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BLOOD SAFETY AND AVAILABILITY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

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BLOOD SAFETY AND AVAILABILITY

THURSDAY, SEPTEMBER 23, 1999

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

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Fred Upton (chairman) presiding.

Members present: Representatives Upton, Cox, Bilbray, Ganske, Bryant and Strickland.

Staff present: Alan Slobodin, majority counsel; Anthony, Habib, legislative clerk; Chris Knauer, minority counsel; and Brendan Kelsay, minority clerk.

Mr. UPTON. Good morning, everyone. I apologize in advance for my cold, my bad ears.

This morning the subcommittee holds the first of three oversight hearings on the safety and availability of the U.S. blood supply. The issue of the blood supply is not a remote one to any of us. Every 3 seconds, a person needs blood. Michigan hospitals, as one example, use a pint of blood every 43 seconds. According to one estimate, 95 percent of us will need a blood transfusion by the time we're 75. And we expect the blood to be there and for it to be safe.

Recently, we have seen some anecdotal reports about blood shortages during certain times of the year in some areas of the country. We have heard about elective surgeries postponed because of blood shortages and increased risks to patients who may have an immediate need for a transfusion. In one example last year, one third of the 38 American Red Cross blood regions were down to only a day's supply of type O blood and nine regions were on emergency appeal, meaning they had less than 1 day's supply of type O blood. In another example, this past winter about half of all U.S. blood banks had less than a day's supply.

In looking at the long-term trend, an internal memo dated July 2 of this year from the NIH noted, "A gradual decline has occurred in blood donation by the U.S. general population over the past 10 years."

Another internal NIH memorandum dated August 6, 1999, states, "There is an immediate need to monitor the blood supply for adequacy. The time is approaching when supply will become a safety issue."

I ask unanimous consent that both of these memoranda be inserted in the record in their entirety.

[The information referred to follows:]

TO: Ruth Kirschstein, M.D., Deputy Director, NIH
FROM: Director, NHLBI
SUBJECT: Monitoring the US Blood Supply

In following up to Dr. Sachter's memorandum of July 22, the NHLBI concur with the importance assigned to monitoring the adequacy of the US blood supply, especially in view of the imminent deferral of potential donors who have spent time in the United Kingdom.

The Institute is prepared to respond by arranging for monthly data collection from a sample of blood collection centers, with analysis focusing on trends and possible seasonal shortages. If Feasible, data will also be collected from transfusion services, emphasizing the detection of shortages, if they occur, and their adverse effects, if any, on patient care. The mechanisms by which this data collection will be supported are under review, but the cost seems unlikely to exceed $300,000 annually and may be somewhat less.

Other PHS Agencies and parts of the private sector will be involved to ensure that the data meet the needs of the government and of the blood collectors and that there is a smooth transition between procedures used to satisfy immediate requirements and a long term solution to providing necessary blood data.

CLAUD LENFANT, M.D.

cc:
Dr. Alving
Dr. McCurdy

DEPARTMENT OF HEALTH & HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

MEMORANDUM

Date: August 6, 1999
From: George J. Nemo, Ph.D.
Paul R. McCurdy, M.D.
Subject: Blood Data
To: Director, NHLBI
Through: Director, DBDR

The PHS has an immediate need to monitor the nation's blood supply for adequacy. This action is necessary to determine the effect of deferring blood donors who have spent an aggregate of 6 or more months in the UK between 1980 and 1996. This deferral policy will be activated by an FDA Guidance document which is expected to be released by the end of August. Other safety-related initiatives such as the recent introduction of nucleotide amplification technology (NAT testing) are also likely to have an adverse effect on supply, while improving safety. The time is approaching when supply will become a safety issue.

The NHLBI has long been aware of the limitations on information about the collection and transfusion of blood. The Institute supported the data system of the American Blood Commission (ABC) in the late 70s, but with drew that support because the ABC tried to accomplish too much and failed to provide useful data in a timely fashion. One of the NHLBI SCOR programs in Transfusion Medicine provided considerable information for over a decade on the collection and use of blood in the U.S. These data were not obtained frequently enough, however, for decision-making purposes. The Institute also sponsored a workshop on blood data in 1989, but its recommendations were never implemented.

To be most helpful, data to be collected must be carefully determined and examined in the light of detecting seasonal and other changes in supply and demand for blood and its components. Thus, setting up data collection and analysis is a research activity and well within the purview of the NHLBI. It is anticipated that in the future, most likely in FY2002, the data system will be established to be contracted for management by another agency as a service (e.g., CDC).

Hence, it is recommended that the NHLBI support through appropriate mechanisms blood data collection and analysis to evaluate ways of accomplishing this activity and to support necessary initiatives to improve blood safety while maintaining an adequate supply.

Attached is a note addressing several issues relating to blood data collection and analysis and a plan for the Institute to obtain blood data on a timely basis.

cc: Ruth Kirschstein, M.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

August 3, 1999

TO: Assistant Secretary for Health and Surgeon General
FROM: Deputy Director, National Institutes of Health
SUBJECT: Procedures to Monitor the Blood Supply

Dr. Varmus has asked me to respond to your memorandum of July 21. Following the meeting of the Blood Safety Committee on June 8, at which there was much discussion about the likely reductions in the number of blood donations in the United States, I met with Dr. Claude Lenfant, Director, National Heart, Lung, and Blood Institute (NHLBI) , the staff of its Division of Blood Diseases and Resources and Dr. Paul McCurdy, a consultant to Dr. Lenfant and to me. The following plan is the result of those discussions:

The plan consists of six discrete activities, three of which, currently supported by NHLBI, will be continued and three proposed new ones which can be implemented after approval by the National Advisory Council of the Institute. Descriptions of the research plan are attached.

The current expenditures for FY1999 for the ongoing projects, #1, 2, and 6 and the total proposed for FY2000 are:

	FY99	FY2000
#1 and 2	$1,137,500	$500,000
#6	$180,000	Not determined as yet

The new projects, #3, 4, and 5, if approved by the Council, will start in fiscal year 2000 and are projected to be:

FY00	$1,638,347
FY01	$1,638,347
FY02	$1,165,786

As these studies progress, and in some cases, start, NIH will work with your office and the Blood Safety Committee to assess the need for, and types of studies, to be planned regarding blood donations.

RUTH L. KIRSCHSTEIN, M.D.

Attachment

July 2, 1999

NHLBI RESEARCH PLAN TO INCREASE THE U.S. BLOOD SUPPLY

With demand for blood increasing and supply decreasing, the AABB National Blood Data Resource Center estimates that overall demand will exceed supply in the year 2000. The recent decision of the U.S. Public Health Service to recommend deferral of donors who have visited and/or resided in the United Kingdom and the Republic of Ireland for a cumulative period of six months or greater between 1980 and 1996 will likely contribute to this problem.

Understanding why people donate blood is paramount to insuring the adequacy and safety of the blood supply. The National Heart, Lung, and Blood Institute (NHLBI) through its Retrovirus Epidemiology Donor Study (REDS) plans to conduct a survey of donor motivations. Furthermore, the Institute plans to evaluate the use, effectiveness, and safety of blood donation incentives. A study is also being developed to determine the feasibility of increasing the frequency of donations in repeat blood donors by one donation per year. A longitudinal study is being planned on the recruitment and retention of blood donors. Another project is being planned to determine the feasibility and cost effectiveness of using double red blood cell collection by apheresis as a means of increase red cell donations. The Institute is also supporting a study that is evaluating a computer-assisted interactive video donor screening system. Brief descriptions of these studies follow.

1) Evaluation of the Impact of Recruitment Strategies on Blood Donation Behavior

Extensive literature exists on ways to recruit blood donors. However, few attempts have been made to study the real-time interactions of blood centers with their donors on a large scale, or to conduct controlled experiments to determine the positive and negative impact of specific recruitment programs, especially those offering various forms of incentives. The primary goal of this study is to produce measurable

improvement in donor recruitment efficiency as measured by new and repeat donation behaviors in those subgroups, while monitoring any major changes in deferrable risk.

In Phase I of the study, REDS will interact closely with a small group of mobile blood collection units for approximately 6 months. The recruitment strategies used for donors at a sample of these mobile units such as telerecruiting, direct mailing, and media appeals will be documented and donor responses to these recruitment strategies will be measured. A combination of mail and on-site survey techniques will be used to measure prevalence of deferrable risk and, donor attitudes and responses to recruitment practices.

Based upon data derived from previous REDS Donor surveys and available data from Phase I, four REDS blood centers will implement and evaluate experimental incentive programs in Phase II of the study. In this phase, specific incentives and promotional strategies such as cholesterol testing, gifts, or time off from work will be provided to the same mobile units, with the goal of measuring the positive and negative impact of these specific interventions. Prevalence of deferrable risk and recruitment efficiency among sites that implemented new incentives programs will then be measured and compared to similar data obtained in Phase I before implementation of the incentives. The survey instruments for this study are being developed. It is anticipated that the documents will be submitted to the office of Management and Budget (OMB) in October 1999 and the study initiated in January 2000.

2) Study of donor Motivations

Little appears to be known about what motivates some people to become regular blood donors, or why only about 39 percent of first-time donors return. Adequate information pertaining to donor motivation in various ethnic groups is also lacking; data which would be valuable for minority recruitment efforts. With the current difficulties in maintaining an adequate blood supply, it is important to discern the reasons behind people's decisions to donate, so that better recruitment strategies can be formulated.

The REDS group is in the process of developing a donor survey to examine motivational factors. The survey will be conducted at all five REDS blood centers at both fixed and mobile recruitment sites. Donors will be presented with a questionnaire to be completed during the donation process. Previous REDS donor surveys have yielded low response rates from certain groups of donors, such as first timers, minorities, and the young. It is thought that using the approach of surveying donors while they are still at the center will increase response rates for these groups and be of minimal cost.

Approximately 37,000 donors will be surveyed over a 6-month period at the five REDS centers. The survey will be identity-linked to enable follow-up of donors in the REDS donation database. This will permit REDS investigators to compare actual donation behaviors to stated intent. Questions pertaining to motivational factors and demographic data will be collected. Blood centers will also track incentive use and recruitment techniques at both mobile and fixed sites to permit evaluation of the association between actual exposure to incentives and reported donor motivational factors. The survey document is currently being developed and will be submitted to the OMB in October 1999. The study is scheduled to begin January 2000.

3) Study to Increase Blood Donations

A study is being planned within REDS to increase the frequency of blood donations in repeat blood donors by one donation per year. For many years, data have repeatedly shown that most blood donors give but once a year (50-70%, most recent REDS data). If a second blood donation is given within 1-2 years of the first, the individual is more likely to become a "regular donor," defined as one who gives every 1-2 years for several years. It is hypothesized that arranging for donors who give 1-2 times yearly to donate blood once more per year is feasible and will increase the blood supply and eliminate shortages.

The study would be conducted in two or more REDS blood centers. For a sample of a blood center's fixed and mobile sites, arrangements would be made for each donor, while resting in the canteen after donating, to make an appointment for the next donation (after 3-6 months). A reminder (card and/or call) will be sent before the appointment. Control sites will have no such appointment plans. Endpoints would be the number of donations at the test sites with an appointment system, compared with those sites who use current procedures. This study will be conducted at two REDS blood centers and is scheduled to be completed in two years.

4) Study on the Recruitment and Retention of Blood Donors

A gradual decline has occurred in blood donation by the U.S. general population over the past ten years. As a result, recruitment and retention of donors is a top

priority for virtually all of the nation's blood collectors and each blood center now spends an increasingly large proportion of their overall resources to maintain the current supply.

What appears to be missing from this intense recruitment activity is a structured approach to understanding the reasons why sub-populations of donors appear for donation the first time, and why they appear for return donations with varying levels of frequency. When stratified by demographic subgroups, improved understanding of these factors should help to inform the design of experimental studies and demonstration projects related to recruitment and retention and allow rapid transfer of information to the field.

At the five REDS centers and three additional blood centers (chosen to represent the overall U.S. population), a representative sample of approximately 25,000 active donors will be invited to participate in a linked study of blood donation patterns. The follow-up of each donor will last for two years. Two weeks following enrollment and at six month intervals thereafter, mail surveys will be sent to study participants to gather information about donation experiences, blood donation recruitment exposures (ads, telephone calls, sponsored donations, incentive offerings, etc.), reactions to these exposures, rationale for becoming a donor in the first place and actual or intended post-enrollment donation.

A subset of this study will involve the over sampling (an additional 10,000) of college-age donors to participate in a similar, but more targeted version of this study. Surveys distributed to this subset of donors will include questions about donations made during high school, donation patterns of their parents, how they were first introduced to the donation experience, and what types of opportunities, fed back, or appeals will encourage them to become lifetime donors.

