors in the event of a biological attack, because if we had a smallpox

outbreak it is very possible that you could see in a specific area that a number of donors could no longer donate and we would have to be involved in shipping blood in. But I do think that we have studied very carefully both past history and worked with the Department of Defense and all the blood organizations; and, sadly, we believe that it is true that in most of the things that—anything that we can conceive of, we would not have a need for blood beyond which we could provide.

Ms. DARIOTIS. But I think we are talking about the kind of response that we expect to see in those types of disasters where the donors line up. But, again, we have to remember that if there is an immediate mass need it's still, as we have all been concerned, it's having that daily blood on the shelf that will start out the support; and then we know the donors will be there to help us.

Mr. JONES. I think the other—we haven't really considered, I don't think, what a nuclear event might be, and the impact on that would probably bring about a lot more demand for blood and blood products which we might not have on the shelf today if it were really an event that involved a dense population area. Therefore, we would have to really get into moving it around; and I'm not sure we're prepared for that, in my opinion.

Mr. GREENWOOD. Dr. Goodnough, do you want to offer your perspective on that question?

Mr. GOODNOUGH. Well, perhaps if I could put my hat on as Director of Transfusion Service at a very large hospital. We have had to cancel or reschedule elective surgery three times since calendar year 2000 because we didn't have enough blood group O or blood group A, and we have almost had to cancel or reschedule elective surgery several times because of platelet availability issues.

When we open up for business in the morning, we need 110 units of blood group O and blood group A on hand, 30 for the trauma program, 30 for the transplant program and then 40 for everybody else in a 1,200 bed hospital; and three times in the last 2 years we have had to reschedule elective surgery. So we have an ongoing concern about blood inventory, and we are part of Dr. Heinrich's blood surveillance program. We are participating in that and trying to get a handle on blood usage at the hospital level.

Mr. GREENWOOD. I think—Ms. Dariotis, I think you made reference to organs expiring or going bad or becoming useless because of postponed surgery. Is that a serious—I mean, I've done a lot of work in organ donation and I know how dismal our ability to keep up with the demand is there. That's shocking to learn that—of the relatively few organs that we have available that we are losing them because of lack of blood availability.

Ms. DARIOTIS. I don't think we are sure of the exact numbers. I think the problem for us all, and speaking as a community-based blood center, is hospitals are reluctant to talk about the fact when they cancel surgery. They're reluctant to talk about the fact that they may not be able to have enough blood on the shelf. I mean, I know I have that local experience, so I'm not sure we have all the data out there that tells us the true adequacy of our suppliers. So don't—we challenge the GAO. We do not believe the supply is adequate.

Mr. JONES. If I could just add one more practice in transfusion medicine that's becoming more common, and that is when you don't have type O—don't have type RH negative blood available, frequently—more and more frequently patients are receiving type RH positive blood to substitute for RH negative. This is a type mismatch which doesn't matter so much on the first transfusion, but if that patient needs blood again they can't receive RH positive blood. So it's an evolving practice that's being driven by shortages of RH negative and the blood supply in general.

Mr. GOODNOUGH. If I could address your organ donation question, we make an internal decision not to shut down the trauma program and not to shut down the transplantation program so we always have blood for them. That's why we consider rescheduling elective surgical procedures.

Mr. GREENWOOD. Thank you.

The gentleman from Florida.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Most of you, if not all of you, were here and in our prior panel; and I asked this question of the prior panel as well. The GAO conclusion that the blood supply is generally adequate, if each of you could respond to that, I would appreciate it. Ms. Lipton.

Ms. LIPTON. I think the blood supply is generally adequate except on the days when it's not; and I think the AABB would say, no, it is not generally. It might be generally adequate. It is not adequate to do what we need to be doing in the United States.

Mr. DEUTSCH. Mr. Ross.

Mr. ROSS. The American Red Cross blood supply is not adequate at a 2-day level. I am not sure the data set or the time period that the GAO took their survey of inventories as I have not seen the report. But certainly September 10, 2001, 1 year ago today, we had 80,000 units inventory, and today we only have 50,000. So I would say it's not adequate.

Ms. DARIOTIS. I think I will repeat what I said. We don't believe the blood supply is adequate. Maybe adequate to avoid canceling some surgeries, but it depends on the area of the country, and we—I think our efforts with that task force to be able to move blood around will help to address emergencies but will not help—we don't have enough blood on the shelf at any given day.

Mr. JONES. At a meeting last week we heard a lot about regional shortages and seasonal shortages, and I would just remind you that when there's a regional shortage in the New York area it involves 20 million people. A regional shortage in a smaller population may not be quite so serious. But we experience regional shortages frequently.

Mr. GOODNOUGH. Yes. I would second the idea that I feel that the blood supply is not adequate, and there are two points of emphasis. One is that a unit of blood conserved is a unit of blood preserved; and, second, the national blood inventory should be a resource for people who cannot plan ahead. That is for urgent or emergent surgeries. For elective surgery or medical settings, which we estimate comprises 20 percent of all blood transfused, alternative strategies to blood transfusion are available and should be the treatment of choice.

Mr. DEUTSCH. Sometimes I wish we had both panels here so they can try to defend themselves.

All right, one of the things that each of you I guess has pointed out, I guess the various regional, seasonal, in some cases daily shortages. Could you describe just a little bit how blood centers who are not collecting enough blood that is needed for life-sustaining procedures and surgeries, how do they shift the blood around from different regions, different groups? If someone could just give us that sense.

Mr. ROSS. Yeah. The American Red Cross has 36 blood regions throughout the United States. We have an active inventory management system where we have conference calls that go on daily on a regional basis and on a national basis where we attempt to balance the inventory throughout the system. We will move blood to any part of the country or to any blood center that needs it when we have it. So that's our attempt. It's just a balancing system.

Ms. DARIOTIS. I think when you talk at the local level, if you're talking within my community blood center, it's a lot of running around with our couriers grabbing blood from one hospital and carrying it to the next hospital as we call our friends and beg for help. Because they will do the same with us, and we will provide that same level at the national level. ABC has the ability to communicate through our e-mail network the emergent needs of our centers and can look for individual support, and we will see centers commit and moving blood around the United States that way.

Mr. DEUTSCH. And Dr. Jones.

Mr. JONES. Because of our increased demand in the hospitals in our area, we seem to be the center that's always cited as always being short. I can just say that we have relationships with virtually every large and even a lot of small blood collectors around the country. We have two full-time people that manage this day-to-day. So I think we have a pretty good way of receiving blood and finding out where it is, and that's less formal than the Red Cross, but is seems to work.

Ms. LIPTON. The AABB also runs the National Blood Exchange which is an exchange program that attempts to really alleviate these imbalances of supply. It's accessible to any blood collector who meets AABB standards and is accredited by us. They can ship blood, and it's open to any hospital, and we actually ship quite a few units through the National Blood Exchange. We operate 24/7. Our people are on beepers and available to inventory managers across the country every day.

Mr. DEUTSCH. Each of the industry representatives here has described a blood shortage that exists; and I guess, even saying that, you know, the projections are that it will worsen. Can you describe—and you have mentioned some things—but both steps that are being taken by the blood community to boost this percentage—and, again, you have talked a little bit, but if you can focus in on what HHS can do to assist this effort as well.

Ms. LIPTON. I think the single biggest thing would be for us to see an initiative as exists right now with organ donation. Blood donation is, "part of that program," but it's really the stepchild of the program. It's incorporated into the title, but there really isn't anything underneath the program. And we believe that if organ dona-

tion is important, organ transplantation can't happen without blood donation, and we would like to see really some money put into that effort working with the blood organizations as to what we are doing.

As I said, we are all trying to work together to get an unbranded, multi-year campaign that is not a funded campaign at this moment. And to really reiterate what Allan Ross said, all of this is a matter of money. And it costs money and it really isn't a matter of public service advertising. It's paid advertising.

Mr. GREENWOOD. The Chair thanks the gentleman.

We have votes, so I'm going to try to squeeze a question or two in before we go, and then we will adjourn. This is for Mr. Ross.

Last fall, the Red Cross announced a crash program to freeze 100,000 units of blood. According to an article by Douglas Starr in the July 29, 2002, New Republic, the Red Cross ended up only freezing fewer than 10,000 units while tens of thousands of others continued to accumulate and contributed to the overall waste. Mr. Starr writes that this resulted in a lack of glycerol needed to protect the red cells from breaking as well as a lack of aluminum canisters freezing bags and even FDA approval to use the freezing process chosen. The question is, is this report by Mr. Starr accurate?

Mr. ROSS. The Red Cross developed the capacity to freeze upwards of 100,000 red cells by October 5, 2001. We ceased to freeze because of issues surrounding the technical aspects that Dr. Epstein referred to in his previous testimony. It will be about 20 months before we can get the program back on track in order to adopt the new technology which provides 14-day post-thaw dating, but we still have the capacity to freeze 100,000 units if necessary. We have all the necessary supplies, all the necessary reagents, and all we need are the units.

Mr. GREENWOOD. Okay. We're going to stop here. Thanks to the witnesses for testifying, and we will keep the record open.

There's some—if it weren't for the vote, there were some other questions that I'd like to ask you, so with your permission and with unanimous consent we will submit some of those questions in writing to you and ask that you respond to the committee.

Thank you again. The hearing is adjourned.

[Whereupon, at 12:40 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

AMERICAN ASSOCIATION OF BLOOD BANKS
October 7, 2002

The Honorable JAMES C. GREENWOOD
Chairman
Subcommittee on Oversight & Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515-6115

DEAR CHAIRMAN GREENWOOD: On behalf of the American Association of Blood Banks (AABB), I am writing in response to your September 20 letter outlining questions from Members of the Subcommittee that will be included in the record of the Subcommittee's September 10 hearing regarding the blood supply. The AABB appreciated the opportunity to participate in this hearing and offers the following responses to your questions.

Question 1. Because of screening for blood-borne diseases, donors have more questions to answer and the donation process takes more than an hour on average. Are the blood centers taking any actions to make blood donation less complicated and

less time-consuming? For example, are donor questionnaires being automated? Is this a good idea?

Response. The AABB is very aware that the blood donation process is viewed as complicated and time-consuming and has undertaken a major effort in concert with the rest of the blood banking community to address the issue of donor history questions. In June 2000, the AABB initiated activities of an interorganizational task force to streamline the uniform donor history questionnaire. This task force is composed of representatives from AABB, America's Blood Centers, American Red Cross, Armed Services Blood Program, and Plasma Protein Therapeutics Association, and liaisons from the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA). Members include an ethicist public member, a statistician, and survey design experts.

In March 2002, the task force submitted its proposal to the FDA for review and approval. That proposal includes:

- a revised full length questionnaire for first time and infrequent donors;
- an abbreviated questionnaire for frequent donors and proposed guidelines for its use;
- a medication deferral list as a companion document to both the full length and abbreviated questionnaires;
- new donor educational materials; and
- user brochures which contain instructions for blood centers and for donor screeners regarding how the new material should be utilized.

Donor comprehension of both the full length and abbreviated questionnaire have been tested using focus groups conducted by the task force and one-on-one cognitive interviews conducted by the CDC's National Center for Health Statistics. This is the first time that all donor questions have been subjected to a rigorous evaluation.

These new materials are expected to improve the donor screening process and at the same time maintain a high level of safety of the blood supply. The new questionnaires are user friendly and easy to follow. Since the questionnaire is designed to be self administered, the donor may proceed at his/her own pace. Rather than long involved questions that must be answered by all donors, the questionnaire uses broad "capture" questions. For example, if a donor indicates he or she has not traveled outside the United States, there is no need to query the donor about travel destinations that might require deferral. If the donor indicates he or she has traveled outside the United States then the donor screener will ask follow-up questions as advised by the detailed flow charts in the user brochure. The abbreviated questionnaire is expected to be especially helpful in decreasing the time for frequent donors.

In June 2002, FDA presented this proposal to its Blood Products Advisory Committee (BPAC), which in turn unanimously endorsed it. At the September BPAC meeting, FDA asked the committee to consider the question of self-administration of the questionnaire for all donors, including first time donors. BPAC endorsed the concept of self-administration. The Interorganizational Task Force on the Uniform Donor History Questionnaire is eagerly awaiting a response from the FDA so that implementation can begin.

Implementation of this revised questionnaire will represent a significant step forward. However, in the future additional steps to simplify and improve further the donor questioning process will be needed. The number and complexity of questions are directly related to the broad scope of regulations and guidance documents issued by FDA. As our task force developed the revised uniform donor history questionnaire over the last year, FDA explicitly stated that it would not consider revising certain questions at this time. For example, even though certain questions, such as the one dealing with Creutzfeldt Jacob disease (CJD),[1] are of little value in enhancing blood safety and potentially confuse donors, FDA requires that they remain on the questionnaire. The AABB is hopeful that in the future FDA will work with us to further simplify the process by editing or deleting such questions.

In addition, as testing for infectious disease becomes more effective, the utility of some existing questions has been greatly reduced. The AABB believes that FDA could simplify the donor questioning process without adversely affecting blood safety.

Automation of donor questionnaires

The AABB supports computer assisted self interviewing (CASI) and the task force designed the questionnaires with that possibility in mind. Not all blood centers, however, will be able to adopt automation in the immediate future. For that reason,

[1] CJD, or Creutzfeldt Jacob disease, is a condition that is distinct from variant Creutzfeldt Jacob disease (vCJD). Scientific evidence affirmatively suggests that CJD is not transmissible by blood.

the task force determined that the questionnaire itself should be improved as the first step toward automation. Broad capture questions with additional follow-up questions are ideally suited to a computerized interview. Automating the process, as well as improving the questions, will continue to be the focus of the task force's future activities.

Question 2. The GAO reports that blood collections have increased 21% between 1997 and 2001, and that collections for the first half of this year are on pace with the same period in 2001. Even with the recent donation shortfall this summer, these emerging data suggest collections, overall, have been on the upswing. Do you tend to agree with GAO's general finding with regard to donation trends? Why?

Response. The AABB believes that the 21 percent figure used by GAO is misleading. GAO's assertion that collections increased 21 percent between 1997 and 2001 may be based on collection data from the National Blood Data Resource Center (NBDRC). However, neither the NBDRC nor the AABB agree with the calculations and analysis used to arrive at this figure.

According to monthly data collected by NBDRC, 2001 collection levels were relatively level, over the prior year, not significantly increasing prior to September. NBDRC data suggest that most of the increase in collections experienced in 2001 was due to post-September 11 donations. After the first six months of 2001, NBDRC projected that year would end with approximately 14.5 million units collected, as compared with 12.6 units collected in 1997. Had the September 11 anomaly never occurred, NBDRC estimates that there would have been closer to a 15 percent increase in collections from 1997 to 2001.

Going forward, NBDRC's monthly collection data from the first six months of 2002 suggest that collections during that period were roughly comparable to collections during the same six-month period in 2001. It should also be noted that GAO's report covers the period before June 2002, when FDA's new donor deferral policies relating to variant Creutzfeldt Jacob disease (vCJD) were fully implemented. These policies resulted in increased deferrals and likely a reduction in collections, although the exact number is not known due to a lack of accurate analytical data.

It is important to note that blood supply is a function of both collections and utilization. If supply is to be sufficient, donations must increase at a rate that exceeds the increase in utilization. According to NBDRC data, usage of whole blood and red blood cells (RBC) increased significantly in 2001 versus 1999. This increase in utilization is expected to continue this year and into the future. Increased collections will be needed to keep pace with this increase in demand.

A troubling sign that demand may be surpassing supply, at least in certain communities at certain times, is the increase in hospitals postponing surgeries due to insufficient blood inventory. NBDRC data from its 2001 Biennial Nationwide Blood Collection and Utilization Survey indicate a significant increase in the number of hospitals that had to cancel or postpone surgeries in 2001 due to blood shortages. The percentage of hospitals in the NBDRC survey that reported such action in 2001 was 12.8, compared to 7.4 in 1999. Another hospital survey conducted by the American Hospital Association in 2001 indicated similar shortage problems. In the AHA survey, 57 percent of hospitals experienced a blood shortage in 2001. According to AHA, "blood shortages cause interruptions in hospital operations and patient care, such as cancelled or rescheduled surgeries, and ambulance diversions. One in three hospitals reported that shortages are growing more severe."[2]

In addition, in order to meet patients' needs, one must consider not only the overall statistics regarding blood collections in general, but also the collection and inventories of distinct blood types in all regions of the country. For example, less than a three-day supply of O negative red blood cells in any community may indicate a shortage, despite a sufficient supply of red cells of other types.

Question 3. Your testimony raises a point about donor deferral policies affecting different regions in different ways, due to demographics and so forth, and that federal policy makers must take this into account. Please explain how the blood community is working to respond to this issue. Is it going to provide a coordinated response to these safety and risk decisions?

Response. FDA blood-related regulations, like AABB Standards, are applied uniformly across the country. Nonetheless, regulators as well as the blood community itself must be aware of the unique issues and needs facing distinct regions of the country. In this light, the blood community and policy makers should, when possible, facilitate the distribution of blood to communities in need.

Currently the distribution of blood among various regions of the country is quite efficient. Systems such as the AABB's National Blood Exchange allow for resource

[2] "Statement of the American Hospital Association before the Advisory Committee on Blood Safety and Availability of the Department of Health and Human Services," Sept. 5, 2002.

sharing by blood centers and hospitals with surpluses to facilities facing shortages. However, there are inherent difficulties in relying on external supplies to address possible blood shortages. A local blood center, understandably, will always provide for its own community first and outside regions later. Therefore, the answer to addressing blood shortages lies in increasing the amount of reserve available to all patients across the country.

In this light, the AABB is currently discussing with blood centers and the Armed Services Blood Program the possibility of establishing a national blood reserve. A national reserve is needed to use in case of a military conflict, domestic disaster or act of terrorism. In addition, such a reserve could be used to meet a serious blood shortage in a particular region of the country, assuming existing resource sharing agreements were not adequate.

Question 4. Dr. Jones of the New York Blood Center states "the overall supply curve does not depict the type-specific donation problem experienced by all blood collectors." Are we measuring the wrong way? What is the industry doing about this? The federal government?

Response. It is critical that blood supply data include information about the collection, inventories and utilization of specific blood types. Gross data alone are not sufficient. Some blood types are in greater demand than others. The particular phenotypic mix needed to serve one region's population will differ from the mix needed in another region, depending on racial and other demographic factors. For example, the phenotypic needs in New York City do not match those in Iowa.

Since 1999, the NBDRC has collected and analyzed quantitative national blood supply data by blood group and type through its Biennial Nationwide Blood Collection and Utilization Survey. This survey provides detailed annual data from both blood centers and hospitals describing units collected, processed, distributed, transfused and outdated. The whole blood/red blood cell distribution, transfusion and outdate data are stratified by blood group and type. The NBDRC is the sole provider of weighted *national* estimates for these blood services activities, which it monitors over time.

For the past 18 months the NBDRC has also collected monthly type-specific collection, inventory and distribution data from a statistically representative sample of U.S. blood centers. In addition, NBDRC gathers annual collection data by blood group and type from a 100 percent sample of U.S. blood centers by QuiKount, a web-based survey conducted in odd-numbered years.

However, the ability of NBDRC to continue collecting such data is in question. Absent a commitment of federal funding, the NBDRC will not be able to continue these critical efforts.

Unfortunately, the federal government has not demonstrated an ongoing, reliable long-term commitment to collecting blood supply data, including type-specific collection and utilization data. Current federal government blood supply data collection programs are ad hoc, seemingly uncoordinated and lacking a long-term vision and commitment. If the United States is to adequately understand the dynamics of blood supply and demand, and, ultimately, to anticipate future blood needs, such a commitment is essential. Frequent, uninterrupted quantitative data collection is needed to forecast supply and demand, and, therefore, to avoid shortages.

Question 5. What were the recent (September 5) Advisory Committee on Blood Safety and Availability's recommendations to the HHS?

Response. s a memorandum from CAPT Lawrence C. McMurtry, Acting Executive Secretary, Advisory Committee on Blood Safety and Availability, summarizing the meeting, including the resolutions passed that day.

Question 6. What will a seven-day supply look like? Is it seven-day supply at each hospital, blood center?

Response. This supply should be a seven-day supply at every blood center. As stated during the hearing, this figure represents the goal in seeking to prepare for a potential disaster or act of terrorism. Today, the supply in almost all blood centers falls notably below this target.

Question 7. Although there is public concern over wastage, and the industry recommendations to avoid this in the future, the Red Cross testimony suggests a seven-day goal will increase wastage. Will this be significant? How does the blood community plan to address public concerns about increasing wastage?

Response. Moving to a seven-day supply may well increase the number of blood components that go unused. However, it is important to note that in most cases at least one component from each blood donation will be used to benefit patients, even if the red blood cells, which have a relatively short shelf life, need to be discarded due to outdating. The blood community will work hard to limit the discard of outdated components as much as possible, through rotation of more recently collected units and other measures.

The blood community, along with policy makers and other interested parties, must work together to educate the public about the inevitable necessity to discard certain blood components in order to maintain an overall adequate blood supply. Together we should send a uniform message to the public focusing on the need to maintain an adequate supply of all blood types at all times.

Question 8. Does the industry believe the nvCJD (Mad Cow disease) restrictions should be relaxed?

Response. The AABB does not believe that the FDA's recent deferral policies relating to vCJD should be relaxed at this time. However, the AABB believes that the impact of this policy on the blood supply nationally and regionally should be carefully monitored. If it appears that the blood supply in any particular region is no longer adequate due to the implementation of this new policy, then the FDA and the blood community may need to reconsider the policy and/or explore additional means of ensuring that blood is readily available to patients in such regions. In addition, FDA must continually reevaluate information relating to this policy and reconsider the policy as updated information becomes available. Such donor deferral policies must be based on current scientific knowledge.

The AABB appreciates your ongoing interest in the safety and availability of the nation's blood supply. We welcome the opportunity to work with you and other policy makers to ensure patient access to a safe, readily available blood supply. If you have additional questions or require further information, please do not hesitate to contact me or Theresa Wiegmann, AABB director, Division of Government and Legal Affairs.

Sincerely,

KAREN SHOOS LIPTON, *JD*
Chief Executive Officer

AMERICA'S BLOOD CENTERS
October 7, 2002

The Honorable JAMES C. GREENWOOD
Chairman, Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Room 2436
Washington, D.C. 20515

DEAR CONGRESSMAN GREENWOOD: Pursuant to your letter of September 20, 2002 and in follow up to my testimony before the House Energy and Commerce Subcommittee on Oversight & Investigations on September 10, 2002, I am submitting answers to your questions.

Question 1. Because of screening for blood-borne diseases, donors have more questions to answer and the donation process takes more than an hour on average. Are the blood centers taking any actions to make blood donation less complicated and less time-consuming? For example, are donor questionnaires being automated? Is this a good idea?

Response: America's Blood Centers has been working diligently over the last four years with the American Red Cross (ARC) and the American Association of Blood Banks (AABB) in trying to develop more efficient, yet effective ways of screening donors. However, regulatory concerns from FDA require validation that new methods (such as computer-assisted screening, self-administered health histories, shortened questionnaires for repeat donors, dropping oral questioning, etc.) are no less effective than current methods. Such proof has been difficult and time consuming to obtain. Consequently, progress has been very slow.

We understand FDA's concerns in this area, however. Methods for screening donors by health and behavior history remain the primary way of reducing the risks of transmission for diseases we either do not or can not test for, or where tests still have a "window" (i.e., the interval between infection and when a test turns positive). The current donor screening system has evolved over the last twenty years as the effective "overlapping layers of protection." For example, the rates of disease markers in volunteer blood donors are roughly one one-hundredth of that found in the general population. Said another way, we eliminate over 99 percent of infected donors even before we collect and test the blood. The problem is that the long and involved screening adds considerable time to the donation process, which we know is discouraging to would-be and repeat donors. The difficulty, then, comes in trying to peel away some of the layers of screening and substituting them with ones that are more efficient but as effective.

Having said the above, the national blood organizations have recently submitted proposals to FDA for shortening the health history and are awaiting a favorable response.

Question 2. The GAO reports that blood collections have increased 21% between 1997 and 2001, and that collections for the first half of this year are on pace with the same period in 2001. Even with the recent donation shortfall this summer, these emerging data suggest collections, overall, have been on the upswing. Do you tend to agree with GAO's general findings with regard to donation trends? Why?

Response: ABC agrees with the GAO that blood collections in the United States have increased, but strongly disagrees with their conclusion that this increase has kept pace with demand. The GAO report covers a period of tremendous instability in our nation's blood donations and does not include the period of substantial drops in donation rates since June 1, 2002 when half the nation's blood collectors implemented new vCJD guidance. While ARC initially reported little impact of their vCJD deferral policies, their earlier implementation dates coincided with the surge of donations after September 11th. ARC now reports critical blood shortages with severe reductions in donation rates. None of this is addressed in the GAO report.

In addition, the GAO report bases much of their assessment of the blood supply on information gathered from sentinel hospitals. Hospitals are an insensitive barometer of supply; blood centers are a far more reliable gauge of supply variances. Blood centers work hard to maintain in their hospitals whatever supply the hospitals may require to assure that the blood is on the shelves when needed by patients. Thus, blood center inventories, which are a buffer against emergencies, may drop to low levels long before the impact is felt by local hospitals.

ABC's data indicate that the available blood supply in the period before September 11, 2002 as compared with the months before to September 10, 2002 (the release date of GAO's report on the blood supply) has decreased from an average of between four to five days to less than three days supply on the shelves of blood centers. This low supply means many communities around the country have not recently had an adequate blood supply to meet the needs of a major local disaster. This fact is bolstered by AABB's testimony that the number of canceled non-emergency surgeries in hospitals has increased over the last year because of increasing blood shortages. The American Hospital Association also conducted a survey last year showing increasing cancellations of non-emergency surgeries.

The simple facts are that blood demand is increasing because of an aging population and expansion of blood-consuming medical and surgical therapies, while we continue to indefinitely defer willing donors because of precautionary measures. The lives of over four million Americans depend on blood transfusions, yet less that three percent of the population donates the 15 million or so units of blood needed to support patients. Tens of millions more Americans are healthy enough to give blood but are difficult to reach for a variety of reasons.

Blood centers are pouring millions of dollars into new resources to boost donations, but are hard pressed to meet these competing trends of increased blood need and the elimination of willing donors. As ABC testified, the blood community needs help. We require more national and high level attention on the problems of blood supply to convince many busy Americans to assure the blood will be there when it is needed.

Question 3. Ms. Lipton's testimony raises a point about donor deferral policies affecting different regions in different ways, due to demographics and so forth, and that federal policy makers must take this into account. Please explain how you are working to respond to this issue. Is ABC going to provide a coordinated response to these safety and risk decisions?

Response: Yes. ABC traditionally works with FDA, locally affected blood centers and the other national blood organizations to assess the impact of any new donor deferrals. It is true that such policies frequently impact areas of the US differently.

For example, we know that the impact of the Mad Cow Deferrals of recent years has hit the coastal cities more than the heartland (and more East Coast than West) because of the travel patterns of the populations that live in those areas. No recent deferral has had more varied local impact than the Mad Cow Deferrals that took place in June 2002. Areas of the US with high active or retired military populations have seen deferral rates climb as high at 10 percent, even among high school donors (for military dependants who spent time on bases in Europe). Our response is to try and compensate by increasing collections and/or contracts for imports of blood from other areas of the US.

When this month's next round of Mad Cow Deferrals are implemented, the impact will be felt most acutely in New York City, as the deferral will halt the supply of so-called Euroblood. ABC members have boosted imports to the New York Blood Center by nearly an additional 75,000 units in the last year. However, we know that

for reasons mostly related to 9-11, New York's blood collections have fallen in 2002 rather than increased as planned. Health and blood officials are concerned that the loss of Euroblood will create a public health crisis. Media appeals may help in the shortterm, but it is unclear how the needs of New York can be addressed in the long term, given the spreading shortages around the US. ABC will do its best to help.

Another aspect of the regional differences in impact of a new deferral policy is that export blood centers, which are mostly rural, can easily absorb a new donor deferral policy. But such policies also severely reduce their available exports. Thus, urban centers, which are often dependent on imports from rural centers, experience a double hit from new deferral policies, i.e., both reduced local collections and reduced shipments of blood from rural centers. This double hit has certainly been seen with the latest round of Mad Cow Deferrals and their impact on urban and import-dependent centers in cities such as New York, Pittsburg, Chicago and Los Angeles.

Question 4. Dr. Jones of the New York Blood Center states "the overall supply curve does not depict the type-specific donation problem experienced by all blood collectors." Are we measuring the wrong way? What is the industry doing about this? The federal government?

Response: Group O blood has always been used disproportionately in trauma. As the blood group in greatest demand, Group O is in the shortest supply when blood demands increase and new deferrals are put in place.

For this reason, the ABC "Stoplight" (on www.americasblood.org), which daily measures the blood supply provided by ABC members, uses Group O as the lead indicator for determining a shortage and "days of supply." The definitions used in the Stoplight are enclosed with this letter. Although "days of supply" is a surrogate marker for actual numbers, we believe the Stoplight represents a more sensitive way to measure supply because it takes into account local variances in how supply is distributed, measured and responded to.