5) Feasibility of Increasing Red Cell Donations using Apheresis Procedures

This project will study the use of double red blood cell (2RBC) collection by apheresis as a means to increase red cell donations. The 2 RBC procedure collects the equivalent of two whole blood derived packed RBC units from one donor in a single procedure. Donors who give typically only once or twice a year, if recruited to give 2RBC donations would effectively double their donations. This would be of particular value for Rh negative donors and those with blood types always needed such as group O.

Practical limitations have existed in the length of time required for 2RBC donations (35-40 min.), donor size and hematrocrit requirements, and relative cost of the procedure. The costs of disposable collection equipment, however, have begun to decline. The purpose of this project would be to demonstrate the feasibility of converting whole blood donors to 2RBC donors, and that this conversion can be performed in an economically feasible manner. This project will be conducted at two blood centers and is scheduled to be completed within two years.

6) Computer-assisted Interactive Video Donor Screening

The Institute is supporting a grant program to develop an interactive, multimedia video blood and plasma donor health history system; and to evaluate its acceptance and feasibility in operational settings. The principal aims of the program are to improve overall operational systems for screening donors and collecting blood and plasma; and to improve the safety of blood and plasma supplies. these aims will be evaluated in two stages. In the initial stage, the interactive video screening software will have no decision logic and the nursing staff will determine donor suitability from the printed output of the screening system. In the final stage, it is planned to integrate the interactive video donor screening system into the data management system of the donor center resulting in a "paperless" health history assessment.

Mr. UPTON. We have become concerned, as have the blood banking community and public health experts, about the apparent tightening of the blood supply. There seem to be several factors that are contributing to this trend of an apparent tightening of our blood supply: A growing population over 65 that will need more operations and thus more blood transfusions, younger generations donating at lower rates than the past generations, and improved screening and testing, to name just a few.

Officials in both the blood banking community and the government have raised concerns about these trends. In response to these concerns, Chairman Bliley asked the GAO to conduct an assessment of the availability of the U.S. blood supply. We look forward

to hearing the GAO's testimony on the supply and the demand trends.

We're also pleased to have two experts, Marian Sullivan of the National Blood Data Resource Center and Dr. James AuBuchon, of the Dartmouth-Hitchcock Medical Center, who will also discuss the matter.

At the same time concerns have been raised about the blood shortages and the trends in the blood supply, a new Federal policy will further decrease that blood supply. Last month, the FDA issued a new policy that requires that individuals who spent a total of 6 months or more in the United Kingdom between 1980 and the end of 1996 be prohibited from donating blood because of concerns over theoretical risk of spreading a new variant of CJD, Creutzfeldt-Jakob Disease, or the human form of the mad cow disease.

This new donor exclusion policy was taken as a precaution since little is known about this new variant of mad cow disease, how it is transmitted, what the incubation period is and whether it is transmissible through blood transfusions. However, the new policy has been estimated to reduce the blood supply by 2.2 percent.

Chairman Bliley asked the GAO to analyze this policy and the expected loss to the blood supply. The GAO will be testifying on this new policy.

To alleviate blood shortages and especially to offset the expected loss to the blood supply, the Department of HHS asked the FDA and HCFA to identify a strategy to increase the blood supply by easing restrictions on the distribution of blood collected from hemochromatosis patients. This is an iron overload disorder that is genetic and not a transmissible disease.

These patients are not less safe donors because of their disease. However, because of their disease, these patients require blood removal as therapy and most patients are charged for the removal. A concern is that a financial incentive to donate at no cost, rather than having blood removed therapeutically, might cause the donor to be less truthful about acknowledging risk behaviors.

Ways are being considered to remove financial incentives for these patients. Chairman Bliley again asked the GAO to evaluate the potential impact of a change in policy to allow units of blood collected from these patients to be distributed. The GAO's testimony before us today will cover this area as well.

We're also pleased to hear the testimony from the Inspector General at HHS concerning error and accident reports. In May 1995, the IG issued a report that concluded the FDA could improve the safety of the blood supply by doing a better job of collecting data on errors and accidents made by hospitals and blood banks.

The audit found that the FDA was not insisting that hospitals and blood banks submit error reports in a timely fashion and that FDA does not get these reports at all from unlicensed facilities that handle about 10 percent of the blood used in the U.S. In contrast, blood centers that account for about 80 percent of the blood supply are covered by consent decrees that are required to submit error and accident reports within 30 days.

The IG recommended that the FDA expedite regulations that would be more specific about the timeframe in which reports are

required to be submitted and that would require unlicensed blood establishments to submit their reports. The IG will be testifying on the status of the implementation of these recommendations.

Today we lay a foundation for oversight efforts. In future hearings, we will have witnesses from the Department of HHS, as well as the FDA and from the blood banking community.

I was a member of this subcommittee in the early 1990's when we investigated the contamination of blood supply with the AIDS virus. Since that time, a number of measures have been taken by the government and the blood banks to provide greater assurance of safety.

They have also been technological advances such as nucleic acid testing and viral inactivation that could make the blood supply even safer. This subcommittee will continue to oversee blood safety vigorously, with a watchful eye on availability.

I look forward to working with my colleagues on this subcommittee, the administration, the blood banking community, the public health and medical communities, and especially the patients who receive blood transfusions, to provide absolutely the strongest assurance possible for the safety and availability of the Nation's blood supply.

And I yield to my friend from Ohio, Mr. Strickland, for an opening statement.

Mr. STRICKLAND. Thank you.

I thank you, Mr. Chairman; and I want to thank you for holding these hearings. This is an important issue. It could potentially affect every American citizen. And it is proper that we hold these hearings to find out what we, as a Congress, need to do or can do to make sure that our Nation's blood supply is adequate and safe; and I look forward to hearing from the witnesses. Thank you.

Mr. UPTON. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman.

I want to welcome all of those in the audience, including our panel of witnesses. I have reviewed the qualifications and certainly we have a very distinguished panel who are competent to testify about the issues that are before us today, which has been said already twice this morning, this is a very important issue for this country.

I must apologize that sometimes we have overlapping schedules, and I will be in and out today. We are downstairs marking up a bill in another subcommittee on the Commerce Committee, on which I serve as well, and on the floor with a bill that has to do with class action litigation, something that is very near and dear to my heart, and I will have a role in that.

So all that to tell you I must leave after making the statement. But I will try and get back and hear some of the testimony. I would like to be available to ask some questions.

I know there are issues out there, and there appears to be some conflict among our witnesses as to the adequacy—the state of our current Nation's blood supply, the effect on the new FDA policy regarding transfusions—or not transfusions, but obtaining blood from people who have been to England, and the reporting requirements, all important matters that I'm sure this panel will discuss in detail.

But, again, I must apologize for missing this. I will have the opportunity to review your testimony if I should miss it. And I want to especially thank the chairman of the Oversight Subcommittee, Mr. Upton, for his foresight in having this hearing.

I mentioned to someone this morning as I came up, it's about blood safety, but you don't think too much about that until you, yourself, or someone in your family needs that blood, and then you say I hope that blood is safe, and I trust that blood is safe.

But it's good to have this hearing, and I appreciate, Mr. Chairman, you for calling this. And I yield back my time.

Mr. UPTON. Thank you.

Mr. Cox.

Mr. COX. Thank you, Mr. Chairman.

The FDA has told us—in fact, Commissioner Jane Henney—that blood safety is one of FDA's top priorities; and today the purpose of our oversight hearing is to ensure that is and remains the case.

Four years ago, the Office of Inspector General at the Department of Health and Human Services completed a study and report that recommended the FDA expand its use of error and accident information; and, at the same time, the Public Health Service, which is FDA's oversight agency, agreed with that recommendation and told Congress that there would be a proposed rule issued by February 1996. But 1½ years later, there still had not been a proposed rule issued.

Finally, in September 1997, that proposed rule was issued, but we are told now that a rule in final form is going to be postponed until sometime in 2001. And because we wish this to be a top priority, not a secondary priority, of FDA, we are concerned that the reason given by FDA for delay of its final rule is "because of multiple public-health-related priorities of the agency". In other words, this isn't a top priority. That's the way I understand FDA's statement.

I'm sure we will be told today that it is and remains a top priority, but we will have to look to results rather than rhetoric. Error and accident reports are the basis for FDA's oversight of the blood industry. Some 13,000 reports were filed last year, but there is indication that they are still not on an overall systemic basis being provided promptly. Furthermore, those establishments that do not shift blood interstate—and thus are not subject to the licensing regime—are not on a continuing basis, as was identified some 4 years ago, submitting reports that provide data to FDA for its oversight of the blood supply.

And when 10 percent of the blood supply is missing from this equation, it raises obvious concerns of the establishments that are unlicensed. Representing about 10 percent of the supply, they accounted for only 1 percent of the report. So either the situation with these establishments is completely different than with all of the licensed establishments or we are simply not getting the information from them, which is more likely the case.

So today's hearing is properly focused on what FDA is doing now and, even more importantly, what they're going to do tomorrow morning; and I think this panel of four is especially well-suited to address those questions.

And I thank the chairman for scheduling the hearing.

Mr. UPTON. Thank you, Mr. Cox.

At this point it's been noted we have a number of subcommittee meetings this morning, and I would ask that all members of this subcommittee under unanimous consent request be allowed to offer as part of the record any opening statement that they may have.

At this point, without objection, so ordered.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

Mr. Chairman, thank you for these hearings concerning the safety and availability of the Nation's blood supply. Last June, I asked the General Accounting Office (GAO) to conduct an assessment about the blood supply. I specifically asked the GAO to provide: (1) information on recent trends in blood supply and demand, (2) the expected impact on the blood supply by a new ban on donors who have traveled to the United Kingdom, and (3) the potential impact on the blood supply from a change in policy to make it easier to distribute units of blood collected from patients with an iron overload disorder. I appreciate the GAO's work and believe the GAO's findings will provide a sound foundation for this Subcommittee to investigate in a careful, fair, and balanced manner. In addition, the Office of Inspector General (IG) at HHS, will report to the Subcommittee on the status of FDA's implementation of the IG's recommendations concerning certain blood safety reports.

However, today's hearings about blood, and the hearings to come, mean more to me than just facts and figures. It's about people's lives. It's about a young married couple, Bruce and Kristina Wenger, of Hanover, Virginia, who were the first unrelated partial liver transplant case in the United States.

Four years ago, Bruce was diagnosed with a rare liver disease. By the beginning of 1998, Bruce was about to die from this disease and would have left his young wife and infant son. But his wife, Kristina, volunteered to donate part of her liver. Tests showed her liver was compatible. On Valentine's Day 1998, 60 percent of Kristina's liver was removed and transplanted into Bruce. The transplant team was led by Dr. Robert Fisher, director of the liver transplant program at Virginia Commonwealth University's Medical College of Virginia.

During the operation Bruce received five pints of packed red cells. Kristina didn't receive any blood products: Her own blood was recycled. According to the blood bank at the Medical College of Virginia, partial liver recipients use an average of 40 blood products, including red cells, fresh frozen plasma and platelets.

Bruce is now back at work part time as an estimator for a homebuilder. Kristina is a Captain in the Marine Corps Reserves and a full-time mom. Bruce was kept alive for his son, Bruce Jr. And I am delighted to report that last week the Wengers had their second child. The transplant, and the blood transfusion that made it possible, were gifts of life and love.

Throughout the years, hundreds of thousands of people in my district like Bruce have needed blood during operations. The good news is that the blood supply has never been safer, with more advances coming to improve blood safety. But blood still has risks. We still must be vigilant on safety. However, the greater challenge now appears to be on the supply side. Our task is to ensure that the blood is there and that the blood is safe.

As we learn more about blood, and look at ways to improve the quantity and quality of the blood supply, my thoughts will be with the people. People like Bruce and Kristina Wenger.

Mr. UPTON. At this point, we would like the witnesses to come forward: Janet Heinrich, Associate Director of Health Financing and Public Health Issues at GAO; Thomas Roslewicz, Deputy Inspector General for Audit Services at the Department of Health and Human Services; Marian Sullivan, Executive Director of the National Blood Data Resource Center; and James AuBuchon, Professor of Pathology and Medicine at Dartmouth-Hitchcock Medical Center.

As you all know, this is a subcommittee where we take testimony under oath. Do you have any objection to that?

[Witnesses sworn.]

Mr. UPTON. You're under oath and you may have a seat. Your statement will be made part of the record in its entirety. We would like, if we can, to limit your statement or your opening to 5 minutes or so.

Dr. Heinrich, we will start with you. Thank you for coming.

TESTIMONY OF JANET HEINRICH, ASSOCIATE DIRECTOR, HEALTH, EDUCATION AND HUMAN SERVICE DIVISION, GENERAL ACCOUNTING OFFICE; THOMAS D. ROSLEWICZ, DEPUTY INSPECTOR GENERAL FOR AUDIT SERVICES, ACCOMPANIED BY JOSEPH GREEN, ASSISTANT INSPECTOR GENERAL FOR AUDITS, PUBLIC HEALTH SERVICE AUDIT DIVISION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; MARIAN T. SULLIVAN, EXECUTIVE DIRECTOR, NATIONAL BLOOD DATA RESOURCE CENTER; AND JAMES P. AUBUCHON, PROFESSOR OF PATHOLOGY AND MEDICINE, DARTMOUTH-HITCHCOCK MEDICAL CENTER

Ms. HEINRICH. Thank you very much.