Question 5. What will a seven-day supply look like? Is it seven-day supply at each hospital, each blood center?

Response: While there is a proposal that blood centers try to achieve a seven-day supply to meet emergency demands for blood, there is no national consensus whether this is either the best or only way to meet extraordinary needs for blood. In reality, when the average national supply is less than three days for a sustained period, as it is now, it is more important to determine how the current day-to-day needs will be met, rather than to set a seemingly desirable but unrealistic goal.

To explain, blood centers around the country have set levels for ideal local supply based on historical need. This may rage from a three-day to a ten-day blood center supply (i.e., the blood on the shelves of blood centers). The factors in setting a high or low blood center inventory goal include whether the blood center manages hospital transfusion services (as is done in many parts of the US), what supply would be needed to respond to a major local disaster (as determined in disaster preparedness models), and whether in an emergency extra supply can easily be shipped in from other nearby blood centers. Based on these factors, most blood centers believe that a three to five day supply of Group O red blood cells is ideal. Blood centers that are also the transfusion services for area hospitals will attempt to maintain an inventory at twice that level. Where the blood centers are not also the transfusion services, most area hospitals will maintain another three to five days' worth of supply. Much of that is committed (i.e., "crossmatched") to specific patients, although it could be diverted for general use in an emergency. So all totaled, based on current goals (and not in times of severe shortages), the US already maintains a six to ten day blood supply.

A realistic alternative to every blood center attempting to boost their local supply would be in better assuring transportation in times of a disaster whereby thousands of units already in inventory could be shipped within a few hours from larger designated "reserve hub" blood centers to an area with extraordinary need. Such an alternative is based on what already happens informally in times of disaster. ABC has discussed this model with the military blood program (for meeting both military and domestic needs), and it is under consideration by the blood Interorganizational Task Force on Domestic Disasters and Acts of Terrorism.

Question 6. Although there is public concern over wastage, and the industry recommendations to avoid this in the future, the Red Cross testimony suggests a seven-day supply goal will increase wastage. Will this be significant? How do you plan to address public concerns about increasing wastage?

Response: As stated above, a seven day supply would be difficult to manage and could significantly increase wastage. However, public concerns could be addressed by relaying that this is the price of preparedness. Certainly, the public is aware that America's current preparedness consumes billions of dollars in added resources. As

suggested above, there may be other ways to address disaster preparedness, especially in times when we struggle to meet non-disaster blood demands.

Question 7. Do you believe the nvCJD (Mad Cow Disease) restrictions should be relaxed?

Response: ABC has consistently warned HHS about the ramifications of these deferrals on the supply of blood and has asked for specific assistance from HHS to deal with the resulting shortages, to no avail. These deferrals are a major contributor to increasing shortages around the country. As noted above, the next round of deferrals, which take place at the end of this month, could have a devastating impact on patients in the New York City area.

HHS and FDA have vowed to review the risk/benefits of the precautionary Mad Cow Deferrals based on emerging data from Europe. We have urged that be done at least every six months (such as at meetings of FDA's Transmissible Spongiform Encaphalopathies Advisory Committee).

In summary, we thank you, Mr. Greenwood, and the committee for holding the September 10, 2002 hearing on the important issue of "America's Blood Supply" in the Aftermath of September 11, 2001.

To reiterate three important points made in my testimony and in the above answers to your questions:

- The blood supply is very fragile and may not meet future patient needs. Blood use is increasing at a time when our donor population is aging and as increasing precautionary restrictions are being placed on otherwise healthy individuals willing to give blood.
- The private sector needs a designated office inside HHS that focuses on blood availability and coordinates this important public health issue with the private sector. We suggest that, as they do for organs, tissue and marrow, the Health Resources and Services Administration be charged to work with the private sector on helping to increase the public support for assuring an adequate blood supply.
- Congress can help by assuring funding for new public educational initiatives on blood donation, by encouraging every Congressman and Senator who can to give blood publicly and frequently, and by working with their local blood suppliers to participate in public events that would help create a culture of donation in the US.

Regarding the last point, ABC staff will be in touch with committee staff to talk about your idea of helping to spotlight the need for blood donations by hosting a Congressional event.

Thank you again for your efforts.

Sincerely,

JEANNE DARIOTIS
President

STOPLIGHT DEFINITIONS

Green = 3-day available supply* or more of all red blood cell types = Preferred Level, or enough blood for one major emergency to strike. No special action required.

Yellow = 2-day available supply = Minimum Safe Level = Don't have enough blood to release to take care of patients in a major trauma or emergency. Actions may include scheduling special blood drives, going out on appeal to the media and/or cutting back on routine stock orders for consignees.

Red = 1-day available supply or less = Critical Level = Not enough blood on hand to meet routine or emergency needs. Actions may include evaluating hospital inventories (to anticipate transfers as needed), triaging of blood orders based on need, and advising physicians to cancel non-urgent surgeries if supply decreases to half-day or less.

June 1, 2002

*Available supply excludes blood being held for completion of processing (such as awaiting test results); that is, the definition includes blood available for distribution to consignees. Some centers may use Group O as the sole or primary indicator available sufficient supply.

SOCIETY FOR THE ADVANCEMENT OF BLOOD MANAGEMENT
September 30, 2002

The Honorable JAMES C. GREENWOOD
Chairman, Subcommittee on Oversight & Investigations
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House office Building
Washington, D.C. 20515

DEAR CONGRESSMAN GREENWOOD: Thank you for your letter dated September 20 containing specific questions concerning the nation's blood supply and the efforts and accomplishments of the Society for the Advancement of Blood Management. We appreciate the opportunity to follow upon our testimony of September 10th before your Subcommittee.

Question 1. Although your organization was only established recently, can you cite some real-life examples of how blood conservation initiatives are helping the management of the blood inventory?

Response. Attached to the end of this letter is a partial list of the activities of SABM over the past year. Through education, demonstration of clinical efficacy and peer-reviewed medical publication, the improvement of outcomes by following the dictum, "transfuse last" rather than the current practice of "transfuse first" preserves the store of donated blood for the most needy patients. Hospitals following these practices can and do reduce blood transfusions by 50% while improving outcomes through better medicine. This result is by no means unique as over 150 United States hospitals with similar programs continue to reduce blood usage in both medical and surgical patients. Major liver surgery, cardiac surgery, and bone marrow transplantation are all being done successfully by SABM members without the need for transfusion or with vastly reduced transfusion requirements. SABM has shown transfusion reduction does not require expensive technology. Rather, significant reductions can be accomplished through attention to detail, careful patient management, reduction of phlebotomy and acceptance of a lowered transfusion trigger. These are all included in SABM educational programs.

Question 2. If blood conservation measures were adopted more widely, how would supply requirements of the nation's blood supply be affected?

Response. Surveys of current transfusion practices in the United States show that identical patient populations, e.g., cardiac surgery patients, are transfused at different hospitals at rates that range between less than 50% to 100%. The decision to transfuse is most often based on long standing local habits, i.e., "we've always done it that way," and outdated physician knowledge rather than medical necessity. Widespread adoption of blood conservation and management can reduce this unnecessary blood usage, thereby decreasing the demand on the blood supply, and preserving the blood supply for patients who are in true medical need. Based on our experience, we believe that a 50% reduction in supply requirements is currently possible.

Question 3. Are there inherent dangers in adopting blood conservation measures?

Response. The basic tenet of medical care is to first, do no harm. Risk to patients can be classified broadly into those inherent in a product, those unique to patients, and those caused by inappropriate treatment or incorrect use of a product, i.e., iatrogenic. Blood conservation measures include cessation of blood loss, careful surgical technique to avoid blood loss, transfusion at a lower hemoglobin level, and use of the patient's own blood. Stopping bleeding and preventing blood loss during surgery are common sense measures that have no inherent dangers. The absolute, lowest or critical hemoglobin is as yet unknown. SABM's experience has shown that successful outcomes in severely anemic patients who refuse transfusion is now commonplace, showing that the risk of limiting transfusion has minimal relative risk. Techniques to use the patient's own blood include pre-deposit, cell salvage and hemodilution. Pre-deposit carries the same risks inherent in collection and storage of blood and is less of a risk than using allogeneic blood. The technologies of cell salvage and hemodilution have evolved to the point that risk results only from incorrect use. Drugs used in blood conservation have some inherent risks as do any medications, but their risk to benefit ratio is minimal if they are used correctly. SABM generally agrees that adequate fluid resuscitation and volume replacement, well-controlled cardiovascular vital signs, and sufficient oxygen delivery to vital organs such as the heart, brain and kidneys are keys to maintaining and restoring health.

Blood transfusions have the potential benefit of delivering some oxygen to tissues and as volume replacement. This past month's major events in blood news (absent the Congressional hearing and SABM Symposium in Washington, DC) underscore

typically and increasingly relevant blood safety issues: First, the West Nile virus is present in the national blood supply but is not detectable. Second, the September 25, 2002 issue of the *Journal of the American Medical Association* describes prospective data on 4,670 critically ill patients. Patients who receive transfusions are associated with diminished rather than improved organ functions and a shortened life expectancy. An accompanying Editorial reviews this article and 21 other pertinent medical articles urging vigorous examination of blood conservation strategies for critically ill patients for their apparent savings in morbidity and mortality. SABM believes that appropriate use of blood conservation eliminates the risks inherent in allogeneic blood. Existing and currently accumulating evidence of an improvement in outcomes in the non-transfused patient suggest that the adoption of blood conservation strategies benefits patient, institution, and payer alike.

Question 4. How best can blood conservation measures be deployed in preparation for a large scale disaster where blood would ordinarily be required in large amounts?

Response. SABM seeks a venue to present just such measures for large scale deployment. Several blood conservation strategies when combined, lead to significant savings of blood. Products currently in the drug and device approval process are in need of faster progress with real-world clearances for limited observational assessments. Artificial oxygen carriers, which have been approved for use outside the United States, appear more than promising as initial fluids for resuscitation of traumatically injured patients. These agents can be stored and transported without the Spartan requirements needed for blood. Their early use in a large-scale disaster can reduce blood wastage. Unfortunately, lacking regulatory guidance, they are used now only in the context of "compassionate care" in patients who refuse human blood transfusions. Although multiple studies of these agents have been done, they have all addressed their use as absolute substitutes for blood, a goal they may never be able to achieve. As a result, they are languishing in the regulatory bog. Hemostatic agents and dressings that can staunch overwhelming bleeding are in a similar regulatory status despite excellent clinical efficacy in disaster victims in Israel. A fresh look at the potential of oxygen therapeutics and hemostatic agents and some forward movement are needed.

Question 5. How does the STORMACT (Strategies TO Reduce Military And Civilian Transfusions) work that your organization has been doing with the military bear on the issue of the national blood supply?

Response. A high percentage, between 50-70% of blood transfusions, are given in the urgent or emergent critical care setting of the trauma ward, surgery or intensive care unit. When blood conservation measures are employed in this setting, dramatic reductions in transfusions are observed. Similarly, the US soldier in combat faces a situation where blood conservation measures are mandatory. Blood is simply not available on the battlefield so conservation measures are an absolute requirement to preventing death from exsanguination. When reviewing battlefield resuscitation practices on the advent of entering Afghanistan, the existing battlefield resuscitation practice dated to the Vietnam era. Military medical leaders decided to critically examine and modernize these practices. SABM was called and STORMACT was created in October, 2001. Learning of the existing practice, SABM recommended changing the resuscitation fluid from a water-based solution to a thicker, colloid based intravenous solution, a so-called "volume expander" which remains within the circulation far longer. The amount required is also half of the water-based solution in size and weight. Furthermore, the integrated approach practiced in blood conservation translates to the civilian trauma setting as well. Israeli trauma physicians use advanced blood conservation techniques learned from the Israeli Defense Forces. The Israeli's have available pharmaceutical compounds which can and usually do stop hemorrhage and have been shown to save lives following severe trauma. These are also bogged down on the slow track rather than the express track of the US regulatory process. As such, by regulation, they are unavailable to our US military troops until cleared.

The relevance to the national blood supply is twofold: first, the military collects, stores, and then disposes of tremendous amounts of unused blood at great expense. Records from the Gulf War as well as Operation Enduring Freedom show that the majority of the blood assigned to our forces was never used and was discarded as an outdated, unusable product. Second, blood conservation and the practice of using alternatives to blood transfusions help immensely in conserving blood for the truly needy.

Thank you for your interest in blood conservation as a central strategy in the preservation of the national blood supply. References used appear at the end of the document.

For the Society for the Advancement of Blood Management, we remain,
Sincerely yours,

RICHARD SPENCE, MD,
President
ARYEH SHANDER, MD, FCCM, FCCP,
Executive Director
HENRY BENNETT, PH.D.,
Administrator

2001-2002 ACTIVITIES (PARTIAL LIST) OF THE SOCIETY FOR THE ADVANCEMENT OF BLOOD MANAGEMENT

August 11, 2001,
Founding Meeting, Four Seasons Hotel Vancouver, British Columbia

September 19-20, 2001, XVIII Congress of the Brazilian College of Hematology, Sao Paulo, Brazil, "History and Actual State of Art in Bloodless Medicine and Surgery" and "Reducing Blood Loss and Managing Extreme Anemia in Intensive Care"

September 29, 2001, Board of Directors Meeting, Arizona Biltmore Resort and Spa Phoenix, AZ

September 30, 2001, "Iron, Erythropoiesis, and Physiology of Erythropoietin Response to Anemia," 2001 Symposium on Blood Conservation in Medicine and Surgery, Phoenix, AZ

October 8, 2001, STORMACT I, Hahnemann Medical School Philadelphia, PA

October 22, 2001, "Anemia and Erythropoietin" Hematology/Oncology Grand Rounds, University of Michigan, Ann Arbor, MI

November 6, 2001, Ontario Hospital Association Blood Issues Session Managing Scarce Blood Resources: Alternative Solutions Today, "Administrative Issues Involved with Establishing a Program of Bloodless Medicine and Surgery"

November 17, 2001, 1st SABM Regional & Board of Directors Meeting, The W New York Union Square New York, NY

November 20, 2001, Presentation on promoting blood conservation within the Federal expenditures on healthcare, Department of Health and Human Services Washington, DC

November 28-29, 2002, Bloodless Medicine & Surgery Conference Warsaw, Poland, "Tolerance of Anemia and Reduced Circulating Blood Volume"

December 5, 2001, STORMACT II, Naval Medical Research Center in Silver Spring, MD

January 9, 2002, Pinnacle Health System, Harrisburg, PA, "Transfusion Practice: A Time for Change"

January 22, 2002, "The State of Anemia," Medical Grand Rounds, Case Western Reserve University, Cleveland

January 25, 2002, STORMACT III, Four Seasons San Diego, CA

January 25, 2002, "Iron Dependence of Erythropoiesis in the presence and absence of erythropoietin therapy," Master Class in Nephrology, Berlin

January 26, 2002, 2nd SABM Regional Meeting, Four Seasons Resort Aviara,, 7100 Four Seasons Point Carlsbad, CA 92009

February 4-5, 2002, 10th Winter Symposium on Intensive Care Medicine Crans Montana, Switzerland, "Perioperative Blood Management" "Erythropoietin in the ICU"

February 8, 2002, Medical Symposiums, Incorporated, and the Texas College of Emergency Physicians present Emergency and Critical Care Medicine, Saint Martin French West Indies, "Blood Substitutes"

February 9, 2002, American College of Surgeons San Juan, Puerto Rico, "Artificial Oxygen Carriers in Bloodless Surgery"

March 8, 2002 "The State of Anemia." Ohio State Cancer Center, Columbus, Ohio

March 7, 2002, Northside Hospital & Heart Institute-St. Petersburg, FL, "Transfusion Practice: A Time for Change"

March 15, 2002, "The State of Anemia," Cancer Center Rounds, Henry Ford Hospital, Detroit, MI

March 23, 2002, Blood Conservation Symposium, Johanniter Hospital Oberhausen Oberhausen, Germany, "Permissive Anemia" "Indications for Acute Normovolemic Hemodilution."