Mr. Chairman and members of the committee, I am pleased to be here today as you discuss the availability——

Mr. UPTON. If you could just move the mike just a little closer. Thank you.

Ms. HEINRICH. As you discuss the availability of blood to meet the Nation's requirements, as well as recent and proposed FDA policy changes regarding blood donations.

At the committee's request, we have examined trends in the Nation's blood supply, the effect of a ban on donors who have traveled to the UK and the potential effect of policy changes to allow blood collected from people with hemochromatosis to be distributed. And we did issue a report to you earlier this week.

I will focus on the trends in the blood supply and our analysis of the policy changes recommended by HHS. We found that while there is concern for shortages of certain blood types, seasonal patterns and occasional shortages in certain regions of the country, the blood supply, as a whole, is not in crisis. The blood supply has decreased over the last decade, and there is some evidence that, in recent years, the demand for blood has increased. However, any conclusions about the trend in the blood supply are hampered because information about the supply has not been gathered routinely. The last survey was conducted in 1998.

The total decrease in units collected between 1994 and 1997 was 5.5 percent, according to the National Blood Data Resource Center. Most of this decline was in donations targeted for specific individuals, especially autologous collections taken from individual patients for personal use prior to surgery, rather than in the allogenic or community supply of blood available to anyone.

During the same period, there was a decrease in the community supply of about 2 percent. We believe that the NBDRC study overstates the decline in the blood supply. Overall, the blood banking system had an adequate supply to meet increasing demand as total units transfused increased by 3.7 percent during the same period.

The supply cushion is growing smaller. Blood centers gave us data showing less than 1 day's supply on hand for some blood types, such as O & B in some regions this summer. Blood centers

have no incentives to collect more blood than can be used. In 1997 only about 4 percent of the allogenic blood supply expired before being transfused.

With 93 percent of available supply used in transfusions, blood centers state that they are below the comfort level in many regions. Blood banks can mitigate the effects of local blood shortages by transferring blood from regions with an excess supply to those with shortages. The American Association of Blood Banks National Blood Exchange and the American Red Cross together moved about 1.1 million units of blood between blood centers last year.

Estimates of the future demand for blood are uncertain. Blood banks want to ensure that trauma patients and others who may require many units of blood can be promptly treated whenever the need arises. Persons that are 65 and older receive twice as much blood per capita as young individuals, so we do expect that the aging population may increase the demand. Further, the number of surgical procedures that require blood or blood products are increasing.

On the other hand, some evidence indicates that the use of blood can be substantially reduced without effecting clinical outcomes. For example, the amount of blood used for hospitals vary widely, and at least one pilot program has shown that the use of blood can be substantially reduced without affecting the clinical outcomes.

Improved surgical techniques and better understanding of the clinical thresholds that trigger blood transfusions has reduced the demand for blood in some instances as well.

In response to concerns for the safety of the blood supply, FDA has issued a guidance recommending that collections be prohibited from donors who traveled or resided in the UK for a total of 6 months or more between 1980 and 1996 because of the theoretical risk of transmitting new variant CJD through blood transfusions.

Transmission by blood in humans has not been documented, although animal research suggests that infection by blood is theoretically possible. The 6-month residence interval was selected to balance the twin goals of minimizing losses in blood and eliminating as much risk as possible.

Would you like me——

Mr. UPTON. If you can.

Ms. HEINRICH. [continuing] to summarize?

Mr. UPTON. Yes, that would be great.

Ms. HEINRICH. The other policy that you asked us to evaluate was making hemochromatosis patients available to donate blood. We estimate that that might mean that we have 300,000 units, 3 million units, it's very hard to estimate exactly how much. There are concerns, though, about financial incentives for these individuals to donate blood because of the issues of cost incentives that must be addressed before the inclusion of hemochromatosis patients blood enter the community supply. We are concerned about how quickly this blood would be available.

This concludes my prepared statement, Mr. Chairman. I will be happy to answer any questions.

[The prepared statement of Janet Heinrich follows:]

PREPARED STATEMENT OF JANET HEINRICH, ASSOCIATE DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH ISSUES, HEALTH, EDUCATION, AND HUMAN SERVICES DIVISION, GAO

Mr. Chairman and Members of the Subcommittee: I am pleased to be here as you discuss the availability of blood to meet the nation's requirements as well as recent and proposed policy changes regarding blood donation that may affect the future supply.

A recent report by the National Blood Data Resource Center (NBDRC), a group representing blood banks, projected that the demand for blood will outstrip the available supply by next year. At the same time, the Department of Health and Human Services (HHS), which oversees the nation's blood supply, has initiated a major policy change—and is considering another—that could further affect the blood supply. Specifically, the Department's Food and Drug Administration (FDA) has recommended prohibiting blood donations from individuals who spent a total of 6 months or more in the United Kingdom between 1980 and the end of 1996 because of concerns over the possible transmissibility of new variant Creutzfeldt-Jakob disease (nvCJD), the human form of "mad cow" disease. HHS has also proposed removing barriers to donation by individuals with hemochromatosis—an iron-overload disease that may be treated by drawing blood—to make up some of the loss in blood donations from the decreases in donations and losses that may result from the U.K. donor exclusion.

In light of these developments, you asked us to discuss the results of our recent correspondence on the blood supply.[1] In that report, done at the Committee's request, we provide information on (1) recent trends in blood donation and the demand for blood transfusions, (2) the expected effect of a ban on donors who have traveled to the United Kingdom, and (3) the potential effect of policy changes to allow units of blood collected from individuals with hemochromatosis to bedistributed. The points I will present today are discussed in more detail in the correspondence.

In summary, we found that, while there is cause for concern about shortages of certain blood types or in certain regions, the blood supply as a whole is not in crisis. We believe that the NBDRC study overstates the decline in the blood supply. Most of the decline found by NBDRC was in donations targeted for specific individuals, rather than in the community supply of blood available to anyone in need. Further, the projection of a shortage relies on data from only 2 years. The U.K. donor exclusion policy has been estimated to reduce the blood supply by approximately 2.2 percent. Blood banks fear that the actual loss due to this exclusion will be greater, but it is not possible to assess the validity of their concerns. Estimates of the potential increase in the blood supply from donations by individuals with hemochromatosis vary widely, from 300,000 to 3 million units. Regardless, use of such donations will require changes to current regulations, which may delay their availability for some time.

BACKGROUND

About 8 million volunteers donate approximately 12 million units of whole blood each year. Sixty percent of the population is eligible to donate, and about 5 percent of the eligible population actually donate each year.[2] There are four sources of whole blood from volunteer donors for transfusion. The first, allogeneic donations, is the most important category, accounting for roughly 90 percent of the blood supply. Blood from allogeneic donations is available to any patient in need, and efforts to increase the blood supply usually focus on increasing participation in blood drives or otherwise raising the number of allogeneic collections. Second, autologous collections involve blood taken from patients before a medical procedure for their own use. Third, directed collections involve blood donated for use by a particular patient. A small portion of the autologous and directed collections ultimately are "crossed over" to the general supply. Finally, less than 2 percent of the total blood supply is imported.

Blood banks maintain a supply cushion to meet the uncertain demand for blood. Local demand for particular blood types varies over the course of the year, and blood banks want to ensure that trauma patients and others who may require many units of blood can be treated promptly whenever the need arises. The supply cushion

[1] *Blood Supply: Availability of Blood to Meet the Nation's Requirements* (GAO/HEHS-99-187R, Sept. 20, 1999).

[2] To be eligible to donate, a person should be at least 17 years of age, weigh at least 110 pounds, be in good physical health, and pass a physical and medical history examination.

means that some blood is discarded—in 1997, for example, about 4 percent of the allogeneic blood supply expired without being transfused.

New variant CJD is a chronic, progressive neurodegenerative disease that is inevitably fatal. It has a long, but unknown, incubation period. As of August 1999, there had been 43 confirmed cases—41 in the United Kingdom, 1 in France, and 1 in Ireland. It is suspected that all of these individuals contracted nvCJD from eating contaminated tissues from cattle infected with bovine spongiform encephalopathy ("mad cow" disease) in the United Kingdom, probably prior to 1990. Estimates of the number of U.K. residents who will ultimately manifest nvCJD range from the hundreds to more than 500,000. In the United States, there have been no documented cases of nvCJD.

Hemochromatosis is the most common genetic disease in Americans of European descent—about 1 in 10 may carry the gene for this disease, and as many as 1 million Americans have evidence of hemochromatosis.[3] The proportion of individuals, however, who have the mutations associated with hemochromatosis and later develop the disease is unknown because not all of these individuals become ill. Treatment of hemochromatosis has two phases: (1) iron depletion therapy, in which the patient receives a therapeutic phlebotomy, or drawing of blood, about 1 to 2 times a week for several months up to 3 years to remove excessive iron stores, and (2) maintenance therapy, in which the patient continues to undergo therapeutic phlebotomies but less frequently (2 to 6 times a year) to keep body iron stores low and iron levels normal for the remainder of the patient's life.

RECENT TRENDS IN SUPPLY AND DEMAND

The blood supply has decreased over the last decade, and there is some evidence that in recent years the demand for blood has increased. However, any conclusions about the trends in the blood supply are hampered because information about the blood supply has not been gathered routinely. The last systematic survey of the blood supply was conducted by NBDRC in 1998, which measured units collected and transfused in 1997. NBDRC will release the results of a new survey of blood collections this November, and the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) has recently arranged for NBDRC to collect data on blood donations on a monthly basis from a sample of blood centers.

Earlier this year, NBDRC projected that the demand for blood will outstrip supply by next year.[4] We found that current evidence indicates the blood supply has declined more slowly than assumed for that projection. NBDRC's projection rests on the overall 5.5 percent decrease in the blood supply from 1994 to 1997, and on the observed 3.7 percent increase in the number of units transfused during those years. (See table 1.)

Table 1: Blood Supply Trends

	1989	1992	1994	1997	Percent change (1994-1997)
Total units collected	14,229,000	13,794,000	13,340,000	12,602,000	-5.5
Total community supply	13,296,000	12,303,000	12,075,000	11,837,000	-2.0
Total units transfused	12,059,000	11,307,000	11,107,000	11,517,000	+3.7

Our analysis of the blood supply data found that the 5.5 percent figure suggests a more serious decline than actually occurred in the community supply of blood (available to anyone in need). Most of the 5.5 percent decrease came from a drop in blood not included in the community supply, which decreased only about 2 percent from 1994 to 1997. The number of units designated for particular transfusion patients, both autologous and directed donations, decreased by 37 percent from 1994 to 1997, accounting for two-thirds of the overall 5.5 percent decline. Indeed, there was an even larger decline in the number of such units that had been collected but not used.[5]

[3] There are two genetic mutations, C282Y and H63D, associated with hemochromatosis. C282Y is considered the major mutation; fewer data are available on the prevalence of hemochromatosis in other populations.

[4] This projection did not consider the consequences of excluding travelers to the United Kingdom from donating blood or of any other policy changes that may affect the blood supply.

[5] The number of autologous and directed units collected but not transfused dropped 63 percent between 1994 and 1997.

While other evidence seems to indicate that the blood supply cushion has narrowed, it is difficult to determine if shortages are worse now than in earlier years because blood banks have no incentive to collect more blood than can be used. The American Red Cross informed us that the number of days' supply decreased below the comfort level in many of its centers and gave us data showing less than 1 day's supply on hand for some blood types in some regions at one point this summer. America's Blood Centers reported anecdotal evidence of shortages in many of its affiliated blood banks this year. Shortages occur more frequently in some regions, as do shortages of blood types O and B. Furthermore, the 1998 NBDRC survey found that at least some surgeries and medical procedures have been postponed due to blood shortages. Specifically, 8.6 percent of the hospitals surveyed indicated that elective surgeries were cancelled on 1 or more days in 1997 due to blood shortages; 24.7 percent of hospitals said that they were unable to meet nonsurgical blood requests on 1 or more days in 1997.[6]

Blood banks can mitigate the effects of local blood shortages by transferring blood from regions with an excess supply to those with shortages. The American Association of Blood Banks' National Blood Exchange and the American Red Cross together moved about 1.1 million units of blood between blood centers last year. This blood is purchased by centers in shortage areas from centers with surpluses of particular types of blood.

Estimates of the future demand for blood are also uncertain. On the one hand, persons aged 65 and older receive twice as much blood per capita as younger individuals, so the aging of the population may increase the demand for blood products. Further, some procedures requiring blood are being performed with increasing frequency, and the range of treatments requiring blood or blood products is increasing. On the other hand, some evidence indicates that the use of blood can be substantially reduced. The amount of blood used for the same procedures varies widely among hospitals, and at least one pilot program has shown that clinical outcomes would not be affected if the use of blood were substantially reduced. Similarly, improved surgical techniques and better understanding of the clinical thresholds that trigger blood transfusions has reduced the demand for blood in some instances.