April 5, 2002, STORMACT IV, Hurlburt Field 100 Bartley Street, Suite 210E Hurlburt, FL

April 8, 2002 Euroanesthesia Industrial Luncheon Workshop Nice Acropolis Center Nice, France, "Oxygen Therapeutics: Structure and Clinical Correlation"

April 8, 2002, ESA/EAA Industrial Luncheon Workshop Nice Acropolis Center Nice, France, "Oxygen Carriers: Preclinical Overview and Rationale for Use"

April 15, 2002, STORMACT Roadshow, Walter Reed Bethesda, MD

April 17, 2002, Transfusion Practice: Outcomes and Economics, Hackensack University Hospital, Hackensack, NJ

April 19, 2002, Transfusion Practice: A Time for Change, 2nd Panhellenic Transfusion Congress, Patras, Greece

April 20, 2002, J Soc Anesth Annual Meeting, Fukudka, Japan, "Perioperative Transfusion Strategies in the U.S."

April 21, 2002, A Live CME Lunch Symposium at the Society of Cardiovascular Anesthesiologists 24th Annual Meeting, Optimization of Fluid Management: An Outcome Based Approach, New York Marriott Marquis

April 22, 2002, Third Annual NATA Symposium, Rome, "RBC vs. Erythropoietin Therapy."

April 29th, 2002, NY Regional Blood Center, "Blood Rounds on the Net" Live teleconference on blood conservation techniques for clinicians sponsored by the primary blood bank for the New York City region

May 2, 2002, First Annual Northwest Conference on Bloodless Medicine and Surgery. Swedish Medical Center, Seattle, "Erythropoietin, Iron and Erythropoiesis." "Transfusion Guidelines"

May 7, 2002, Anemia in the ICU Patient, University of Missouri Department of Surgery, Columbia, MO

May 9, 2002, Transfusion Practice: A Time for Change, Huntsville Hospital, Huntsville, AL

May 14, 2002, STORMACT Roadshow, Overview—Blood Management Issues in 2002 and Beyond—Military and Civilian Perspectives, STORMACT IV, Brooke Army Medical Center, San Antonio, TX

May 15, 2002, Transfusion Practice: A Time for Change, St. Joseph's Medical Center, St. Louis, MO

May 18, 2002, The Carolinas Regional Symposium on Blood Management, Spartanburg Regional Healthcare System and supported by restricted educational grants donated by the Society for the Advancement of Blood Management and OrthoBiotech

May 24-26, 2002, A Curriculum in Bloodless Medicine and Surgery, Österreichischer Kongress über Blutsparende Medizin, Vienna, Austria

May 30-31, 2002, AABB Oxygen Therapeutics Conference, Bethesda, MD, "Oxygen Therapeutics and Their Role in Medical Anemias" "Clinical Uses of Oxygen Therapeutics"

May 31, 2002, "The State of Anemia." University of California at Davis Oncology Journal Club, Sacramento, CA

June 7, 2002, STORMACT V, Englewood Hospital and Medical Center Englewood, NJ

June 20, 2002, Transfusion Practice: A Time for Change, North Broward Hospital, Ft. Lauderdale, FL

July 12, 2002, SABM Board of Directors Meeting, Courtyard Marriott 21 North Juniper Street Philadelphia, PA

July 25, 2002, Clinical Uses of Oxygen Therapeutics, Mt. Sinai School of Medicine, New York, NY

August 6, 2002, Anemia in the ICU, Shawnee Mission Medical Center—Shawnee Mission, Kansas

August 7, 2002, Anemia in the ICU, Luke's Medical Center—Kansas City, Missouri

August 15, 2002, Clinical Uses of Oxygen Therapeutics, Legacy Good Samaritan Hospitals, Portland, OR

August 22-23, 2002, Blood Management 2002 and Beyond, 17th Annual Surgery for Trauma Day, USUHS, Bethesda, MD

September 10, 2002, SABM invited testimony, US House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight & Investigations, "America's Blood Supply in the Aftermath of September 11, 2001" Washington, DC

September 20-21, 2002, SABM 2002 Symposium, Grand Hyatt Washington Washington, DC

Publications (partial list):

V. Martyn, S.L. Farmer, M.N. Wren, S.C.B. Towler, J. Betta, A. Shander, R.K. Spence, M.F. Leahy. The theory and practice of bloodless surgery. Transfusion and Apheresis Science; 2002;27(1):29-43.

Goodnough LT, Shander A, Spence RK, Bloodless Medicine, (Accepted for publication in British Medical Journal).

Scott-Connor CEH, Spence RK, Shander A, Singleton C, Bennett HL, Rock WA. Hemostasis, Thrombosis, Hematopoiesis and Blood Transfusion, *The Physiologic Basis of Surgery,* 3rd ed., ed. Patrick O'Leary, MD, Lippincott Williams-Wilkins, Philadelphia, PA; 2002:pp. 531-576.

STORMACT: Advances in Battlefield Resuscitation, Freilich D, Goodnough L, Kaplan LJ, Kellum JA, Spence RK, Shander A, Wright J, In press.

Current Research Activities:

COGNIGEN Trial of Blood use in Cardiac and Orthopedic Surgery, Principal Investigator—Aryeh Shander, MD. Englewood Hospital.

A Microeconomic Analysis of the Cost of Blood Transfusion, Richard K. Spence MD, Birmingham Baptist Health Systems, Birmingham, Alabama.

Blood Transfusion, Survival and Cancer Recurrence in 19,333 Patients, Richard K. Spence MD, Birmingham Baptist Health Systems, Birmingham, Alabama.

Nadir Hemoglobin and its Impact on Survival in the Acutely Bleeding Patient, Richard K. Spence MD, Birmingham Baptist Health Systems, Birmingham, Alabama, Aryeh Shander, MD. Englewood Hospital.

HLK 213: Phase II Randomized, Single-blind, Controlled Clinical Trial to Evaluate the Efficacy ands Safety of Hemolink™ in Subjects Undergoing Primary Coronary artery Bypass Grafting Surgery—several SABM member centers

HLK 214: Phase II Randomized, Single-blind, Controlled Clinical Trial to Evaluate the Efficacy ands Safety of Hemolink™ in Subjects Undergoing Revision Coronary artery Bypass Grafting Surgery—several SABM member centers

Grant Applications:

NIH RO1 grant application—*Promoting Physician Change in Transfusion Practice*—submitted in response to RFA-HL-01-011, Trials Assessing Innovative Strategies to Improve Clinical Practice.

NIH RO1 grant application—*Hemostatic Mechanisms of recombinant Factor VIIa During and Following Surgery*—submitted in response to RFA HL-02-001, Transfusion Medicine/Hemostasis Clinical Research Network.

References used in this letter:

2002Vincent JL, Baron J-F, Reinhart K, et al. Anemia and blood transfusion in critically ill patients. JAMA, 288: 1499-1507.

2002 Hubert PC, Fergusson DA. Red blood cell transfusions in critically ill patients. (Ed.) *JAMA,* 288(12): 1525-6.

PUBLIC HEALTH: Blood Supply Generally Adequate Despite New Donor Restrictions, *Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives,* GAO-02-754, Washington, D.C.: United States General Accounting Office.

2001 Ozawa S, Shander A, Ochani TD. A practical approach to achieving bloodless surgery. *AORN J.*, 74: 34-47.

NEW YORK BLOOD CENTER
October 7, 2002

JAMES C. GREENWOOD
Chairman
Subcommittee on Oversight and Investigation
House Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515-0115

DEAR CHAIRMAN GREENWOOD, I briefly testified during your hearing entitled "America's Blood Supply in the Aftermath of September 11, 2001" held on September 10, 2002 when I accompanied America's Blood Centers and presented the experience of the New York Blood Center (NYBC) and the New York metropolitan area with the nation's blood supply. NYBC has been the blood center most impacted by recent events, including September 11.

I appreciate the opportunity to submit our responses to the follow up questions you sent to ABC, AABB and others. Also attached is a paper I wrote called "How Big is the Room?" which proposes a collaborative study of the entire chain of events that impact the blood supply and its availability for patients. I have circulated this paper to many in the industry and have received unanimous support and willingness to contribute. What is troubling now is that there is no comprehensive understanding of how all the recruiting functions, donor restrictions, blood testing, processing and distribution impact on the total supply. In effect, we are flying blind and really have no precise sense of how close we might be to catastrophic blood inadequacy that could acutely or more likely chronically impair our ability to care for patients needing blood transfusions.

I have proposed a collaborative program whereby total risk is assessed. This risk includes the current and future blood safety regulations in light of the risks to patients of not receiving adequate supplies of blood.

I hope your subcommittee takes these concepts into consideration and that we can move forward with FDA and other regulators of blood safety to a more comprehensive and rational approach. Thank you for considering our views and including them in the record.

Sincerely,

ROBERT L. JONES, MD

Cc: Peter Deutsch, Ranking Member of the Subcommittee
Attachments

RESPONSES TO CHAIRMAN GREENWOOD'S FOLLOW UP QUESTIONS ON "AMERICA'S BLOOD SUPPLY IN THE AFTERMATH OF SEPTEMBER 11, 2001"

Question One: Because of screening for blood-borne diseases, donors have more questions to answer and the donation process takes more than an hour on average. Are the blood centers taking any actions to make blood donation less complicated and less time-consuming? For example, are donor questionnaires being automated? Is this a good idea?

Response: Blood donor questionnaires are becoming so complex that they may be losing their value by confusing blood donors or by promoting indifference to the questions. Blood centers are always trying to simplify the process, but regulation frequently inhibits innovation because of the approval process and restrictions that mandate certain processes. It is a very good idea to automate the questionnaire administration process but FDA requires that many of the questions be asked by trained personnel directly with the donor, thus losing much that is gained from automation.

The FDA adds questions without any validation testing as to their comprehension or efficacy in eliciting the proper information. On the other hand, FDA will require that any blood center proposal for changes be accompanied by data that assures that the blood supply will not be made less safe. Few organizations have the resources to carry out such studies which, by nature, need to be extremely large due to the low number of deferrals any particular question may capture.

FDA has recently come out with a draft guidance entitled "Streamlining the Donor History Form" which requires that all questions be asked *verbally* of first time donors as well as new questions of repeat donors or those who have not donated for a specified period of time. This new requirement would slow down the process tremendously, require additional resources (staff, space) be added, and create an untrackable system where it would be impossible to determine if any questions had been added since a donor had last given. Computer-assisted administra-

tion of questionnaires might be useful but would also require additional resources (funds for technology, logistics for bringing hardware out on blood drives, etc).

Question Two: The GAO reports that blood collections have increased 21% between 1997 and 2001, and that collections for the first half of this year are on pace with the same period in 2001. Even with the recent donation shortfall this summer, these emerging data suggest collections, overall, have been on the upswing. Do you tend to agree with GAO's general findings with regard to donation trends? Why?

Response: While there are clear and persistent trends showing increases in blood donations on both a national and annual basis, the magnitude of these increases are not keeping pace with either the increased utilization of blood products or the constant erosion of the blood donor base and supply. The donor base erosion is due to increasingly frequent introduction of "blood safety" precautions that, while causing large decrements in supply, are sometimes producing only marginal, if any, demonstrable increase in blood safety.

The GAO report primarily covers the years 1997 through 2001, a period of tremendous instability of the blood donation pattern of the nation. It does not include data from June 2002 to the present, when half the nation's blood collectors implemented the new vCJD guidance and experienced substantial drops in donation rates. In the GAO report, Red Cross reported little impact of implementing their own deferral policies, although their implementation dates of last fall coincided with the surge of donations after September 11. However, they now report critical blood shortages with severe reductions in donation rates, along with the rest of the country's blood collectors, and admit that loss of donors from the vCJD policies may reduce their ability to respond to seasonal donation losses. None of this more recent data is addressed in the GAO report.

Question Three: Ms. Lipton's testimony raises a point about donor deferral policies affecting different regions in different ways, due to demographics and so forth, and that federal policy makers must take this into account. Please explain how you are working to respond to this issue. Is ABC going to provide a coordinated response to these safety and risk decisions?

Response: An all-voluntary blood supply depends heavily on local community commitment to blood donations that at least perceptually are targeted for local use. Blood programs tend to take care of their community blood needs first before exporting blood for use in another part of the country. Economics does play a role in increasing geographic elasticity and willingness to move blood from areas of excess to areas of increased donation difficulties and shortages. However, the volumes of excess blood available are also subject to seasonal variation, thereby increasing the vulnerability of areas where donations are inordinately impacted by regulation.

Question Four: Dr. Jones of the New York Blood Center states "the overall supply curve does not depict the type-specific donation problem experienced by all blood collectors." Are we measuring the wrong way? What is the industry doing about this? The federal government?

Response: Type-specific shortages have always been the rule. The nation's and local blood supply are routinely short of all Rh negative blood and seem never to have adequate supplies of type O and type B. These types are in high demand relative to collections.

Two methods are emerging to attempt to create better balance between collections and transfusion type mix. One is increasing use of automated collections which allows for greater productivity in the donation process. For example, donors can give two units of red blood cells via automation, therefore increasing the yield per donation for specific blood types such as O negative. Another method is to target racial and ethnic groups that have higher percentages of certain blood types such as the Hispanic groups that have a higher percentage of type O blood.

Another more dangerous way of dealing with type-specific shortages is the hospital practice of giving Rh positive blood to Rh negative recipients. This practice can save lives in the short term but sensitizes the recipient to the Rh positive blood and if the recipient ever receives another Rh positive (emergency) transfusion a severe and possibly fatal transfusion reaction would occur.

Question Five: What will a seven-day supply look like? Is it seven-day supply at each hospital, each blood center?

Response: A seven-day supply would be what is on the shelf at a blood center including blood being processed for use. Since processing takes about two days, the net immediately transfusable supply is five days. This does not include the supply that is in the hospitals, which is usually two to five days in our experience.

Question Six: Although there is public concern over wastage, and the industry recommendations to avoid this in the future, the Red Cross testimony suggests a seven-day supply goal will increase wastage. Will this be significant? How do you plan to address public concerns about increasing wastage?

Response: There is little question that having a seven-day supply will increase wastage. However, most of this wastage will be in the common or more plentiful blood types such as Type A and AB. The type-specific collection strategies mentioned above should help this problem.

Question Seven: Do you believe the nvCJD {Mad Cow disease) restrictions should be relaxed?

Response: Yes. We believe the restrictions should be changed. The FDA Transmissible Spongiform Encephalopathies Advisory Committee made sensible recommendations when they applied the precautionary principal regarding BSE and vCJD to the United Kingdom where 98% of the bovine disease and 98% of the human disease are found. It is prudent to restrict donations from residents and long-time visitors to the UK until the scope of the vCJD problem is better defined. However, extension of the vCJD donor restriction to all of continental Europe cannot be supported either scientifically or medically by logical extension of the precautionary principal and, certainly, by its major detrimental effect on the blood supply. We would recommend relaxing the pan-European restriction until there is definite epidemiological evidence to support it.

How Big is the Room?

THEORETICAL LIMITS TO BLOOD DONATIONS AND SUPPLY

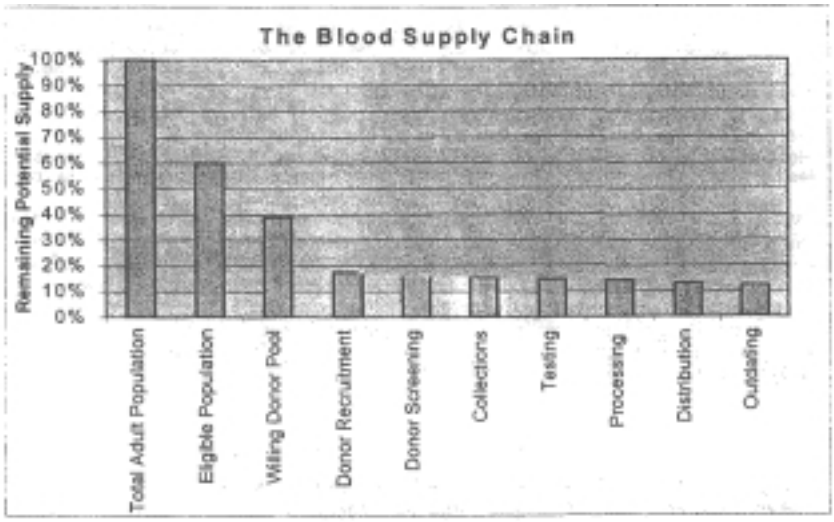
Robert L. Jones, MD

Donated blood for transfusion is a cornerstone of hospital medical practice. But recent years have seen blood shortages of increasing severity—particularly of red blood cells. Accepted industry lore asserts that up to 60% of the population is eligible to donate blood but only 5% donate at present. This estimate, based on historic US demographics, leaves the impression that there is essentially an unlimited reserve of blood donors and donations to meet our nation's transfusion needs. However, the experience of the blood donor organizations across the country suggests that this blood donor reserve is increasingly difficult to recruit, smaller than we thought, or both.

Although positively motivated by blood safety and efficacy, technology and regulation have taken a measurable toll on the number of donations contributing to our national blood supply. Each regulatory or technologic intervention applies to one or more points along the supply chain of blood production—beginning at donor recruitment through collections, processing, testing and distribution. The supply chain is linear and what seems not appreciated is the additive impact of the interventions on the available donor pool and ultimately the supply of red cells for transfusion. As we conceptualize the supply chain and make assumptions about the beginning donor pool, it is possible that by understanding the impact of each intervention we could more accurately estimate the actual size of the potential donor base and thus the potential blood supply under various circumstances.

Given persistent and worsening state of blood shortages, it seems prudent to study the supply chain in order to estimate the true magnitude of the nation's blood donor pool and thus the upper limit of the US blood supply available for transfusion. The study would look at each segment of the supply chain and calculate the supply removed from the total resulting supply from each intervention, either regulatory or technologic. For example, donor deferrals remove a calculable percentage of the eligible donors depending on the criteria. There are also donors lost who perceive they fall into the criteria—a more difficult estimate. Other examples are those who are either deferred or whose donations are discarded because they test positive for a viral marker. There are also those who are false positives or have indeterminate results. Then there are the effects of technology applied directly to the blood products such as the loss of red blood cells produced by leukofiltration. Finally, we should consider the impact of pathogen reduction technology on the transfusable cells.

All of these factors can be integrated into a retrospective meta-analysis of this important subject. A diverse group of individuals familiar with various parts of the supply chain would be gathered to make determinations of impact at each point of intervention. The goal of the group would be to examine all interventions in total to determine 1) an estimate of the true size of the US blood donor base, and 2) an estimate of the upper limits of a volunteer blood supply as currently structure in the US.



The figure above represents the framework of such a study and how graphically such subtractions from the blood supply could be shown. The actual segments and numerical contributions would be determined by the study. Those shown are only preliminary and speculative as to magnitude.

RESPONSE FOR THE RECORD OF THE FOOD AND DRUG ADMINISTRATION

The following is being provided in response to the follow-up questions from the September 10, 2002 "America's Blood Supply in the Aftermath of September 11, 2001" Hearing before the House Energy and Commerce Subcommittee.

Question 1. Based on FDA's experience in reviewing and evaluating new safety tests to screen the blood supply, what would be involved in developing a blood screen for West Nile Virus?

Response: Three factors are critical for development of a blood screen for infection with West Nile Virus, namely identification and development of appropriate test technology, manufacture and validation of tests by industry sponsors, and for licensure, meeting standards for test performance, including sensitivity and specificity.

Because individuals may be infected with West Nile Virus without experiencing symptoms, donor deferrals based on symptoms, although useful, have limited value. Therefore, while the true risk is unknown and under study, we currently believe that testing for infection with West Nile Virus will likely be necessary if the WNV epidemic continues in the U.S. It is known that there is a short period (about 2 week or less) when recently infected persons may have virus in their blood in the absence of antibodies. Also, the limited available data suggest that virus is no longer present when antibodies become detectable. For these reasons, scientists believe that the most promising technology for donor screening is direct detection of the West Nile Virus itself, rather than antibodies to the virus. Also, a direct test for West Nile Virus must be sensitive enough to detect the relatively low levels of virus that are found in the blood of asymptomatically infected individuals. At this time, the best candidate technology is thought to be nucleic acid amplification, although other methods, such as tests for virus proteins may be feasible. Nucleic acid tests have already been successfully licensed to screen blood for Hepatitis C and HIV. Discussions are underway among the CDC, FDA and industry both to encourage and facilitate studies to determine whether existing nucleic acid amplification technology platforms for detection of Hepatitis C and HIV could be rapidly adapted for blood bank use to detect West Nile Virus and to stimulate the development of other approaches to address the problem of donor screening.

Because it has the greatest capacity and experience to address the problem, it is important that industry step forward and take the lead in the development and manufacture of a suitable test for West Nile Virus. FDA has already contacted potentially interested industry members to inform them of the need for test develop-

ment, and we believe that industry is responding. On September 20, 2002, FDA, CDC, and representatives from several State Public Health Laboratories and blood organizations participated in a meeting organized at by the American Association of Blood Banks and AdvaMed to engage members of the device industry in a discussion of practical issues related to developing a test for West Nile Virus and ways to accelerate test development. We discussed the available technologies, possible technology transfer, and FDA's willingness to work closely and flexibly with industry to facilitate test development. In order to facilitate test development, the FDA, CDC, and certain State Public Health Laboratories and blood organizations already have agreed to create mechanisms to share positive samples and other materials that can be used as reference materials to facilitate test development and standardization, including regulatory controls.

In a number of meetings with potentially interested industry sponsors, FDA has made it clear that it seeks to encourage widespread availability and studies of donor testing for WNV under Investigational New Drug (IND) applications as soon as possible to screen for West Nile Virus infections at blood centers in areas in need, even before licensing. FDA has also discussed its current thinking on standards for licensure of a donor-screening test for West Nile Virus. Additionally, FDA is planning to announce a public scientific meeting in early November to discuss technological issues related to test development for West Nile Virus, to present FDA's current thinking regarding test development, availability under IND licensure, and to further encourage test development. To date, we have been gratified by the level of interest and initiative shown by the diagnostic testing industry, and the potential of public-private interactions to facilitate these activities. While there are significant technological barriers for industry to overcome, based on their stated plans and capabilities, we are hopeful that a suitable screening test can be made widely under IND by next year's transmission season.

Question 2. Please update the Committee on the status of development of a West Nile Virus vaccine. Also, please comment upon the risk issues surrounding vaccines (particularly the Smallpox vaccine) and the blood supply.

Response on the development of a vaccine for WNV: While there is currently no licensed vaccine available to prevent WNV infection, FDA is aware of several approaches to vaccine development and believes that vaccination is a potentially viable strategy to address this increasing public health threat. Because of the increased presence of WNV in the U.S., the National Institute of Allergy and Infectious Diseases (NIAID) has supported research in this area. NIAID announced that in 1999 it funded a fast-track project to develop a candidate WNV vaccine with Acambis PLC. As reported in "Trends in Molecular Medicine 7:350-254(2001)," Acambis has developed a live-attenuated vaccine candidate for WNV. For this reason, it is possible that future vaccine recipients may need to be deferred from blood donations for the period of viremia, which is still to be accurately determined.

Scientists at CBER are also engaged in studies which may hold promise for developing a vaccine effective against WNV. Most people who become infected with WNV will have either no symptoms or only mild ones. More severe disease occurs in approximately 1/150 of those infected and is manifested as encephalitis, meningitis, meningoencephalitis, or flaccid paralysis. Encephalitis refers to an inflammation of the brain; meningitis is an inflammation of the membrane around the brain and the spinal cord, and meningoencephalitis refers to the combination of both. Flaccid paralysis is a condition of weakness or paralysis that resembles poliomyelitis. There are currently no drugs on the market to treat this virus, although two drug products are currently being studies under IND. Given the important and increasing public health impact of WNV infection, including the potential threat to blood safety, and the lack of available vaccines and therapeutic measures, FDA places a high priority on facilitating the development and review of potential vaccines and therapeutic products for WNV infections.

Response to risk issues surrounding vaccines and the blood supply: Blood donors are usually deferred for two to four weeks after receiving a live vaccine. In the case of smallpox vaccine, which is a live virus vaccine (vaccinia virus) that is administered by puncturing the skin, it is not certain whether the blood of vaccinees contains the live vaccine virus, or for what time period such a condition could persist. For these reasons, FDA is cooperating in research studies to define frequency and duration of viremia in persons who receive smallpox vaccine. Therefore, until further information is available, FDA believes precautions will be needed to prevent transmission of the vaccine virus by transfusions, especially to those blood recipients who may have depressed immunity. Such a precaution may involve temporary deferral of blood donors who have received the smallpox vaccine. FDA is developing a guidance document for blood establishments that will provide recommendations for deferral of blood and plasma donors who have recently received a smallpox vaccina-

tion, or contacts of such persons who develop evidence of infection with the vaccine virus.

The U.S. Government has a plan under consideration, which would vaccinate first responders prior to any smallpox attack. This plan is not expected to significantly diminish the blood supply, because relatively few people would be vaccinated at one time. To address the possibility of mass vaccination over a period of time, prior to a smallpox attack, FDA will work with blood organizations, including the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (which includes representatives from the American Red Cross) and with organizers of the vaccine program within DHHS, to formulate strategies that would alleviate any impact on the blood supply.

The recently announced plan to institute urgent mass vaccination of the U.S. population if there is a smallpox attack, could have a major potential impact upon the blood supply, if it were to be implemented in an emergency situation, and blood donors who had received smallpox vaccination were to be deferred from donation. FDA, in discussion with its PHS partners and OPHP, is actively considering potential strategies to best address this scenario.

Question 3. Assistant Secretary Hauer, in his testimony (page 2), references FDA's recommendations—endorsed by the Department's Advisory Committee—to address future emergency demands on the blood supply. Please outline these recommendations and the status of their implementation.

Note to OL: DHHS can add additional information as needed.

Response: The CBER strategic plan that was endorsed by the DHHS Advisory Committee for Blood Safety and Availability contains four elements that are intended to protect the blood supply and assure blood availability in the face of potential disruptions and biological threats from terrorism.

- Actions to protect the blood supply
- Actions to assure continued supply
- Actions to treat affected individuals
- Outreach activities

Specific working groups have been established to ensure progress in each area, based on available funding. The accomplishments to date of the CBER strategic plan include:

- CBER has developed a set of standard SOPs for responding to a real or potential bioterrorist threat. Following these procedures, FDA staff responded well to simulated smallpox and botulinum bioterrorist events.
- FDA has collaborated with the NIH, CDC and DOD to develop a bioweapons agent list of concern to the blood supply. These agents could potentially be transmitted by asymptomatic donors exposed to a bioweapons agent. The list provides a focus for the development of prevention measures.
- In collaboration with the CDC, NIH and DOD, CBER scientists are developing gene chip microarray and other sensitive detection systems that could be used to detect bioterrorist agents. When fully developed these systems would be used, when needed, to assess the threat of bioterrorist agents in blood and blood products as part of FDA's lot release program. As appropriate, CBER will work with the blood industry to assist in transfer of the technology to diagnostic product manufacturers to accelerate the development of donor screening tests for bioterrorist agents. The knowledge gained will also assist in facilitating the review of test kits that may be submitted to FDA to assure the safety of donated blood.
- CBER scientists are researching pathogen inactivation/removal methods that could be used to protect blood and blood products from bioweapons.
- Immunization of the public at large with live virus vaccines poses potential challenges to blood safety due the possibility that live virus could persist for a period of time in the blood of a recent vaccinee. In response to the potential threat of smallpox, the government has identified a stockpile of vaccine for the entire country. Immunization of large numbers of the population poses its own concerns including the potentially serious impacts of live virus vaccination on individuals with compromised immune systems and the potential impact of the temporary deferral of large numbers of immunized individuals from blood donation. To address these concerns, FDA has taken the following steps:
  - FDA is preparing a guidance document on the deferral of donors who have been immunized to prevent smallpox.
  - FDA is working with CDC and manufacturers to help facilitate the development and availability of Vaccinia Immune Globulin (VIG) used to treat individuals with compromised immune systems who may be exposed to the vaccine and to treat severe complications of the vaccine.
  - There has been monthly monitoring of VIG supplies and doses available

- Cooperative communication with VIG manufacturers, the Department of Defense, and CDC concerning VIG potency and availability, monitoring of VIG studies, and progress towards licensure.