EXPECTED EFFECT OF EXCLUDING DONORS WHO HAVE RESIDED OR TRAVELED IN THE UNITED KINGDOM

Last month, FDA issued guidance recommending that collections be prohibited from donors who had traveled or resided in the United Kingdom for a total of 6 months or more between 1980 and 1996—because of the theoretical risk of transmitting nvCJD through blood transfusions—which has raised concern among some about the effect such a policy would have on the blood supply. FDA will review this policy at 6-month intervals, to consider any new scientific information and the policy's effect on the blood supply.

While it has not been shown that nvCJD is transmissible by blood transfusion, animal research suggests that infection by blood is theoretically possible—in some cases, direct injection of blood from a contaminated animal into the brain of another has caused infection. However, no cases of transmission by blood in humans have been documented. In the United Kingdom, 4 donors subsequently diagnosed with nvCJD gave blood that was transfused into 10 recipients. None of these recipients have developed nvCJD to date, although they may later because of the long incubation period.

Effect on the Blood Supply

The 6-month U.K. residence interval was selected to balance the twin goals of minimizing losses to the blood supply and eliminating as much risk as possible. A survey of blood donors by the American Red Cross found that 23 percent of donors had traveled to the United Kingdom between 1980 and 1996. Only one-fifth of the blood-donor travelers had been in the United Kingdom for more than 30 days, and just 1 in 10 of them had a cumulative stay of 5 months or more. The Red Cross analysis estimated that the 6-month exclusion criterion would result in a 2.2 percent reduction in the blood supply and eliminate 87 percent of the risk of collecting blood from a person infected with nvCJD.

Blood banks have expressed concern that this exclusion will result in more than a 2.2 percent loss. First, there is the possibility that some potential donors will fail to attend to the details of the policy and not donate blood even though they are eligible to do so. For example, donors who traveled to the United Kingdom only in

[6] Among all hospitals responding to the survey, the mean number of days with surgeries cancelled was 0.44 and the mean number of days with unmet nonsurgical blood requests was 2.1.

1997 may stop donating even though they remain eligible to do so. Second, there is concern that potential donors may become discouraged because their friends or neighbors are excluded, heightening the sense that it is difficult to pass all the screening criteria for giving blood. Third, there is worry that excluded U.K. travelers will not return to donate blood if, and when, the restriction is lifted.

Blood banks are also concerned about other burdens imposed by this exclusion. For example, according to research conducted by the American Red Cross, donors who resided or traveled in the United Kingdom are disproportionately repeat donors. Without these donors, the blood banks will need to recruit a large number of first-time donors to replace them because first-time donors are roughly twice as likely to have disqualifying medical conditions as regular donors. Second, the effect will vary by blood center, as those with a larger proportion of U.K. travelers will lose more of their donors than other blood collection centers. The Red Cross survey found that the proportion of donors affected in some blood centers were 35 percent greater, and others 50 percent less, than the overall average.

Risk Reduction

Estimates of the degree of risk reduction achieved by this exclusion are problematic. First, the degree of potential risk to be mitigated is unknown. Second, because the prohibition applies only to future donations, some blood from donors who would now be excluded has entered the blood supply in the recent past. Third, because so little is certain about how nvCJD is acquired, estimates of the beneficial effect of any prohibition threshold—other than a complete ban on potential donors who have traveled to the United Kingdom at all—are uncertain. For example, the Red Cross estimate assumed that the risk of acquiring nvCJD increased directly with each day spent in the United Kingdom. Any change in this assumed relationship would lead to a significantly different risk reduction estimate. Indeed, HHS told us that the Department did not totally agree with the Red Cross risk formulation and that its choice of the 6-month threshold was based on other information. In particular, HHS told us that all of the individuals in the British cases (41 of the 43 known cases) were born in the United Kingdom and resided there for at least 10 years between 1980 and 1996; thus, the Department reasoned that any exclusion threshold of 1 year or less would reduce the presumed risk tenfold or more.

POTENTIAL FOR BLOOD DONATIONS FROM INDIVIDUALS WITH HEMOCHROMATOSIS

In April 1999, the Public Health Service's Advisory Committee on Blood Safety and Availability recommended that policy changes be made to allow blood collected from individuals with hemochromatosis to be distributed for transfusion.[7] Making hemochromatosis patients eligible to donate would essentially guarantee an increased number of donors because they have to periodically have blood drawn to treat their condition. Members of the advisory committee concluded that blood products from individuals with hemochromatosis carry no known increased risk to recipients. Therefore, they recommended that HHS change its policies and remove any barriers to the use of this blood. At the same time, the advisory committee recommended that HHS take steps to eliminate any financial incentive for these individuals to donate blood. Since individuals with hemochromatosis may have to pay to have their blood drawn through therapeutic phlebotomy,[8] there would be a financial incentive to avoid this cost by donating blood. Unless this incentive is removed, FDA is concerned that these potential donors will not truthfully answer screening questions about risk factors that would disqualify them from donating, thereby compromising the safety of the blood supply.

According to one survey, most individuals with hemochromatosis are insured or partially insured for therapeutic phlebotomies. However, even though therapeutic phlebotomies are necessary medical treatment for some individuals, insurance does not always cover the costs. The average cost of the procedure per unit of blood ranges from $52 at blood centers to $69 at physician offices and $90 at hospitals, with an average out-of-pocket cost of $45 for all respondents to the survey.[9] These

[7] Hemochromatosis is a disease of iron regulation that results in excessive iron absorption and accumulation, leading to organ damage. The human body cannot excrete excess iron, so it remains in the body unless it is lost through menstruation, childbirth, hemorrhage, or blood donation. Iron is highly toxic when an excessive amount is absorbed. Some clinical chronic conditions associated with hemochromatosis include severe fatigue, diabetes mellitus, heart disease, cirrhosis of the liver, and cancer.

[8] Therapeutic phlebotomy is the removal of a full unit of blood from an individual, about 500 mls, for the purpose of treating a disease.

[9] S. M. McDonnell and others, "A Survey of Phlebotomy Among Persons With Hemochromatosis," *Transfusion,* Vol. 39 (1999), pp. 651-6.

out-of-pocket costs are a financial incentive for persons with hemochromatosis to not disclose any disqualifying conditions and volunteer for blood donations. In one study, 37 percent of the hemochromatosis patients surveyed reported being voluntary donors before their diagnosis and 54 percent of the individuals attempted to donate blood after diagnosis.[10] The results from the National Donor Research and Education Study sponsored by NIH show that about half of the individuals who responded that they had hemochromatosis (only 0.4 percent of those surveyed) were volunteer donors. At present, there is no routine screening for this disease.

In the United States, blood obtained by therapeutic phlebotomy from individuals with hemochromatosis is currently discarded. Although hemochromatosis is inherited, not transmitted, and there is no evidence that the use of hemochromatosis blood for transfusion carries any risks to the recipients,[11] hospitals and physicians hesitate to use this blood. FDA permits the use of blood from individuals with hemochromatosis, as long as they meet the same donor suitability criteria as any other donor, but it requires that this blood be labeled as coming from a hemochromatosis donor, which effectively impedes the use of this blood. Some in the U.S. blood industry consider hemochromatosis donors to be the same as paid donors, implying a decreased level of safety.[12] In 1996, the American Association of Blood Banks issued standards discouraging transfusion of blood from donors who had therapeutic phlebotomies. Because many blood centers conform to these standards, this policy effectively excludes most individuals with hemochromatosis from donating blood.

FDA has agreed to make the necessary regulatory changes to remove barriers to donation once financial incentives for hemochromatosis patients are removed.[13] There are several different requirements that would need to be changed. FDA currently requires an 8-week interval between donations to prevent iron depletion of donors, but individuals with hemochromatosis at the initial stage of treatment undergo therapeutic phlebotomies 1 to 2 times a week. FDA also requires blood from therapeutic bleeding, including for hemochromatosis, to be labeled with the disease for which the bleeding was performed, which discourages health care providers from using this blood.

As an initial step, FDA recently agreed to consider case-by-case exemptions to existing regulations on blood labeling and frequency of blood collection for blood establishments that can verify that therapeutic phlebotomy for hemochromatosis is performed at no expense to the patient. However, FDA officials have publicly stated that in making these exemptions, they will require a commitment from blood collection facilities to concurrently provide safety data, including viral marker rates, incidence of transmissible infections based on seroconversion rates, frequency of postdonation reports of undisclosed risks, and reports of adverse events.

Individuals with hemochromatosis have the potential to make up some of the loss in blood donations due to the U.K. donor exclusion policy. Estimates of increases in the blood supply through donations by these individuals vary widely, from 300,000 to 3 million units—although the former is generally considered a better estimation. Regardless, changes to current regulations affecting blood from hemochromatosis patients will occur considerably later than FDA guidance to exclude donors, which has already gone into effect. It seems unlikely that the issue of coverage of therapeutic phlebotomies by insurers will be quickly addressed and that anything less than full reimbursement may be considered undue donor incentive. Therefore, unless blood centers absorb the costs of providing therapeutic phlebotomies to persons with hemochromatosis, it is also unlikely that FDA will revise current regulations.

CONCLUSIONS

On the basis of the information we reviewed, we conclude that the blood supply is not in crisis. However, there is cause for concern about the possibility of some regional shortages and shortages of some types of blood. These may be exacerbated somewhat by the U.K. donor exclusion policy, which will affect blood banks dif-

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[10] S. M. McDonnell and others, "A Survey of Phlebotomy Among Persons With Hemochromatosis."

[11] The processing of whole blood units into packed red cells removes most of the iron-enriched serum.

[12] Data show that blood from paid donors is more likely to transmit disease than that from volunteer donors; R. A. Sacher, "Hemochromatosis and Blood Donors: A Perspective," *Transfusion,* Vol. 39 (1999), pp. 551-4.

[13] The American Association of Blood Banks has also indicated that, if FDA changes the regulations, it would make changes to its standards related to the use of blood from patients with hemochromatosis, so that centers could remain in compliance with the association's requirements.

ferently. Potential additions to the blood supply from hemochromatosis patients cannot occur for some time, since blood from these individuals will not be entered into the community supply until issues related to who pays the costs of therapeutic phlebotomies are resolved and regulatory changes are implemented.

This concludes my prepared statement, Mr. Chairman. I will be happy to respond to any questions that you or Members of the Subcommittee may have.

CONTACTS AND ACKNOWLEDGMENTS

For future contacts regarding this testimony, please call Janet Heinrich at (202) 512-7119. Key contributors to this testimony include Marcia Crosse, Martin T. Gahart, and Angela Choy.

Mr. UPTON. Thank you very much.

Mr. Roslewicz.

TESTIMONY OF THOMAS D. ROSLEWICZ

Mr. ROSLEWICZ. Thank you, Mr. Chairman.

If I may, I would like to invite Mr. Joseph Green to join me at the table. He is the Assistant Inspector General for Audits at our Public Health Service Audit Division.

Mr. UPTON. That would be fine. I need to swear him in as well. I should have.

Mr. ROSLEWICZ. His staff was responsible for this audit.

[Witness sworn.]

Mr. ROSLEWICZ. Thank you, Mr. Chairman.

Mr. UPTON. Thank you.

Mr. ROSLEWICZ. I'm pleased to discuss the results of our work requested by the subcommittee concerning the Food and Drug Administration's error and accident reporting process for blood.

Errors and accidents are events occurring in blood establishments that may affect the safety, security or potency of blood and blood products. Examples include incorrectly labeling blood products or shipping the unit that has repeatedly tested reactive to a viral marker test, such as human immuno deficiency, HIV virus.

According to FDA, it is important that the agency receive error and accident reports from blood establishments so that it can accurately monitor actions taken to respond to problems and facilitate a rapid response where the public health may be at risk. We issued a final report on May 31, 1995, detailing our findings and recommendations to the Commissioner of Food and Drugs.

At that time, FDA agreed to take specific regulatory steps to strengthen its oversight of the blood industry. As I discussed below, the agency proposed regulations in 1997 to improve the error and accident reporting process but does not anticipate issuing the final regulations until February 2001.

The FDA is the Federal agency responsible for regulating blood establishments, which include human blood and plasma donor centers, blood banks, transfusion services, and other blood product manufacturers. Such regulation, which is the responsibility of the Center for Biologics, Evaluation and Research—CBER—includes registering establishments, licensing products and issuing and enforcing safety rules. The Office of Regulatory Affairs directs the agency's field staff, which performs inspections of blood establishments, to ensure, for example, that they are complying with current manufacturing practices and implementing all the safeguards over blood and blood products.

In the early 1990's, we chose to review FDA's error and accident reporting process because it was critical to FDA's oversight of the blood industry. Further, the agency planned to expand the use of the error and accident reports to upgrade the quality of the blood industry.