- DHHS and CBER participate actively in the AABB Inter-organizational Task Force on Disasters and Bioterrorism. This group has been formed to help to manage blood supplies in the face of disruptions from natural or man-made causes.
- Following the tragic anthrax attacks of last year, the FDA issued guidance to industry on deferral of donors potentially exposed to anthrax and the retrieval of blood products. FDA is preparing a guidance document to address donor and product management in the face of possible or confirmed infections with West Nile Virus. Additionally, FDA is taking steps to accelerate the development of a screening test for West Nile Virus infections in donors. These actions are being viewed concurrently as a model for actions that would be taken to address emergence of a bioterrorism agent as a blood safety threat.

Question 4. Some experts believe that the blood supply could be boosted by making it much easier for blood centers to accept blood donations from patients who have a genetic condition that causes an iron-load (called hemochromatosis) requiring periodic blood-letting and whose blood could provide thousands of units for donations. But only 29 out of the nation's 4,000 blood centers used donations from these patients because it requires special permission from the FDA and extra expense. Is the FDA considering any new policies to make it easier for blood centers to accept donations from patients who have hemochromatosis?

Response: Hereditary hemochromatosis (HH) is an inherited disorder of iron metabolism that results in iron accumulation and damage in multiple organs. Early initiation of therapeutic phlebotomies to remove iron, which is present in red cells, may restore a normal life expectancy and improve symptoms in these patients. Although FDA allows blood from patients with HH or other conditions that was drawn for therapeutic reasons to be used for transfusion, FDA regulations (21 CFR 640.3(d)) require that such blood be labeled with the disease state that necessitated the therapeutic phlebotomy. Because blood centers charge HH patients for the therapeutic phlebotomies, there has been a concern that patients with HH who also had risk factors that would cause them to be deferred would deny risks to avoid payment for the phlebotomy.

On April 29, 1999, the Public Health Service Advisory Committee on Blood Safety and Availability (ACBSA) recommended that the Department of Health and Human Services (DHHS) "create policies that eliminate incentives to seek [blood] donation for purposes of phlebotomy" from patients with diagnosed hemochromatosis who require phlebotomy as therapy for their disorder. Further, ACBSA recommended that DHHS "create policies that eliminate barriers to using this resource" to augment the country's blood supply. This issue was further discussed at the FDA Blood Products Advisory Committee meeting on September 16, 1999. Based on the recommendations of BPAC, FDA issued Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis (August 2001). In its guidance document, FDA stated its recommendations that use of blood from patients with hemochromatosis can be permitted in the absence of special labeling and without the restriction of one donation per eight weeks if: 1) the individual meets all other suitability requirements, and 2) the establishment does not charge a fee for any phlebotomies performed on individuals with HH including those who do not meet suitability requirements.

At present, FDA is allowing establishments to obtain a variance from the special labeling and donation frequency requirements so long as the establishment meets the conditions stated in the guidance. That is, the individual meets all other suitability requirements, and the establishment does not charge a fee for phlebotomies performed on any individual with HH. A persisting obstacle to increased donations by individuals with HH remains reimbursement for the phlebotomy. Also, management of phlebotomies for HH donors requires considerable logistical support that is difficult for many blood centers to develop and maintain.

Question 5. Two years ago, the HHS Advisory Committee on Blood Safety and Availability voiced support for moving the error-and-accident reporting system toward a no-fault reporting system to encourage more reporting and better use of data to produce better blood safety, such as continually reducing the probability of transfusing an incompatible blood type to a patient. Is FDA taking actions to move the blood error-and-accident reporting system toward a no-fault reporting system such as the one used in commercial civil aviation?

Response: In April 2000, the Advisory Committee on Blood Safety and Availability considered the issue of a national reporting and analysis system as a basis "to reduce and prevent morbidity and mortality due to human and system error."

The committee acknowledged "the right of patients to know of any risk or harm suffered as a consequence of any error or accident related to blood products received" and endorsed the concept of a voluntary system for reporting information, so long as the acts were not reckless or intentional. At the same time, the Advisory Committee recognized that "these error management systems should complement, and not replace, current regulatory activities, notably but not exclusively in the area of product safety."

FDA agrees that a mandatory reporting system for errors and accidents is necessary for ensuring patient protection while a voluntary anonymous reporting system also may have benefit and can be complimentary. CBER's Biological Product Deviation Reporting (BPDR) system, implemented on May 2001, collects and analyses events that may affect the safety, purity, and potency of biological products. This system was previously known as Errors and Accidents and has been extended to apply to all blood establishments, including hospital transfusion services, rather than only to licensed blood establishments. The BPDR system is an important component in the Center's overall efforts of assuring blood safety by providing CBER with timely information on real or potential recalls, significant problems that may exist at a given establishment which require investigative follow up, as well as an indication of broader problems in manufacturing across the industry. Although not a "no-fault" system, the individual report data are collected with the further intent of identifying and sharing with industry areas where processes can be improved. Such areas can then be targeted generally for focus during inspections by our field investigators or to identify problems at particular establishments.

The "Medical Event Reporting System-Transfusion Medicine (MERS-TM)" is an error reporting system that was developed with funding from the NIH and now is in use at some blood centers as a funded pilot project. Dr. Harold Kaplan, Columbia Presbyterian Hospital, NYC, is the leading investigator. MERS-TM serves as a model for non-punitive, no fault, medical event reporting system. Although it is not a system designed for reporting information to FDA, we have encouraged its use and see this as an adjunct system that provides useful information to address events that may contribute to errors in transfusion medicine. FDA encourages the use of all means of identifying and managing of product deviations, including a supplemental system such as MERS-TM.

The issue of errors and accidents related to transfusion is part of a larger DHHS initiative on patient safety in which FDA participates actively.

RESPONSE FOR THE RECORD OF THE DEPARTMENT OF HEALTH & HUMAN SERVICES

Question #1 Please clarify whether the recommended changes to a new Emergency Support Function 8 supplement to the Federal response plan, which you testified you forwarded to FEMA, have been in writing and please share them with the Committee, if this is the case.

Answer #1 We have no written changes to the ESF#8 supplement to the FRP. Bob Jevec from DPD confirmed this through John Baab at OER. Bob states that we were awaiting decisions on departmental assignments before suggesting changes to the FRP.

Question #2 Please clarify which federal public health agencies are funding research for developing a diagnostic test for screening for new variant Creuztfeld-Jakob Disease.

Answer #2 Description of the Federal Agencies that are supporting development of diagnostic tests for variant Creutzfeldt-Jacob Disease (vCJD).

The two Institutes at the NIH supporting development of assays for CJD and vCJD are NHLBI and NINDS. NHLBI and NINDS are currently supporting two contracts on CJD/vCJD test development. The two contractors are the University of California, San Francisco (PI Stanley Prusiner, M.D.) And Baltimore Research and Education Foundation (PI Robert Rowher, Ph.D.). This program ends in September 2005.

The NHLBI is also supporting an RFA on the development of assays (3 grants) that are due to expire August 2003.

Also, the Department of Defense is soliciting contract proposals to develop tests for transmissible spongiform encephalopathies (TSE) which can include vCJD. DOD plans to support research in other areas of TSE as well (e.g., chronic wasting disease, etc.). This program is being managed by the DOD Office of Congressionally Directed Medical Research Programs. This program is called the National Prion Research Program.

Question #3 Please update the committee on the status of research and development of "artificial blood" products.

Answer #3: What follows is an article from the Boston Globe dated 10/02/02 telling about FDA's acceptance of an application by Biopure to have its product Hemopure reviewed. This is significant because Baxter Healthcare and its partner in artificial blood, Alliance Pharmaceutical have had to suspend further testing of its product, Oxygent, due to lack of funding. Additionally, the only other U.S. company researching hemoglobin based oxygen carriers (HBOCs), Northfield Laboratories, has stated that it will probably have to conduct new clinical trials.

A Canadian company, Hemosol, has suffered clinical trial delays and recently had to cut staff in an effort to conserve cash.

Last month Biopure revealed that it had received a grant from DOD totaling more than $900,000 to develop a blood substitute for use in military trauma cases.

Boston Globe Article 10/02/02

In a major milestone in its 18-year effort to develop a controversial blood substitute of human use, Biopure Corp. of Cambridge yesterday said the US Food and Drug Administration had accepted its application for the product, Hemopure.

The FDA is expected to take 10 months to respond fully to the application, which was submitted in late July. The agency could ask for additional information or further clinical testing, potentially delaying a definitive decision on the product, which is approved for sale only in South Africa.

Still, the news is a big boost for Biopure, which last year delayed its plans to file the FDA application, infuriating many investors and raising doubts about the product's ultimate viability. Biopure shares, which has lost more than 80 percent of their value in the past 12 months, gained 64 cents, or 19.3 percent, to close at $4.14 on volume of 402.800 shares yesterday.

Thomas A. Moore, Biopure's new president and chief executive, said the company learned the news at 2 p.m. yesterday in a phone call from FDA just prior to receiving an official fax.

"While the FDA will decide whether our application is approvable, this acceptance is further affirmation of the substantive clinical data we've amassed," More said. "This latest 'first' for Biopure should help support our efforts to establish new business relationships and product indications."

Moore said Biopure is in advanced talks with a Far East manufacturer, whom he declined to identify, which would invest in the company and build a production plant to serve Asian markets. The two firms have signed a nonbinding letter of intent, he said, and plan to complete a binding contract by the end of the month. The partner firm would invest $15 million in Biopure over 10 months, purchase $15 million of Hemopure, and would invest up to $145 million in the manufacturing plant.

If the deal comes to fruition, it could give Biopure some needed breathing room. In addition to the delays in filing its so-called Biologic License Application with the FDA, the firm faced a cash crunch earlier this year. The firm's shares fell below a minimum price necessary for the company to draw on a credit line it had arranged by a French company. Instead, the firm had to sell several blocks of shares to investors in private placement.

Moore said Biopure has more than $25 million in cash on hand, down from about $30 million July 31.

More than 12 million units of blood are transfused each year.

Companies racing to supply a viable blood substitute, or oxygen therapeutic, as they are now called, claim there is a growing shortfall of blood for patients who need transfusions. Some estimate the potential market is in excess of $12 billion.

Hemopure is made from cow's blood, from which the hemoglobin is extracted and treated to remove any diseases or pathogens. The so-called bovine hemoglobin is suspended in a saline solution.

According to doctors who have worked with Hemopure, the artificial blood seems to have some advantages compared to the real thing. In the body, red blood cells carry oxygen, but they can only release it to tissues when they are in contact with the capillary wall. Hemopure can release oxygen without direct contact. In addition, it can penetrate further into tissues than red blood cells can, potentially applying oxygen more effectively than real blood.

But there are significant drawbacks. Hemopure rapidly breaks down in the body, and is filtered out by the liver. A unit of Hemopure has a half-life of 24 hours, so the benefits of a Hemopure transfusion rapidly decline. And it is costly: Biopure estimates it costs $700 to produce a unit of Hemopure. Blood in hospitals costs between $100 and $200 a unit.

In another milestone, Moore sad that Biopure had sold its first commercial units of Hemopure in Mozambique. South Africa last year became the first country to approve Hemopure for sale, and the Mozambique sales come under that regulatory approval. The company hasn't yet sold Hemopure in South Africa. Instead, it is pro-

viding the product for free as it conducts a wide-scale education and training effort for South African physicians. The quantities sold in Mozambique are too small to have a material impact on the firm's results.

In addition, Moore said, the firm is awaiting FDA approval of an upgrade to its Cambridge plant that would enable it to sell units of blood substitute for dogs. Until it receives that OK, Oxyglobin produced at the Cambridge plant must be held in inventory. Though sales of Oxyglobin has been below expectations, they provide Biopure with revenue stream while it continues its efforts to commercialize Hemopure.

"We're hopeful of resuming shipments in October or November," said Moore.

Meantime, the company is also preparing regulatory filings for approval to sell Hemopure in the European Union and other overseas markets.

But Biopure faces additional challenges while it awaits further discussions with the FDA. Construction on a Hemopure production plant in South Carolina, which was to begin in February, is still delayed. The local firm that plans to build the $120 million plant still hasn't closed on its financing, Moore said. Once the money is in hand, Biopure still has to execute a lease on the facility before construction can begin.

Other firms working to commercialize blood substitutes include Hemosol Inc. of Toronto and Northfield Laboratories Inc. of Evanston, Ill. Biopure's product contains hemoglobin isolated from cow's blood.

Question #4 According to testimony submitted by America's Blood Centers, at Secretary Thompson's request America's Blood Centers developed and submitted a blood action plan that HHS could use to help increase donations for blood. Despite the Secretary's pledge and numerous attempts in follow-up, no action has been seen from HHS to help bolster supply. Does HHS have a view on ABC's action plan and in any event, what action is the Department talking to ensure adequate availability of the U.S. blood supply?

Answer #4 Secretary Thompson is vitally interested in encouraging organ donation and have instituted a program call Donate Life, the aim of which is to increase public awareness and participation in an organ donation program. He is currently researching ways the Department can take a leading role in increasing the donation of blood as well. When the Advisory Committee on Blood Safety and Availability met on September 5, 2002 one of its recommendations was that the Department promote increased public awareness of the ongoing need for routine blood donations by healthy persons and address methods to alleviate seasonal short-falls.

Question #5 Has HHS examined any data or information relating to the experiences in Israel and how its Mogen David Blood Services are maintaining blood supply in the face of emergencies over the last year? What has HHS found?

Answer #5 Following is an abstract of an article submitted to the journal Transfusion regarding the utilization of blood in Israel. The actual blood transfused is obtained by local donors as a result of local appeals.

CAPT Barbara Silverman, M.D., M.P.H., visited MDA in June of 2002 to analyze MDA supply and utilization data and compare the MDA experience to that of three community sites participating in the PHS sentinel surveillance system. Supply and utilization data were available for the period from October 200-June 2002. MDA also provide detained data on the number and severity of casualties due to terror episodes occurring from January 1-June 15, 2002. The following is excerpted from a draft manuscript describing the MDA experience and the impact of multi-casualty terrorist events on the Israeli blood supply:

In the event of a multi-casualty event in Israel, responding ambulance personnel rank severity of injuries as light, moderate, severe and very serve MDA contacts hospitals slated to receive casualties, consults with them regarding their current blood stocks, and using a predetermined formula, calculates the number and type of additional units to be sent to these hospitals. Previous MDA experience has suggested that an individual wounded in a terror attack will require, on average, 3 units of blood, 1.1 units of plasma, 0.11 units of plasma, 0.11 units of platelets and 0.27 units of cryoprecpitate. However, there is concern that changes in the character and location of terrorist attacks, shorter response time by emergency personnel, and other factors may result in larger numbers of more severely wounded patients surviving to receive in-hospital treatment, resulting in higher per-patient blood utilization.

We considered data from 24 episodes occurring on 30 days between January 15, 2002 and June 15, 2002. These episodes resulted in a total of 176 deaths in the immediate aftermath of the events, 225 persons with moderate or severe injuries, and 899 with minor injuries. Injured persons were transported to a total of 20 hospitals. Mortality figures do not include individuals who may have died later as a result of injuries sustained during these events. In response to these events, MDA supplied

2712 units of blood (approximately 12 units per severely or moderately injured victim) and 1711 units of components to receiving hospitals that requested them. Hospitals that received causalities did not always request additional blood supplies. Blood supplied to hospitals in response to terrorist attacks constituted 3% of total units provided during the period from January 15, 2002 through June 15, 2002, and on average, 14% of total units (95% CI 3%-54%) provided on the affected days. MDA supplied a mean of 676 units per day to hospitals on days on which no such events occurred, a difference that was not statistically significant.

We attempted to determine whether units of blood supplied to hospitals in response to terrorist incidents tended to be used immediately or merely bolstered hospital inventory. For all twenty hospitals that received casualties from terrorist events, we compared mean inventory for the three-day period beginning with a terrorist event to mean inventory on all other days. Mean blood inventory following a request for blood was slightly lower than mean daily inventory on other days (83 vs 89 units), although this difference was not statistically significant. This finding suggest that the amount of blood supplied to hospitals in response to terrorist episodes was used quickly rather than inflating inventory.

We plan to extend this analysis by gather patient-specific utilization data from hospitals. By doing so, we will be able to calculate initialization by severity of injuries and determine whether the algorithm currently in use by MDA for estimating the number of units to distribute per injured patient is appropriate or should be revised.

RESPONSE FOR THE RECORD OF COLONEL GLEN M. FITZPATRICK, DIRECTOR, ARMED SERVICES BLOOD PROGRAM

QUESTIONS FROM SUBCOMMITTEE CHAIRMAN JAMES C. GREENWOOD

Question 1: Dr. Fitzpatrick, please provide more detail to the Committee on the status of the research at Walter Reed Army Institute of research to extend the shelf life for blood from 42 days to 70 days. Also, please discuss how much impact such an extension would have on the blood supply levels.

Answer: Research continues at the Walter Reed Institute of Research into extending storage of red blood cells at 4°C to at least 10 weeks (70 days). Preliminary human studies have been successful, but additional in vivo trials at multiple centers are required in order to collect enough information for FDA licensure. Fielding is dependent on finding a corporate partner for commercial development. No such company has been identified yet. Other projects underway to improve blood support to the field include: (1) developing with corporate partners a small container that will maintain blood at the proper temperature for at least 48 hours in the most severe of field environments; (2) extending the shelf life of frozen red bloods cells after thawing beyond 2 weeks (14 days); (3) corporate partnering for the study of blood "sterilization" to reduce the risk of transmission of infectious agents; (4) coordination of a trauma treatment protocol for hemoglobin-based oxygen carriers (HBOC, also referred to as "blood substitutes"); (5) preparing freeze-dried plasma—plasma is currently stored and shipped frozen, freeze-drying it will significantly reduce the logistical requirements; (6) collaborating with industry to produce a universal plasma in order to eliminate the requirement for blood typing for plasma; (7) methods to improve blood clotting using platelet microparticles, freeze-dried platelets, and other agents such as recombinant factor VIIa.

Increasing the shelf life of refrigerated red blood cells from 42 to 70 days would significantly reduce the logistical burden of supporting contingencies such as Operation Enduring Freedom and continuing operations such as ongoing in Bosnia and Kosovo. Most military operations do not use a lot of blood treating patients, but because of the potential for casualties, blood must be immediately available (on the shelf) at all medical units that could potentially treat casualties. Units supporting operations far forward, such as the Forward Surgical Teams, must accomplish resupply as often as every two to three weeks. This could expose medical personnel to hazardous conditions, as they may have to cross potentially hostile and dangerous areas to acquire fresh units. Increasing the shelf life from 42 to 70 days could reduce the blood requirement by half, decreasing hazards to deployed medical personnel, shipping costs, and donation requirements. The Armed Services Blood Program has provided over 16,000 units of red blood cells to Operation Enduring Freedom. Increasing the shelf life would significantly reduce this requirement.

Question 2: Dr. Fitzpatrick, in testimony from the American Association of Blood Banks and others, there is a discussion of a goal of a 7-day blood supply on the shelves—up from roughly a 2- or 3-day supply at present. You discuss a strategic

reserve in your testimony. Please describe how this relates to the domestic blood community's 7-day "supply on the shelf" goal? Which approach would be more cost-effective to achieve, in your opinion?

Answer: The goal of increasing the national blood supply from a 2- to 3-day level to a 7- to 10-day level and having a national blood reserve are not mutually exclusive. In fact, I believe one supports the other. The key differences are in the ability to rapidly mobilize and move a large number of units of blood to sites within the continental United States or to sites abroad in support of either civil or military needs.

One issue needing clarification is the definition of a 7- to 10-day supply. Neither the government nor the blood industry really knows what a 7- to 10-day supply is and have not agreed on a method to determine that number. Most hospitals maintain a 5- to 10-day supply, while the supply at the blood centers fluctuates from as low as 2 days to as high as 10, but this is not seen at the hospital level because hospital inventories can be maintained even when the collection centers have only a 2- to 3-day supply.

Increasing the national inventory to a 7- to 10-day supply provides a reasonable margin of safety for absorbing periods of decreased donations, but may not meet the need of creating a national reserve because the blood may not be near a civil or military airport and is under the control of the local donor center or hospital. Additionally, there is no process or system established to determine if the "reserve" should be mobilized. Procedures would need to be established to procure and move the blood units to the desired location. I believe the Inter-Organizational Task Force formed to address blood management in an emergency should address these issues and provide such a plan to Congress and Secretary Thompson. A key element of both solutions is a National Blood Donor recruitment effort supported by Congress and the Department of Health and Human Services.

AMERICAN RED CROSS
October 7, 2002

The Honorable JAMES C. GREENWOOD
Chairman
Subcommittee on Oversight & Investigations
2436 Rayburn House Office Building
Washington, DC 20515-3808

DEAR CHAIRMAN GREENWOOD: Provided below are the American Red Cross responses to your letter of September 20, 2002, requesting additional information following the September 10, 2002 hearing before the Energy and Commerce Subcommittee on Oversight and Investigations.

We are pleased to work with you and the Subcommittee on the important issues related to blood preparedness. Jan Lane, Vice President, Government Relations, is available to answer any questions or provide any additional information that may be needed. She can be reached at 202-639-3482.

Sincerely,

ALLAN S. ROSS
Vice President Technical Operations and Biomedical Services

cc: Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight & Investigations

Question # 1—Because screening for blood-borne diseases, donors have more questions to answer and the donation process takes more than an hour on average. Is the Red Cross taking any actions to make blood donation less complicated and less time consuming? For example, are donor questionnaires being automated? Is this a good idea?

Response: The Red Cross has been working with the American Association of Blood Banks (AABB) Uniform Donor Questionnaire Task Force to examine ways to validate questions posed to blood donors to determine accurate health histories. This effort will help ensure that the questions we ask our donors are clearly understood, elicit accurate responses, and provide information the blood banking community needs to ascertain whether the potential donor is eligible to donate. A validation of the donor history questionnaire has been completed and we believe implementation of this questionnaire will assist in minimizing the time involved in the donation process.

The blood banking community has also been urging the Food and Drug Administration (FDA) to consider approving Self-Administered Health Histories (SAHH) to expedite the donation process. SAHH allow donors to answer a series of questions

about their medical history without direct oral questioning by a blood bank staff member. Data presented at a recent Food and Drug Administration (FDA) Blood Products Advisory Committee (BPAC) meeting highlighted the accuracy of this method in eliciting truthful answers from potential donors. When approved by the FDA this process will decrease the amount of time need to donate blood.

Finally, the Red Cross is committed to automating the donor questionnaire process through our electronic Blood Donor Registration project. This project will allow donors to answer medical history questions through an electronic format. This process is expected to save time for the donor and reduce the potential for errors, market withdrawals and recalls.

Question #2—The GAO reports that blood collections have increased 21% between 1997 and 2001, and that collections for the first half of this year are on pace with the same period in 2001. Even with the recent donation shortfall this summer, these emerging data suggest collections, overall, have been on the upswing. Do you tend to agree with GAO's general findings with regard to donation trends? Why?

Response: Red Cross whole blood collections increased 18% between calendar years 1997 and 2001; however, 1997 was one of the lowest collection years on record. It is also important to note that while collections have increased, distributions to the hospitals we serve have increased at an even more rapid rate. In regard to collections, if comparisons are made between fiscal year 2000-2001 and fiscal year 1985-1986, when collections were fairly high, it becomes evident that the growth in collections has remained relatively flat (i.e., only a 3% growth rate over the entire period, or 0.2% annually).

Whole blood collections for the Red Cross from January 2002-August 2002 were at 4,309,220 units. This represents a decrease of 1% from the same time period in 2001. Because collections are unlikely to be as high in September and October 2002 as they were in 2001, our collections are expected to be 4% to 5% lower in calendar 2002 when compared to 2001. Provided below are the number of whole blood units collected by the Red Cross since FY 1986.

Red Cross Fiscal Year Collection History: 1985-86 $6,185,905; 1986-87 $6,422,788; 1987-88 $6,268,119; 1988-89 $6,264,622; 1989-90 $6,382,565; 1990-91 $6,091,984; 1991-92 $6,012,246; 1992-93 $5,848,743; 1993-94 $5,782,087; 1994-95 $5,743,861; 1995-96 $5,783,861; 1996-97 $5,626,689; 1997-98 $5,907,711; 1998-99 $6,107,330; 1999-00 $6,279,839; 2000-01 $6,377,292; 2001-02 $6,789,097; and 2002-03 $6,474,402 (goal).

Question # 3—Ms. Lipton's testimony raises a point about donor deferral policies affecting regions in different ways, due to demographics and so forth, and that federal policy makers must take this into account. Please explain how the Red Cross is working to respond to this issue. Is it going to provide a coordinated response to these safety and risk decisions?

Response: Ms. Lipton stated "...when making any blood related policies, including donor deferral policies, the federal government must carefully consider their potential impact on the blood supply, both national and regional. For epidemiologic and demographic reasons, different deferral policies may affect certain regions of the country more than others. If there is a blood supply problem in any part of the country, in any blood type, there is a shortage. Patient access to an available blood supply is clearly a safety issue as well as a public health priority."

Ms. Lipton stated that policy makers should be aware of the impact of deferrals locally and nationally, but we do not interpret her statement to convey that deferral policies should vary based on geography. Clearly any effect upon the adequacy of the blood supply must be taken into consideration when examining potential criteria to defer blood donors. However, if a deferral policy will increase safety or confidence in the blood supply, it should be implemented—even if this means that the blood banking community must intensify its donor recruitment initiatives to offset potential donor losses.

Historically, certain areas of the country are able to collect more blood than is used; the converse is also true. A number of factors contribute to this situation. For example, a larger proportion of the population in rural areas tend to donate blood as compared to more urban areas. However, the amount of blood transfused per capita in urban areas is significantly higher than in rural areas. This is not surprising in view of the fact that most major medical centers are located in metropolitan areas and many patients, even from rural areas, are treated in these centers for more complex medical situations. In general, donor deferral rates in various geographic areas only contribute marginally to differences in blood collections in varying parts of the country.

On September 5, 2002, at the U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood Safety and Availability (ACBSA), the Red Cross presented information on how we manage the blood supply among our 36

blood regions as a single system (see attachment 1 for a map of the areas of the country served by these regions). The Red Cross monitors blood inventory by all eight blood types in each region every day, along with projections for collections and usage in the coming weeks. Based on that information, projections of local inventories are made, and blood is shipped among the regions to equitably allocate blood throughout our system. Through this inventory management system, the Red Cross is able to respond to different donation and hospital usage rates to ensure blood is available wherever and whenever it is needed.

Question #4—Dr. Jones of the New York Blood Center states "the overall supply curve does not depict the type-specific donation problem experienced by all blood collectors." Are we measuring the wrong way? What is the Red Cross doing about this? The federal government?

Response: Dr. Jones of The New York Blood Center (NYBC) spoke about a recent trend of having to utilize Rh positive blood for certain Rh negative patients. This indicates an increasing shortage of Rh negative blood, which is essential for many Rh negative patients. The Red Cross has also experienced a greater difficulty in maintaining an adequate supply of group O blood, the universal donor blood type.

In leveraging our national presence to minimize the effect of shortages, the Red Cross uses our inventory management system to balance type-specific blood excesses and needs. The inventory in our 36 Blood Regions is monitored daily to determine where our inventory does not match the needs of the hospitals we serve. In these cases, excess blood in one Blood Region may be moved to another Blood Region to satisfy type-specific needs.

The Red Cross has also recognized the demographic changes occurring in our country and the importance of collecting blood from a more diverse donor population. To address this problem, there is an ongoing focus on collecting blood from group O individuals and other specific types to match our collections strategies with patient needs.

Question #5—What will a seven-day supply look like? Is it seven-day supply at each hospital, each blood collection center?

Response: The Red Cross uses a three-month rolling average of its gross total weekday distributions to determine its one-day supply level by blood type and blood region. This number fluctuates monthly as determined by the rolling average. The current one-day supply for the Red Cross system is 25,163 units of red blood cells. The seven-day supply level is currently 176,141 units of red blood cells. This quantity is a sum of all blood types in all regions.