Licensed blood establishments, those that ship their products interstate, are required by regulation to promptly report errors and accidents to FDA. Unlicensed establishments, those operating intrastate, have been requested by FDA to voluntarily submit reports. When errors and accidents occur, all blood establishments are required to investigate them, take appropriate corrective action and, if indicated, initiate a recall. The Food and Drug Administration uses the error and accident reports to gauge the severity of the incident, monitor the actions taken in response to the events reported, and to classify the most serious events as recalls.

In fiscal year 1998, FDA received about 13,000 error and accident reports. Our reviews show that FDA's error and accident reporting process is a valuable management tool because it provides a framework to enable the agency to evaluate and monitor the blood establishments' actions to problems. However, the process would require more prompt and comprehensive reporting to be able to provide an effective early warning device for FDA field offices and the blood industry.

We found two shortcomings that could hamper FDA's plan to expand the usefulness of error and accident reports. First, the blood establishments were not submitting error and accident reports to FDA promptly, as required by Federal regulations. Our sample indicates that the time between the date the error or accident was detected and the date it was reported to FDA ranged from less than 1 month to over 1 year, with an average of a little over 4 months. Only about 14 percent of the error and accident reports we reviewed were submitted by blood establishments within 1 month after the detection of the incident, while 13 percent were reported 6 months or more after detection.

Second, there was no assurance that unlicensed blood establishments were voluntarily submitting their reports. At the time of our review, even though 75 percent of the 2,900 blood establishments were involved in intrastate activity only, and thus were unlicensed, this group provided only 1 percent of the error and accident reports received by FDA.

Overall, we concluded that, without prompt and complete reporting by blood establishments on the number and types of errors and accidents that are detected, FDA may be hampered in its efforts to evaluate and monitor the blood industry.

In May 1995, we recommended that the Commissioner of Food and Drugs, first of all, expedite the development and issuance of revisions to the Federal regulation on error and accident reporting to be more specific concerning the timeframe in which error and accident reports are required to be submitted and, second, expedite the development and issuance of a regulation to require unlicensed blood establishments to submit error and accident reports.

The FDA agreed with these recommendations and assured us that they were already taking action to implement them. The agen-

cy estimated that the proposed regulations would be issued in November 1995. I'm just about finished.

Mr. UPTON. That's fine.

Mr. ROSLEWICZ. In August 1999, staff of the subcommittee requested the Office of Inspector General to determine the status of our 1995 recommendations. Through an August 24, 1999, memorandum, FDA provided the following information: A proposed rule was published on September 23, 1997, first of all, to require blood establishments to report errors and accidents as soon as possible but not to exceed 45 calendar days; and, second, required reporting of all blood establishments, including licensed manufacturers of blood and blood components, unlicensed registered blood establishments and transfusion services.

CBER was in the process of making revisions to the proposed rule based on the comments received during the comment period. In an effort to make reporting requirements effective and less burdensome to the industry, the FDA planned not issuing the final regulation until—they delayed until February 2001 because of multiple public-health-related priorities of the agency.

We recently spoke with FDA officials involved in blood safety to pinpoint reasons for the delay in issuing the final regulation. According to the Director of CBER, the Food and Drug Administration received 97 comments on the proposed rule. The comments were varied and complex and required revision of considerable solutions in order to give a straightforward response. The Director stated that the final regulations were slated to be cleared through FDA by June 2000 and that they would likely be published in February 2001.

Mr. Chairman, that concludes my statement. I will be available to answer questions.

[The prepared statement of Thomas D. Roslewicz follows:]

PREPARED STATEMENT OF THOMAS D. ROSLEWICZ, DEPUTY INSPECTOR GENERAL FOR AUDIT SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman and members of the Subcommittee, I am Thomas D. Roslewicz, Deputy Inspector General for Audit Services at the Department of Health and Human Services. I am pleased to discuss our previous work concerning the Food and Drug Administration's (FDA) error and accident reporting process for blood. We issued a final report on May 31, 1995 detailing our findings and recommendations to the Commissioner of Food and Drugs. At that time, FDA agreed to take specific regulatory steps to strengthen its oversight of the blood supply. As I discuss below, the agency proposed regulations in 1997 to improve the error and accident reporting process, but does not anticipate issuing the final regulations until 2001.

For this hearing, the Subcommittee asked us to summarize the findings and recommendations contained in our 1995 report on the error and accident reporting process, and to discuss the status of FDA's actions with regard to our recommendations. Before providing this information, I will briefly describe the FDA's and the blood establishments' responsibilities in ensuring the safety of our blood supply, including a description of the error and accident reporting process.

BACKGROUND

Organizational and Legal Responsibilities

The FDA regulates the blood industry by licensing products, and issuing and enforcing safety rules. The Center for Biologics Evaluation and Research (CBER) is the FDA component responsible for regulating products used for the prevention, treatment or cure of diseases and injuries, including blood products, vaccines, se-

rums, and toxins. The Office of Regulatory Affairs (ORA) directs the agency's field force, which performs inspections of FDA-regulated establishments.

The PHS Act (Title 42 U.S.C. 262) and the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 331) place the responsibility for the oversight of blood establishments with FDA. The FDA has the authority to register all blood establishments and to license those establishments that ship blood and blood products interstate. Registered blood establishments that are not licensed by FDA (these unlicensed establishments do not engage in interstate shipments of blood products) fall under State licensing procedures. All registered blood establishments—whether licensed or not—are to be inspected by FDA every 2 years, and many are inspected more frequently if they are under scrutiny for previous quality problems. The FDA has several regulatory options available to it, ranging from warning letters to product seizures, for protecting the blood supply. These enforcement options apply to all registered blood establishments.

The Blood Establishments' Role in Ensuring Blood Safety

With the emergence of the Acquired Immune Deficiency Syndrome (AIDS) epidemic, ensuring the safety of the blood supply has become extremely complex. While FDA provides guidance to blood establishments to help them comply with industry standards and safeguards, all blood establishments, including unlicensed establishments, are responsible for ensuring the safety of their blood products. To meet this responsibility, blood establishments are to comply with established current good manufacturing practices, which are defined as those standards that would be generally acceptable in a particular industry and would result in the manufacturing of products which would meet standards of the Federal Food, Drug and Cosmetic Act. They are also required to fully implement all safeguards over blood and blood products including:

- eliminating high risk donors by encouraging them to exclude themselves, and by evaluating their behavioral and medical history as a basis for deferral;
- updating a list of unsuitable donors and checking the donors' names against this list to prevent use of their blood;
- testing the blood for such blood-borne agents as HIV, hepatitis, and syphilis;
- quarantining all donated blood until tests and other control procedures established its safety; and
- investigating all incidents, auditing their systems, and correcting all deficiencies.

When an error or accident occurs that may affect the safety, purity, or potency of blood, licensed blood establishments are required to self-report the incident to FDA. Unlicensed establishments are not required to self-report, but have been requested to do so on a voluntary basis. The FDA has provided guidance to the blood establishments as to what constitutes a reportable error or accident. The reportable incidents include, but are not limited to, the following:

- release of units repeatedly reactive to tests indicating hepatitis or HIV;
- release of units in which testing was performed incorrectly or misinterpreted;
- release of units from donors who are, or should have been, permanently or temporarily deferred due to medical history or a history of repeatedly reactive viral test results for hepatitis or HIV;
- release of units prior to completion of all tests or that are incorrectly labeled, e.g., incorrect expiration date; and
- release of contaminated blood components when the contamination is attributed to an error in manufacturing.

The error and accident report identifies the blood establishment, the donor, the blood product, and the final disposition of the blood product. It contains appropriate dates such as date the incident occurred, date it was discovered, date of the report, and type of error or accident involved. There are three basic types of incidents: (1) labeling error or accident—testing correctly performed, but incorrect label applied to product; (2) testing error or accident—test either incorrectly performed or misinterpreted, or product released inadvertently before tests completed; and (3) manufacturing/control procedure error or accident. The report also lists contributing factors causing the error or accident and the actions taken by the blood establishment.

FDA's Role in Processing Error and Accident Reports

The FDA relies on error and accident reports, in conjunction with inspections and other surveillance activities, to provide a continuing overview of the blood industry. According to FDA, receipt of the reports—which numbered 13,232 in Fiscal Year 1998—helps ensure that the industry identifies instances where additional corrective action is needed, such as additional training and revisions of standard operating procedures.

The error and accident reports are to be submitted "promptly"[1] to CBER's Office of Compliance, which is responsible for analyzing the reports. If the report clearly does not require further evaluation of the severity of the incident, it is sent to the appropriate district office for follow up at the next inspection. The FDA's ORA is responsible for the coordination of all field office activities. The field offices, under the direction of ORA, are responsible for conducting all routine blood establishment inspections.

If an error and accident report indicates that further evaluation of the severity of the incident is warranted, the report is forwarded to Case Management within the Office of Compliance. This group evaluates the error or accident being reported and, based on the severity of the incident, may recommend that it be classified as a blood recall. At the time of our previous review, about 8 percent of the error and accident reports were referred to Case Management to be evaluated for a recall classification.

A recall is a blood establishment's voluntary removal or correction of a marketed blood product that violates laws administered by FDA. The FDA cannot issue a product recall but can request that a firm do so. The FDA recognizes that a voluntary recall is generally more appropriate and affords better protection for consumers than seizure, which is a FDA option when a firm refuses to undertake a recall. In the case of blood, blood establishments are responsible for voluntarily initiating recalls to protect the public health from any defective products. They are also responsible for developing a recall strategy and determining whether the recall is progressing satisfactorily. Blood recalls differ from other product recalls because blood, having a short shelf life, is often used before it can be retrieved. If the blood cannot be retrieved, the blood establishment is responsible for identifying all recipients of the blood subject to the recall so that they can take extra steps to guard their health and avoid infecting others.

The FDA is responsible for classifying the blood establishment's recall according to the health hazard presented by the incident, and conducting its own audit checks to assess whether the establishment has notified all affected parties and taken appropriate action. The FDA publishes all recall actions in its weekly *Enforcement Report* regardless of when the recall was made.

According to FDA, since blood establishments are required to investigate all errors and accidents, including those that are eventually classified as blood recalls, the corrective action is generally completed by the blood establishment before FDA classifies the recall. At the time of our review, FDA told us that compliance with industry standards and safeguards accounted for the relatively few accidents severe enough to warrant a blood recall.

FDA's 1993 Plan For Blood Quality Assurance

Just prior to our review of 1993-1994 error and accident reporting, FDA proposed a plan to establish a blood quality assurance initiative aimed at ensuring the safety of the Nation's blood supply and upgrading the operational quality of the blood industry. As part of the plan, FDA sought to: strengthen its capability to identify blood center operational deficiencies; provide appropriate guidance to the blood industry; educate and assist blood centers in conforming to this guidance; provide more timely decisions on licensing applications and amendments; and carry out inspections that assess the industry's progress in bringing operations to a higher standard.

One component of this plan focused on the blood industry's self-reporting of errors and accidents that may affect the safety, purity, or potency of blood and blood products. The FDA envisioned that the error and accident reports submitted by blood establishments could be used to identify trends and develop appropriate "early warning" guidance to the field offices and the blood industry. Another component of this plan was the consolidation of FDA's multiple automated systems into a single relational data base designed to facilitate the exchange of information between field and headquarters staff and permit FDA to identify trends and problems in early stages of development and issue guidance to blood establishments to prevent errors and accidents.

OIG FINDINGS AND RECOMMENDATIONS ON ERROR AND ACCIDENT REPORT PROCESSING

Our review showed that while FDA's error and accident reporting process was a valuable management tool for evaluating and monitoring blood establishments's actions, it could be more useful with prompter and more comprehensive reporting. The

[1] Regulation 21 CFR 600.14(a) states that error and accident reports are to be submitted to CBER promptly, but does not define the term "promptly".

FDA processed error and accident reports in our sample in accordance with established procedures; however, we identified two shortcomings that could hamper the success of FDA's plan to expand the usefulness of error and accident reports:

(1) *Blood establishments were not submitting error and accident reports to FDA "promptly," as required by the regulation (21 CFR 600.14(a)) and as encouraged by FDA correspondence with the industry in 1991.* Based on a sample of 163 error and accident reports received in the first half of Fiscal Year 1993, we found that the time between the date the error or accident was detected and the date it was reported to FDA ranged from less than 1 month to over 1 year, with an average of a little over 4 months. Only about 14 percent of the error and accident reports we reviewed were submitted by the blood establishments within 1 month after the detection of the incident, while 13 percent were reported 6 months or more after detection.

We concluded that blood establishments, in light of the lack of specificity concerning the term "promptly," were taking a liberal interpretation of the time frame in which they are to report incidents affecting blood and blood products. This concerned us given that there were 17 cases in our sample requiring further evaluation for a possible recall. These cases involved, for example, shipping blood that tested positive for Hepatitis C; shipping mislabeled plasma units; and shipping units of red blood cells that were contaminated after being stored at room temperature.