The Red Cross inventory management plan is to maintain a seven-day supply level at each of its 36 blood regions. Hospital inventories are based on several factors, including but not limited to blood usage requirements, contingency planning, storage capacity, delivery schedules from the blood region, distance from the blood region, and type of healthcare facility (large metropolitan versus small rural). Hospital inventories normally range from one-day to fourteen-days, depending on the above factors.

The American Red Cross is pursuing a number of initiatives to enhance our collections efforts to support a 7 day inventory. We have recently completed significant market research to better understand the attitudes of the American public regarding blood donation. Our goal is to use the data collected from this survey to understand which segments of the population have a greater affinity to the Red Cross and blood donations; understand the marketing approaches that need to be taken to encourage donations; and, implement the tactics that need to be executed to ensure more frequent donations by current donors. In collaboration with the American Association of Blood Banks and Americas Blood Centers, the Red Cross is launching a campaign in Spring 2003 that will serve the dual purpose of helping improve our current collections and improve future inventories through a large scale public education and awareness campaign. Additionally the Red Cross is looking at several other initiatives including establishing national account relationships, co-branding with our partners both in the blood banking industry and with our partners in corporate America, and expanding our collegiate activities—all with the intent of boosting the blood supply in the country.

Question #6—Although there is public concern over wastage, and the industry recommendations to avoid this is the future, your testimony suggests a seven-day supply goal will increase wastage. Will this be significant? How does the Red Cross plan to address public concerns about increased wastage?

Response: Outdates are predominantly determined by two factors: the first factor is the balance between the blood types collected versus the blood types distributed. If there is a blood type imbalance (e.g., more group AB's are collected than distributed), outdates of a particular blood type may increase because of a lack of demand. The Red Cross and others are attempting to address this situation by automating

collection processes, which will enable us to collect only the blood component we need from certain blood group donors. Full implementation of this type of technology will take years to implement because of cost and space issues.

The second major factor that can result in outdates is the shelf life of red cells (42 days). Red cell units are distributed to hospitals everyday where they are either transfused or remain at the hospital for inventory purposes. In some cases, the red cell unit is returned back to the blood region and attempts are made to transfer the unit to a hospital that has a greater demand. The amount of time remaining on the unit when it is returned is a determining factor as to whether or not the unit will be used. The shorter the expiration date, the greater the possibility the red cell unit will not be used. Blood regions work very closely with hospitals to balance the on-hand hospital requirements and the dating of the hospital inventory to minimize outdating of blood products.

There is a cost to blood preparedness that must be recognized. Despite our best efforts, there will continue to be a certain percentage of units that will outdate before they can be transfused. Currently, between 1 to 2 percent of blood products nationwide expire before a hospital can transfuse them. This minimal outdating means that the system is functioning properly. If there was no outdating of blood products, the result would be cancellations of surgeries and blood not being available during emergencies.

As the inventory is increased to 7 days to meet increased demand, the number of units outdating will correspondingly increase. The Red Cross and our blood banking colleagues are careful stewards of the units voluntarily donated to us by altruistic individuals. The goal is to achieve a seven-day inventory level while maintaining a balance between blood types collected versus blood types used.

Question #7—Does the Red Cross believe the nvCJD (Mad Cow disease) restrictions should be relaxed?

Response: The Red Cross believes the current deferral criteria should not be changed. We formally review our donor deferral practices annually and specifically consider our practices regarding vCJD during this review. Notwithstanding the fact that our deferral practices and criteria may require more effort to recruit suitable/qualified donors, our intentionally methodical and conservative approach gives us better assurances that we are providing the safest blood to the patients we serve. We will continue to reevaluate our current deferral practices to ensure a safe and available blood supply.

Question #8—If there were another emergency such as September 11th, would the Red Cross urge people to donate even if there was enough blood on the shelf so that the blood could be used for the strategic blood reserve?

Response: The Red Cross is committed to working with the AABB Inter-organizational Task Force and The Department of HHS on consistent public messaging on the need for blood donations during natural and man-made disasters. This Task Force will provide an effective means for the blood banking organizations and federal government officials responsible for disaster preparedness and public health to coordinate efforts before and after disaster strikes. Through the Task Force, the entire blood banking and public health officials will have an effective means of assessing the need for blood donations following a mass casualty event, coordinating public messaging of the need for blood donations, and the transportation of blood components where needed.

Question #9—On August 22, 2002, CBS News aired a report featuring Joe Szaller, a former mobile medical team manager at the Red Cross Chesapeake regional blood center. According to Mr. Szaller, blood was routinely collected without the required pre-check. He also said that Red Cross employees were put on bloodmobiles without the mandatory safety training and weren't asking donors the right screening questions to identify if they were high-risk donors. CBS News reported that a recent FDA inspection found a long list of safety violations at this blood center, including many of the same ones Szaller complained about. The Red Cross claimed that it was not given a full and fair opportunity to respond to the CBS report. Does the Red Cross want to respond to this report? What actions is the Red Cross taking to improve compliance at its facilities?

A. Background to Mr. Szaller's Employment

The CBS report discussed a Hotline call that Mr. Szaller had made before the Red Cross suspended and terminated him for mismanagement. On February 22, 2001, Mr. Szaller placed an *anonymous* call to the Red Cross Hotline and reported a variety of perceived regulatory violations.

The Hotline service forwarded this information to the Office of General Counsel on the same day for investigation. The Red Cross maintained the strict confidentiality of this information at all times. Only the Office of General Counsel, the In-

vestigator and personnel essential to the investigation were made aware of the anonymous call. Importantly, all Hotline calls are strictly administered by the Office of General Counsel. The Region completed its investigation of the case on February 23, 2001, and returned its findings on March 2, 2001. A response was properly filed with the Hotline service on March 30, 2001.

The CBS report stated that the Red Cross fired Mr. Szaller for mismanagement, despite stellar job reviews and commendations. Mr. Szaller was employed as a Team Manager in the collections department from March 30, 1998 to March 1, 2001. However, Mr. Szaller's employment at the Red Cross was not without incident. On February 20, 2001, his supervisor received a request from members of Mr. Szaller's team (all female) to have a private meeting to discuss their concerns about Mr. Szaller's work conduct. Mr. Szaller's supervisor notified Human Resources of the request by memo dated February 22, 2001. At the meeting, they conveyed their concern over his demeaning and overbearing behavior as their manager, alleging that he regularly misrepresented information, and generally created a very uncomfortable work environment. The Red Cross does not tolerate this type of behavior from personnel, and certainly not from its managers.

On February 23, 2001, Mr. Szaller was suspended based on the investigation into the complaints made by his staff. Those who made the decision to suspend Mr. Szaller were never made aware of his anonymous Hotline call the previous day and, therefore, there is no connection between Mr. Szaller's call to the Hotline and the personnel decisions that were made regarding Mr. Szaller.

On March 1, 2001, Mr. Szaller's supervisor and a human resources representative interviewed Mr. Szaller and some of his colleagues. Mr. Szaller was terminated by letter dated March 6, 2001, based on the complaints made by his staff regarding his unacceptable behavior.

B. Mr. Szaller's Allegations

Blood collected without the required pre-check

Before every donation, the Red Cross carefully screens donors for eligibility in several ways. If the donor can present his or her Social Security Number (SSN) on the day of donation, the Red Cross may use a pre-check device that includes computerized information about ineligible donors based on their SSN. The pre-check device may indicate that the donor is ineligible for a variety of reasons, such as the donor has given blood during the last 56 days, which is the required waiting period between donations, or has tested positive for a viral marker.

If the Red Cross determines that a donor is eligible using the pre-check device, or if eligibility cannot be determined because the donor does not provide an SSN, the donor is given a health history questionnaire, called the Blood Donation Record ("BDR") and is interviewed by a health historian. Based on the responses provided by the donor, the health historian determines if the donor may proceed to a physical health assessment. If the Red Cross permits a donor to proceed to this assessment, Red Cross staff evaluates the physical health of the donor using vital signs, the BDR, and an overall impression of the donor.

If the Red Cross permits a donation, it takes the donated unit of blood, the information about the donor from the BDR, and sample test tubes from the unit o blood, and creates three separate, parallel processing tracks. On one track, the unit of blood is taken to a manufacturing area. On the second track, information from the BDR is entered into a national computer system to create an electronic donation record. On the third track, the sample test tubes are shipped to a national testing laboratory. The Red Cross will not label or distribute a unit of blood until the information from the BDR and the test results are entered into the system and are acceptable.

It is important to note that the pre-check device is not the only means of determining donor eligibility. However, all donors must successfully proceed through the eligibility determination and health assessment process before the Red Cross permits them to donate. Accordingly, there are donors that are allowed to donate blood because their eligibility was determined, not solely by the use of the pre-check device, but rather, through the BDR, health history interview, and physical health assessment process.

Red Cross employees put on bloodmobiles without mandatory safety training

Mr. Szaller alleged that Red Cross employees were placed on bloodmobiles without safety training. The Red Cross has always taken steps to ensure that donor suitability policies and procedures described above are followed, including training and supervisory reinforcement.

The Red Cross is committed to ensuring the health and safety of its employees. Staff are trained according to FDA regulations and to ensure they can successfully

perform their jobs. This training must be complete and documented before they are released to perform their functions. The Red Cross commitment to safety is also exemplified by the implementation of applicable Occupational Safety and Health Administration (OSHA) regulations, offering training programs in both OSHA and Department of Transportation (DOT) requirements, developing an annual national Red Cross safety meeting and, finally, by creating a Safety and Environment Division within Biomedical Services. The Safety and Environment Division staff act as internal consultants providing guidance to Red Cross facilities on various OSHA, DOT and EPA issues. With regard to meeting OSHA bloodborne pathogen requirements, staff who may have a potential for exposure to blood or other potentially infectious materials through their job functions are fully trained in universal precautions and the use of personal protective equipment. In addition, these staff are offered the hepatitis B vaccination series in accordance with OSHA regulations.

Red Cross employees not asking donors screening questions to identify high risk donors

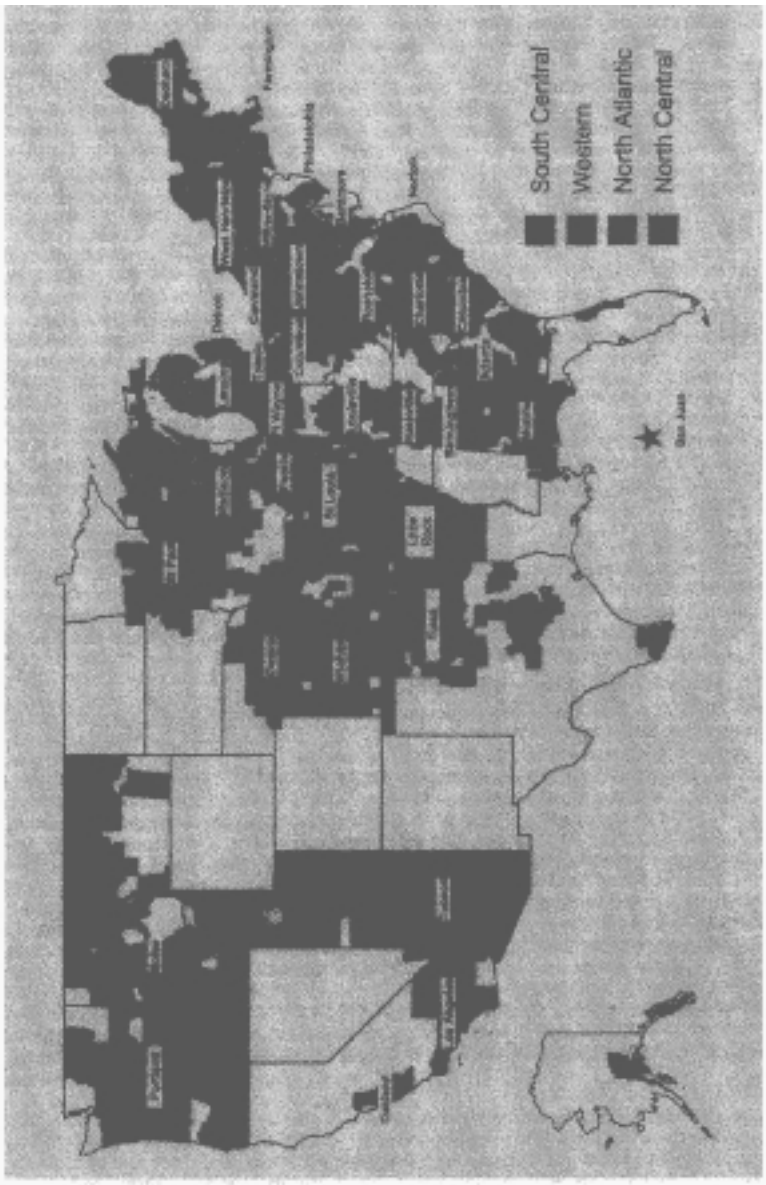
There was also a concern expressed in the CBS report that Red Cross personnel were not asking the appropriate screening questions to identify "high-risk" donors. As explained above, during the donor eligibility determination process, the Red Cross manually creates and reviews a BDR for each blood donor. The BDR provides the primary means of recording and tracking donor suitability and consists of demographic information, physical findings relating to the donor, and a completed health history questionnaire.

The health history section of the BDR is a series of yes/no questions that serve as the initial screening mechanism for purposes of determining donor suitability. The current FDA-approved questions regarding donor suitability are clearly printed on the BDR. Accordingly, whether the donor completes the BDR, or if Red Cross personnel assist the donor in completing the BDR, the appropriate donor suitability questions are presented to the donor. The Red Cross is moving with the rest of the industry toward adopting the new Uniform Donor Questionnaire. These new questions and format were developed by leaders in the blood industry, including the Red Cross and the government, to ensure questions that are being asked are validated and elicit accurate responses from the potential donor.

C. Improving Compliance and Upgrade Investments

Since 1992, the Red Cross has invested millions of dollars into improvements and upgrades. The Red Cross invested approximately $191 million to standardize processes and procedures, to train 12,000 field personnel, and to implement a new infrastructure. The Red Cross also implemented a National Blood Computer System (NBCS) and created a Quality Assurance function. The Red Cross has invested more than $290 million to improve quality. In moving the organization toward a more national system in order to improve the effectiveness of it's operations and to ensure every region nationwide complied with all regulations, the Red Cross consolidated the National Testing System from 50 sub-scale regional laboratories to 9 state-of-the-art standardized testing laboratories.

The Red Cross is focused on improving quality now and in the future. We intend to augment our improvements even further by increasing our Capital Improvement Program's annual operating expenses during the next five years. In addition, the Red Cross plans to upgrade and restructure its Information Technology by enhancing the computing technology platform to allow deployment of new application components and integration with the NBCS applications. We also plan investments to construct new processing facilities and to invest in supply chain infrastructure.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