(2) *There was no assurance that unlicensed blood establishments were voluntarily, as requested by a March 1991 FDA memorandum, submitting the reports.* Data provided by FDA during our review indicated that of the 10,308 error and accident reports submitted to the agency during Fiscal Year 1991, 99 percent were submitted by licensed blood establishments, with only 148 reports—about 1 percent—submitted by unlicensed blood establishments. We found a similar split between the licensed and unlicensed establishments for the error and accident reports reviewed in our sample: Of the 163 error and accident reports in our sample, only 2 were from unlicensed establishments. Acknowledging that FDA was seeking to more effectively evaluate and monitor the blood industry—as outlined in its 1993 plan—we concluded that it should have reports from the full spectrum of establishments.

Comparing the reporting data with the numbers of unlicensed establishments, we believed that the statistics provided by FDA and the data from our sample were more likely indicative of nonreporting, rather than unlicensed establishments having less problems than their licensed counterparts. At the time of our review, about 2,900 blood establishments were registered by FDA: about one-fourth of those registered would have been licensed by FDA, and required to submit error and accident reports related to blood and blood products. The remaining 75 percent of the registered blood establishments would not be shipping blood or blood products interstate and, therefore, would be unlicensed. Unlicensed establishments are not required to submit these reports to FDA except for cases involving fatalities. According to FDA at the time of our previous review, unlicensed establishments accounted for about one-tenth of the blood collected in this country.

We concluded during our previous review that without prompt and complete reporting by blood establishments on the number and types of errors and accidents that are detected, FDA may be hampered in its efforts to evaluate and monitor the blood industry. The FDA pointed out repeatedly that delays in reporting by licensed blood establishments and/or failure to voluntarily report by unlicensed establishments should not cause corresponding delays in initiating action aimed at correcting the specific problems being reported. This is because all blood establishments are required to investigate and correct all errors and accidents detected, independent of the reporting process. While we did not evaluate the timeliness or appropriateness of the blood establishments' actions, we noted that all 163 error and accident reports in our sample contained information showing that some action was taken. According to FDA, the actions reported to be taken by the blood establishments were appropriate.

In May 1995, we recommended that the Commissioner of Food and Drugs:

1. Expedite the development and issuance of revisions to the Federal regulation on error and accident reporting (21 Code of Federal Regulations (C.F.R.) 600.14(a)) to be more specific concerning the time frame in which error and accident reports are required to be submitted;
2. Expedite the development and issuance of a regulation to require unlicensed blood establishments to submit error and accident reports; and
3. Expand CBER's use of existing information in its current error and accident data base to identify blood establishments that regularly fail to submit error and accident reports in a timely manner and provide additional trend analysis reports to FDA field offices and blood establishments.

In its April 28, 1995 response to our draft audit report, the Public Health Service (PHS), FDA's oversight agency at the time of our review, agreed with our recommendations and indicated that FDA was taking action to implement them. The PHS asked us to revise our recommendations to reflect its view that many ideas presented in our report were already being translated into action. For example, PHS asked the OIG to add the word "expedite" to recommendations 1 and 2. The agency also informed us in its comments that the proposed regulation regarding recommendations 1 and 2 would be issued in November 1995, with a final publishing date of February 1996.

STATUS OF FDA ACTIONS ON OIG RECOMMENDATIONS

In August 1999, staff of the Subcommittee requested the OIG to contact FDA to determine the status of the recommendations made in its May 1995 report. In response to our request, FDA's Deputy Commissioner for Management and Systems forwarded a written memo, dated August 24, 1999 providing an update on our recommendations.

Regarding our recommendations to expedite development and issuance of revisions to the Federal regulation on error and accident reporting, to be more specific about the time frame in which the reports are to be submitted, and to require unlicensed establishments to submit such reports, FDA provided the following information:

- A proposed rule was published on September 23, 1997 to: (1) require blood establishments to report errors and accidents "as soon as possible but not to exceed 45 calendar days," and (2) require the reporting of all blood establishments including licensed manufacturers of blood and blood components, unlicensed registered blood establishments, and transfusion service. The introductory portion of the proposed rule states: "FDA regards the proposal to amend the error and accident reporting regulation to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information."
- CBER was in the process of making revisions to "the proposed rule based on the comments received during the comment period in an effort to make reporting requirements effective and less burdensome to the industry."
- The FDA planned a delay in issuing the final regulation until February 2001 "because of multiple public health related priorities of the Agency."

Regarding our third recommendation, focusing on FDA expanding the use of error and accident report information, the agency informed us that summary reports of errors and accidents continue to be sent to FDA's Office of Regulatory Affairs Regional and District Directors and are also available to the industry through CBER's FAX Information system. The FDA further stated that CBER would continue to identify trends for reporting times, but that it would wait until the final rule is published—in February 2001—before making any changes in how the error and accident information is used.

The agency response provided limited detail on the status of our recommendations; however, in anticipation of this hearing, we recently spoke with FDA officials involved in the blood safety area to pinpoint reasons for FDA's anticipated delay in issuing the final regulation. According to the director of CBER, FDA received 97 comments on the proposed rule—comments that were varied and "not straightforward" to address. She stated that the final regulations were slated to be cleared through FDA by June 2000 and that they would likely be published in February 2001.

CONCLUSION

That concludes my testimony, Mr. Chairman. At this time, I would be happy to answer questions from the Subcommittee.

Mr. UPTON. Thank you very much.

Ms. Sullivan.

TESTIMONY OF MARIAN T. SULLIVAN

Ms. SULLIVAN. Good morning. My name is Marian Sullivan. I'm the Executive Director of the National Blood Data Resource Center in Bethesda, Maryland. I'm pleased to have the opportunity to speak to you about the NBDRC; and after briefly introducing you to our organization and our activities, I will summarize for you our

most recent findings regarding the U.S. blood supply and our plan for monitoring it in the next 16 months.

The NBDRC is an independent, not-for-profit corporation, conceived and founded by the American Association of Blood Banks in July 1997. The mission of the NBDRC is to collect, analyze and distribute data on all aspects of blood banking and transfusion medicine. Prior to the founding of the NBDRC, there was no existing organization dedicated to the collection of blood supply monitoring data.

The goals of the NBDRC are to assist members of the blood community in identifying and assessing existing and emerging issues, improving operations, promoting the highest standards of care for patients and donors, and making policy at the national, regional and local levels. In short, we strive to provide whatever information is needed by the community to ensure a safe and efficient blood system.

We rely on the AABB and our own limited membership for the financial support of our operations. Our small staff has worked hard to meet our goals in the brief 25 months since we opened our doors. Our accomplishments include the 1998 Nationwide Blood Collection and Utilization Survey, a comprehensive survey of blood services activities completed by 2,360 blood centers and hospitals. Data from this project have assisted numerous Federal agencies and advisory committees in recent policy discussions and been quoted in the media by the Surgeon General, yet not $1 of Federal funds supported this ambitious NBDRC project.

The NBDRC has also contributed directly to the safety of the blood supply by continuation of the long-term Creutzfeldt-Jakob Disease Lookback Study, now funded by the Centers for Disease Control and Prevention, and the Survey of Donation Incentives, supported by a grant from the National Blood Foundation.

The results of our most recent national survey indicated that 700,000 fewer units of whole blood were collected in the U.S. in 1997 than in 1994, a statistically significant decrease of 5.5 percent. It's important to note that 205,000 of these units were directed donations intended for a specific patient and 643,000 units were autologous donations for the donor's own use. Although we recognize that both directed and autologous donations have been on a steep downward trend since they peaked in popularity in 1992, we cannot disregard the fact that these donations combined to account for .6 million transfused units in 1997, units that would have otherwise come out of the community supply.

On the other hand, the total number of transfused whole blood and red cell units increased by 4 percent in 1997, in comparison with 1994, to 11.45 units. If the rates of overall blood collection and transfusion that occurred between 1994 and 1997 are continuing, the United States may experience a national blood shortage as early as next year.

The NBDRC is committed to conducting another nationwide survey in 2000, even if it must be supported entirely by internal funds and report sales as it was last year. The results of the 2000 survey, which will be available to NBDRC members and customers approximately 12 months from now, will provide data for 1999 and enable us to extend the historical trends analysis.

However, in the interim between surveys, there's little information available regarding the adequacy of the blood supply, other than anecdotal. Some blood centers have recently reported significant increases in collections, while other centers issue repeated appeals for blood. The impact of this on the national supply cannot be carefully assessed without current nationwide data for comparable time periods and donation types.

In order to better estimate the adequacy of the recent supply and to enable us to more accurately project the available supply for next year, the NBDRC is currently conducting a QuiKount of the whole blood donations made at every U.S. blood center. The survey will capture blood collection data for all of 1998 and the first 6 months of 1999 by calendar quarter. This project is supported entirely by internal funding, and the results will be shared with all interested parties in early November.

Finally, I'm very pleased to tell you that we will begin to collect supply data on a monthly basis in approximately 2 months from a representative sample of blood centers under a short-term financial arrangement with the National Heart, Lung and Blood Institute.

Congress has rightly recognized that the safety of our blood supply is a national public health priority. However, patients cannot benefit from safe blood if it is not readily accessible, and long-term blood collection and usage data are needed to detect and avoid potential blood shortages.

The NBDRC urges Congress to support the collection of blood supply monitoring data. We are proud that in our short tenure the NBDRC has established a reputation as the premier source of national blood data. We appreciate the recognition of this subcommittee, the NHLBI and the various advisory committees and agencies which relied on our data to characterize the U.S. blood supply. You have our commitment to continue to provide accurate and timely data to meet the needs of the U.S. public health service as long as sufficient financial support is available.

Thank you for the opportunity to testify today. I will be pleased to answer any questions.

[The prepared statement of Marian T. Sullivan follows:]

PREPARED STATEMENT OF MARIAN SULLIVAN, EXECUTIVE DIRECTOR. NATIONAL BLOOD DATA RESOURCE CENTER

Good morning, My name is Marian Sullivan. I am the Executive Director of the National Blood Data Resource Center (NBDRC) in Bethesda, Maryland. I am pleased to have the opportunity to speak to you about the NBDRC. After briefly introducing you to the NBDRC and our activities, I would like to outline for you our most recent findings regarding the U.S. blood supply and our plan for monitoring it in the next sixteen months.

The NBDRC is an independent, not-for-profit, corporation, conceived and founded by the American Association of Blood Banks (AABB) in July of 1997. The mission of the NBDRC is to collect, analyze, and distribute data on all aspects of blood banking and transfusion medicine. Prior to the founding of the NBDRC, there was no existing organization dedicated to the collection of blood supply monitoring data.

The goals of the NBDRC are to assist members of the blood community at large in identifying and assessing existing and emerging issues, validating new technologies, improving operations, promoting the highest standards of care for patients and donors, and making policy at the national, regional, and local levels. In short, we strive to provide whatever information is needed by the community to ensure a safe and efficient modern blood system.

We rely on the AABB and our own limited membership for the financial support of our operations. Our small staff has worked hard to meet our goals in the brief

25 months since we opened our doors. Our accomplishments include the *1998 Nationwide Blood Collection and Utilization Survey*—a comprehensive survey of blood services activities completed by 2,360 blood centers and hospitals. Data from this project have assisted numerous federal agencies and advisory committees in recent policy discussions, and been quoted in the media by the Surgeon General, yet not one dollar of federal funds supported this ambitious NBDRC project.

The NBDRC has also contributed directly to the safety of the blood supply by continuation of the long-term Creutzfeldt-Jakob Disease Lookback Study, now funded by the Centers for Disease Control and Prevention, and the Survey of Donation Incentives, supported by a grant from the National Blood Foundation.

The results of our previous *Nationwide Blood Collection and Utilization Survey* indicated that 700,000 fewer units of whole blood were collected in the United States in 1997 than in 1994, a statistically significant decrease of 5.5%. It is important to note that 205,000 of these units were directed donations (intended for a specific patient) and 643,000 units were autologous donations (for the donor's own use). Although we recognize that both directed and autologous donations have been on a steep downward trend since they peaked in popularity in 1992, we cannot disregard the fact that these donations combined to account for 0.6 million transfused units; units which would have otherwise come out of the community supply.

On the other hand, the total number of transfused whole blood and red blood cell units increased by 4% in 1997 in comparison to 1994, to 11.5 million units. If the rates of overall whole blood collection and transfusion that occurred between 1994 and 1997 are continuing, the United States may experience a national blood shortage as early as next year.

The NBDRC is committed to conducting another *Nationwide Blood Collection and Utilization Survey* in 2000, even if it must be supported entirely by internal funds and report sales, as it was last year. The previous survey captured blood collection and transfusion data for the calendar year 1997. In February 2000 we will distribute the next nationwide survey to 3,000 hospitals and blood centers.

The results of the 2000 survey, which will be available to NBDRC members and customers approximately twelve months from now, will provide data for 1999, and enable us to extend the historical trends analysis through 1999 as well. However, in the interim between surveys, there is little information available regarding the adequacy of the blood supply, other than anecdotal. Some blood centers have recently reported significant increases in 1998 and 1999 collections, while other centers have issued repeated appeals for blood, beginning well in advance of the anticipated summer shortages this year. The impact of this on the national supply cannot be carefully assessed without current nationwide data for comparable time periods and donation types.

In order to better estimate the adequacy of the recent supply, and to enable us to more accurately project the available supply for the year 2000, the NBDRC is currently conducting a "QuiKount" of the whole blood donations made at every U.S. blood center. The short survey was mailed out last week and will capture blood collection data for all of 1998 and the first six months of 1999 by calendar quarter. The QuiKount project is supported entirely by internal funding, and the results will be shared with all interested parties in early November.

Finally, I am very pleased to tell you that we will begin to collect supply data on a monthly basis in approximately two months, under a short-term financial arrangement with the National Heart, Lung and Blood Institute (NHLBI). Initially, we will enlist the participation of a representative sample of blood centers willing to report their monthly distribution figures very rapidly. Later on, next year, we hope to bring the corresponding national hospital sample on-line in order to capture timely and detailed blood utilization data.

Congress has rightly recognized that the safety of our blood supply is a national public health priority. However, patients cannot benefit from safe blood if it is not readily accessible. Moreover, long-term blood collection and usage data are needed in order to detect and avoid potential blood shortages. The NBDRC urges Congress to support the collection of blood supply monitoring data.

We are proud that in our short tenure, the National Blood Data Resource Center has established a reputation as the premier source of reliable, national blood data, and we sincerely appreciate the recognition of this subcommittee, the NHLBI, and the various advisory committees, task groups and agencies which have relied on our data to characterize the U.S. blood supply. You have our commitment to continue to provide accurate and timely data to meet the needs of the U.S. Public Health Service, both routine and urgent, as long as sufficient financial support is available. Thank you for the opportunity to testify today. I would be pleased to answer any questions.

Mr. UPTON. Thank you.
Dr. AuBuchon.

TESTIMONY OF JAMES P. AUBUCHON

Mr. AUBUCHON. Good morning. My name is James AuBuchon. I'm a physician and professor of pathology and medicine at Dartmouth Medical School and Medical Director of the Blood Bank and Transfusion Service of Mary Hitchcock Memorial Hospital in New Hampshire. I appreciate the opportunity to offer the perspective of a physician who specializes in transfusion medicine in considering blood safety and availability.

Transfusion medicine specialists are pleased, and I'm sure our patients are grateful, that receiving a transfusion today has less risk than ever before. Reduction in the risk of viral transmission has occurred through the diligence of oversight on the part of regulatory bodies such as the FDA and through the dedication of thousands of medical, technical and administrative professionals in blood centers and hospitals.

The success of these efforts has created new dilemmas, however. Dramatic reductions in the risk of HIV have fueled public anticipation of transfusion without any risk. However, continual focus on one type of risk, viral infection, prevents a rational prioritization according to where the greatest residual risk remains. Reducing the risks of transfusion also encourages transfusion in situations where the predictable benefit is smaller.

The consequential increase in demand for blood comes at a time when the demands for increased safety and other factors have reduced the availability of blood. The intersecting interests here are clear particularly when an inadequate blood supply becomes a safety risk for a patient who cannot get a needed transfusion.

It is commonly accepted among transfusion medicine specialists that many transfusions cannot be justified medically. For example, at least a third of plasma transfusions do not occur in situations where the plasma confers benefit. We face three major hurdles in reducing inappropriate transfusion.

One, information. We simply do not have enough data about the effects of transfusing all the different kinds of blood components and all the different kinds of clinical situations where they may be applied. As a result, many transfusion decisions are made on guesses and personal experience. Studies indicate that a conservative approach to transfusion uses less blood in the end and is associated with better patient survival. Clearly, more clinical research is needed to define when transfusion should not be given.

Two, patient variability. Compounding the problem of inadequate research in this field is the inherent variability of patients. What may be a safe level of anemia that does not require treatment for one may be lethal for another. Medical science does not allow us to know enough about each patient to make well-founded individual decisions. The consequences of not transfusing when needed are immediate and catastrophic, whereas the consequences of transfusing when not needed are distant and only remote possibilities; hence, physicians frequently err on the side of treatment.

Three, education. In attempting to change transfusion behaviors, considerable trust must be developed in the transfusion medicine

specialist by the clinician. This must be followed by the investment of considerable time for prompt clinical interactions to redirect the clinician's practice. Many studies have shown that ongoing interactions with clinicians can have a positive impact. However, there is no support for this activity; and only academic medical centers have the trained staff and anything close to sufficient time to attempt it.

Given the demographics of our population, the blood supply situation is only going to get worse. A report of the Office of Technology Assessment 15 years ago noted that while 12 percent of the population was age 65 or over, this segment accounted for 22 percent of all hospital admissions and 45 percent of all transfusions. The graying of the population will not only accelerate blood usage but also reduce the number of available donors.

We may already be seeing the tip of the iceberg of this shortage. Will the periodic shortages we have been experiencing with increasing frequency become perpetual? Will the trends of increasing usage and decreasing availability soon combine to cause the death of a patient needing a transfusion? What can we do to forestall this?

Frankly, I do not hold out the promise of significant reduction in usage because of the advancing age of the population and because of increased aggressiveness of a wide variety of therapies that would require transfusion support. Greater use of autologous blood options is attractive but impractical since most approaches to autologous therapy are more expensive than depending on the community blood supply. Until this blood supply is so short or undependable that elective surgery is frequently postponed, most will not opt for this approach.

Some blood conservation mechanisms are now fairly common in larger hospitals, and these do decrease reliance on the community supply. For example, using equipment to recover red cells lost in surgical wounds for reinfusion back to the patient can decrease the transfusion of banked blood by 50 percent or more in cases that require blood. Smaller hospitals find only occasional use for this equipment, however, and have not adopted it widely.

Other options, such as diluting the patient's blood with a salt solution while collecting several units at the start of a surgical procedure, generally save a unit of blood or less and are not cost-effective. Units of blood donated by patients several weeks ahead of surgery do save the need to call on the community blood supply as often. However, not all patients are in sufficiently good health to donate, and unused units do not augment the blood supply.

Is medical practice likely to change sufficiently to avoid or delay the projected shortfall in blood availability? Physicians and surgeons have become accustomed to a safe and readily available blood supply. It is difficult to make the argument to a physician that he or she should increase the risk of a heart attack in his or her patient in order to maintain the blood bank's inventory so that another patient might have blood available. Increasing the knowledge base of clinicians about appropriate transfusions would tend to decrease usage, but this will require concerted effort of the entire medical establishment, and there are just too few medical specialists in transfusion medicine to accomplish this.

What is needed? The medical community will likely acclimate itself to blood shortages through increased internal audits of blood transfusion decisions in each hospital. This committee and Congress could provide assistance in a variety of ways. I would make a plea for funds for research and educational efforts, and I would ask that when the American Association of Blood Banks comes before Congress each year to define areas in which heightened research activity would be beneficial that Congress accept these recommendations with the knowledge that all in society will benefit from these advances.

Furthermore, Congress can provide needed assistance to us today in our mission by serving as the voice of the people, by helping to define for the blood banking community what society expects from its blood supply.

When the requirements of increased safety and tightening availability conflict, how should choices be made? The FDA, chastened by retrospective criticism of decisions made over 15 years ago, always opts for increased safety, regardless of the costs and with scant attention on supply. Many in our field believe that the public still expects the impossible, a risk-free blood supply. The public's attention to AIDS and hepatitis is focused on minuscule or improbable infectious risks while missing much larger opportunities to make transfusion safer, such as methods to ensure that units are transfused to the right patient.

A clear statement of understanding that safety and availability may have opposing elements and a clear acceptance that a certain level of risk is unavoidable would help all blood bankers and transfusion specialists deal with the reality of our situation productively.

In the same manner, I believe that Congress should recognize that blood is indeed different than other medical commodities. Including its provision in underfunded Medicare prospective payment systems and expecting that the free market will resolve all ills in the blood supply system is mistaken. Heaping additional safety requirements on the blood supply system by Federal fiat without providing specific financial resources to accomplish these tasks creates unresolvable conflicts in the blood collection system. In the end, that constrained system must choose between measures that will augment safety or that will augment supply, a Hobbsian choice that none of us wish to make.

I will urge that the important and sacred place that this precious donated human research has in the medical care system be recognized so that the public's desire for a safe and adequate blood supply can be met.

Thank you.

[The prepared statement of James P. AuBuchon follows:]

PREPARED STATEMENT OF JAMES P. AUBUCHON, PROFESSOR OF PATHOLOGY AND MEDICINE, DARTMOUTH-HITCHCOCK MEDICAL CENTER

Good morning. My name is James AuBuchon. I am a physician and a professor of Pathology and Medicine at Dartmouth Medical School. I am also the Medical Director of the Blood Bank and Transfusion Service of Mary Hitchcock Memorial Hospital in Lebanon, New Hampshire. I appreciate the opportunity to offer the perspective of a physician who specializes in transfusion medicine in considering blood safety and availability.

Those of us in transfusion medicine are pleased—and I am sure that our patients are grateful—that receiving a transfusion today has less risk than *ever* before. Re-

duction in the risk of viral transmission has occurred through the diligence of oversight on the part of regulatory bodies, such as the FDA, and through the dedication of thousands of medical, technical and administrative professionals in blood centers and hospitals. Early information suggests that when appropriately selected volunteer donors are tested with the most advanced technology, there is virtually no risk that their donated blood units will transmit the two most feared viruses, HIV and hepatitis C.

This incredible success story has created new problems for us and for our patients, however. Dramatic reductions in the risk of HIV have fueled public anticipation of transfusion without *any* risk. However, continual focus on one type of risk—viral infections—prevents a rational prioritization according to where the greatest residual risk remains. Reducing the risks of transfusion also encourages transfusion in situations where the predictable benefit is smaller. The consequential increase in demand for blood comes at a time when the demands for increased safety and other factors have reduced the availability of blood. The intersecting interests here are clear, particularly when an inadequate blood supply becomes a *safety* risk for a patient who cannot get a needed transfusion.

Transfusion medicine specialists direct much of their consultative efforts into ensuring that transfusions are clinically indicated. Many clinicians view us as the "blood police" because of our attempts to enforce protocols designed to ensure that this precious, scarce—and potentially dangerous—resource is used wisely. It is commonly accepted amongst our fraternity that many transfusions cannot be justified medically. For example, several studies of the use of plasma have shown that at least a third of plasma transfusions do not occur in situations where the plasma confers benefit, and approximately 10% of red cell transfusions fall into the same category. We face three major hurdles in reducing these proportions.

1. *Information.* We simply do not have enough data about the effects of transfusing all the different kinds of blood components in all the different kinds of clinical situations in which they may be applied. As a result, many transfusion decisions are made based on guesses, hunches and personal experience. Studies indicate that a conservative approach to transfusion uses less blood in the end, results in exposure to fewer donors, and is associated with better patient survival. Clearly more clinical research is needed to define when transfusions should—and need not—be given.
2. *Patient Variability.* Compounding the problem of inadequate research in this field is the inherent variability of patients. Not only are babies different from octogenarians, but not every 80 year old man is the same. What may be a safe level of anemia that does not require treatment for one may be a lethal anemia for another. Medical science does not allow us to know enough about each patient to make well-founded individual decisions. The consequences of not transfusing when needed are immediate and catastrophic, whereas the consequences of transfusing when not needed are distant and only "remote possibilities"; hence, physicians frequently err on the side of treatment. Indeed, there are concerns that, in some circumstances, physicians are undertransfusing, that is, withholding transfusion when it would be beneficial, because of overstated fears about infectious transmission. We must be careful to strike an informed balance between risk and benefit.
3. *Education.* In attempting to change transfusion behaviors, considerable trust must be developed in the transfusion medicine specialist by the clinician; this must be followed by the investment of considerable time for prompt clinical interactions to re-direct the clinician's practice. Many studies have shown that ongoing interactions with clinicans can have a positive impact. However, there is no support for this activity, and only academic medical centers have the trained staff and anything close to sufficient time to attempt this effort. The monetary savings to the institution for reducing component usage will probably not justify the many hours of physician time required. The benefits of clinical consultation that my transfusion medicine colleagues and I can offer patients are just not available in most hospitals.

Given the demographics of our population, the blood supply situation is only going to get worse. A study by the Office of Technology Assessment 15 years ago noted that while 12% of the population was age 65 or over, this segment accounted for 22% of all hospital admissions and 45% of all transfusions. The "graying of the population" will not only accelerate blood usage but also reduce the number of available donors. Fifteen years ago, there were 8 qualified potential donors for every potential recipient. In ten years, it is estimated that this ratio will have dropped to 3:1, expanding the difficulties in recruiting enough blood donors.

We may already be seeing the tip of this iceberg with the recent data developed by the National Blood Data Resource Center, presented today by Marian Sullivan.

Will the periodic shortages we have been experiencing with increasing frequency become perpetual? Will the trends of increasing usage and decreasing availability soon combine to cause the death of a patient needing transfusion? What can we do to forestall this?

Others will be speaking on efforts to increase blood recruitment success. As one who formerly directed a blood center, I will only offer the comment that recruitment efforts take place in the societal milieu. Clearly, societal attitudes about public service and volunteering have changed over the last several decades, and these changes place additional challenges before donor recruiters. The increasing workweek and the pressures for efficiency stemming from global competition make availability of donors at the workplace more difficult as well. Unfortunately, these challenges must be faced with decreased resources as blood collecting agencies are deferring more donors than ever before and spending greater proportions of their resources on testing—all at a time when hospitals are demanding reduced costs because of *their* financial pressures.

What can be done to reduce blood usage? Frankly, I do not hold out the promise of significant reduction in usage because of the advancing age of the population and because of increased aggressiveness of a wide variety of therapies that require transfusion support. Greater use of autologous blood options is attractive but impractical in the current environment. Most approaches to autologous therapy are more expensive than depending on the (very safe) community blood supply. Until this blood supply is so short or undependable that elective surgery is frequently postponed, most will not opt for this approach. Furthermore, since an increasing proportion of patients are treated under some type of fixed payment system, hospitals have a strong financial incentive not to use more-expensive approaches. Indeed, the shortage may have to reach critical proportions before these alternatives are widely used. It is unlikely that one hospital would invest in a more-expensive but blood-conserving approach in order to increase the community's blood supply to be shared amongst hospitals that have maintained a less-expensive system.

Some blood conservation mechanisms are now fairly common in larger hospitals, and these do decrease reliance on the community supply of blood. For example, using equipment to recover red cells lost in surgical wounds for reinfusion back to the patient can decrease the transfusion of banked blood by 50% or more in cases that often require blood, such as cardiac, vascular and orthopedic surgeries. If the patient requires more than about two units of blood, this option may actually save money. Smaller hospitals find only occasional use for this equipment, however, and have not adopted it as widely. Other options, such as diluting the patient's blood with a salt solution while collecting several units at the start of a surgical procedure, generally save a unit of blood or less and are not cost-effective. The future advent of oxygen-carrying solutions will allow collection of more blood while keeping the patient's oxygen carrying capacity at a safe level, but the expected high cost of these solutions will not make their widespread use feasible in the current financial climate; even in cases with large blood losses, the savings to the community blood supply are very modest. Units of blood donated by patients several weeks ahead of surgery do save the need to call on the community blood supply as often. However, not all patients are in sufficiently good health to donate; unused units do not augment the blood supply since most patients either do not qualify as community blood donors or their units were collected sufficiently far enough ahead of surgery that little time remains after surgery to use them for another patient.

Is medical practice likely to change sufficiently to avoid or delay the projected shortfall in blood availability? Physicians and surgeons have become accustomed to a safe and readily available blood supply, and new surgical techniques or chemotherapies are not sidelined because of a projected increased need for blood support. Certainly, more appropriate usage would reduce the demand a significant degree. However, it is difficult to make the argument to a physician that he or she should increase the risk of a heart attack or other bad outcome in his or her patient in order to maintain the blood bank's inventory so that another (unnamed, unknown) patient might have blood available. Increasing the knowledge base of clinicians about appropriate transfusion therapy would tend to decrease usage, but this will require concerted effort of the entire medical establishment. There are too few transfusion medicine specialists, concentrated primarily in academic medical centers, and there are too few resources to make a broad impact on medical practice in the short run.

What is needed? The medical community will likely acclimatize itself to blood shortages through increased internal audits of blood transfusion decisions in each hospital and educational efforts to reduce the demand for blood. This Committee and Congress could provide assistance in a variety of ways. I would make a plea for funds for research and educational efforts, and I would ask that when the Amer-

ican Association of Blood Banks comes before Congress each year to define areas in which heightened research activity would be beneficial that Congress accept these recommendations with the knowledge that all in society will benefit from these advances. Furthermore, Congress can provide needed assistance to us today in our mission by serving as the voice of the people, by helping to define for the blood banking community what society expects from its blood supply. We in the field will continue to strive for increased safety and improved availability regardless of the outcome of this Committee's deliberations. However, when the requirements of increased safety and tightening availability conflict, how should choices be made? The FDA, chastened by retrospective criticism of decisions made over 15 years ago, always opts for increased safety—regardless of the cost and with scant attention to the effect on supply. Recent decisions regarding the potential for transmission of spongiform encephalopathies through transfusion are an example of this. Many in our field believe the public still expects the impossible, a risk-free blood supply. The public's attention to AIDS and hepatitis has focused us on minuscule or improbable infectious disease risks while missing much larger opportunities to make transfusion safer, such as methods to ensure that units are transfused to the right patient. A clear statement of understanding that safety and availability may have opposing elements and a clear acceptance that a certain level of risk is unavoidable would help all blood bankers and transfusion medicine specialists deal with the realities of our situation more productively.

In the same manner, I believe that Congress should recognize that blood is indeed different than other medical commodities. Including its provision in underfunded Medicare prospective payment systems and expecting that the free market will resolve all ills in the blood supply system is mistaken. Heaping additional safety requirements on the blood supply system by federal fiat without providing specific financial resources to accomplish these tasks creates unresolvable conflicts in the blood collection system. In the end, that constrained system must choose between measures that will augment safety or that will augment supply, a Hobbsian choice that none of us wish to make. I would urge that the important and sacred place that this precious, donated human resource has in the medical care system be recognized so that the public's desire for a safe and adequate blood supply can be met. Thank you.

Mr. UPTON. Thank you very much.

Mr. Cox.

Mr. COX. Thank you very much.

In particular, Dr. AuBuchon, your testimony has left us with a strong focus on concerns that we have about the safety of transfusions themselves and about receiving blood. But, just for openers, I want to make sure I have everybody's agreement that, in the United States today, the act of giving blood does not present risks to the donor. That is an exceptionally safe thing for every American to do; isn't that right?

Mr. AUBUCHON. That's absolutely correct. There is no way that the donor can get any infectious disease from the donation process. They will get coffee and cookies, but that's all they will get.

Mr. COX. While we are at it, because this is an open and most public hearing that the American people will pay some attention to, how often can one donate blood safely?

Mr. AUBUCHON. FDA regulations require donation no more frequently than once every 56 days or 8 weeks. That's based on the need for the donor to replenish their red cell supply. Other kinds of donations such as platelets or plasma can be given on a more frequent basis.

Mr. COX. You could, if you wanted to be especially public-spirited, donate blood 4 or 5 times a year completely safely.

Mr. AUBUCHON. Indeed, you could donate theoretically up to 6 times a year. Unfortunately, most American donors donate, however, once or, at most, twice a year. There are a few committed ones who donate at least a gallon each year, but most do not.

Mr. COX. Before I leave this topic, because I just want to make sure that everyone understands our object here is to encourage people to donate blood so that we can increase the blood supply and avoid the problems that Ms. Sullivan is warning about, a possible blood shortage for the whole country, what percentage of the eligible American population is it our best guess currently donates blood on a regular basis, at least once a year?

Ms. HEINRICH. The best information that we have is that 5 percent of the eligible population is giving once a year.

Mr. COX. So it's even worse than voting?

Ms. HEINRICH. Yes.

Mr. COX. By a lot. And 95 percent of eligible Americans aren't yet doing the patriotic thing and donating their blood, and we all on this panel and all of you on that panel——

Mr. UPTON. That's until we pass campaign finance reform.

Mr. COX. [continuing] hope that this happens.

Mr. Roslewicz, the Inspector General's report from 1995, which I've just again reread, uses the word expedite. And how did that word get in the report in 1995?

Mr. ROSLEWICZ. Okay. The process we use when we are conducting an audit is to submit a draft report for comments to the agency before we finalize it; and FDA, when they responded to our draft report—we didn't use the word expedite in the recommendations. We said FDA should just establish a timeframe.

FDA had already, during the course of our audit, been working on making some revisions to the error and accident blood reporting process, so they asked us if we would in our final report use the word expedite, which would then sort of—not sort of—it would show that they were in fact trying to correct the system and make improvements to it.

Mr. COX. Was that the Public Health Service?

Mr. ROSLEWICZ. It was the Public Health Service. At the time, Public Health Service was the oversight agency for all of the PHS agencies. So the Public Health Service Assistant Secretary would have responded for Food and Drug Administration back in 1995. Today, FDA would respond themselves to the draft report.

Mr. COX. So when they reviewed your draft report. They said, put in the word expedite, which according to its plain English meaning suggests hurry it up——

Mr. ROSLEWICZ. Exactly.

Mr. COX. [continuing] get it done?

Mr. ROSLEWICZ. From what they told us, they're already working on it. They had anticipated getting the proposed regulation out in November 1995.

Mr. COX. They wanted this new regulation out because there were a lot of people that aren't reporting either promptly or at all errors and accidents. And by errors and accidents we mean, for example, the release of blood units that are repeatedly reactive to tests indicating, for example, hepatitis or HIV? And we've all understood from your testimony that this doesn't happen all the time. It's rare that you would have to do a recall.

But in order to determine when a recall is in order, you've got to have that information. If they don't send you timely reports, then FDA cannot function as an oversight agency.

In order to fix this problem which you've identified a half decade ago, you recommended with the concurrence of the Public Health Service that the new regulations be expedited, and so they originally said that they were going to do it many years ago, and now they're talking about doing it in 2001. Now, when we live in this high-tech age where everything changes very, very fast, complex inventions are created and deployed in months, certainly a year or two would be adequate to do most complex things in our society.

Why is it that the bureaucracy needs nearly half—this would be more than a half decade by the time they're done on their schedule—to read the comments and issue the regulation that originally they said should be expedited to deal with something as important as the safety of our blood supply?

Mr. ROSLEWICZ. Okay. We have the same question. When we went back in August of this year, at the request of the committee to ask that very question, we were told that they had multiple priorities going on at the same time.

Mr. COX. Did they ever tell you what they were?

Mr. ROSLEWICZ. No, we don't know what those priorities were.

Mr. COX. Do you believe the FDA commissioner when she says that safety of the blood supply is a top priority?

Mr. ROSLEWICZ. Do I believe her? Yes, I would certainly believe her.

Mr. COX. Even though it's taken a half decade to get this reg out?

Mr. ROSLEWICZ. This is something—FDA would have to respond to that better than I can. But my concern would be that, if there are these priorities, what are they? We would have to go back and do an audit to get you specific information. But, you know, we have not audited that specific aspect of what's happened after the issuance of our report.

What we do do, though—we have in our organization, in the Inspector General's Office, what we call an Orange Book. In this Orange Book are all the unimplemented recommendations that we have made to the various agencies within our Department. And this Orange Book repeats these findings and recommendations year after year until they are either implemented or resolved in some manner.

This particular report has been carried forth in all of our Orange Books, which is provided to the Congress as well as to the various components within our Department. So we do try to follow-up and make sure that these things don't fall off the scale. In this particular case, FDA is going to have to explain to you why it's taken so long. I can't speak for the FDA Commissioner.

Mr. COX. I thank you. And I thank you, Mr. Chairman.

I especially want to thank our panel for your obvious interest in this subject, making sure that our blood supply is safe and that it's there that we don't have that shortage next year that Ms. Sullivan is warning us about.

Mr. UPTON. I would just note for the record that we've invited the FDA commissioner to come testify this next month when we continue these hearings.

Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman, and I thank the panel.

Mr. AuBuchon, during the early 1990's, primarily we think because of fear of contacting HIV, we found that many patients and families of patients contributed blood, for example, prior to surgery and thereby increased the blood supply. My understanding is that that practice has fallen off rather dramatically, and I was wondering if it was your feeling that we should encourage that kind of behavior as a way of releasing our supply of blood?

Mr. AUBUCHON. Preoperative blood donation became increasingly popular as the public's fears about HIV in the community blood supply increased from the mid-1980's through the early 1990's. Because of the public's recognition of the increased safety of the blood supply, beginning I would think in about the early 1990's, there was less motivation for patients to donate blood. It takes considerable motivation on the part of a patient to donate blood as they're preparing for elective surgery.

And I think the understanding that the blood supply today essentially does not carry the risk of transmitting HCV or HIV, that the public is less interested in doing that. Once the community blood supply becomes so short that a patient may not be able to reliably schedule elective surgery, then there will be additional motivation for autologous donation. Until that happens, I think we will see a decline in preoperative autologous donation.

Mr. STRICKLAND. The second question for you, Doctor. In your testimony you talk about a lack of transfusion protocols that clearly define when a transfusion is appropriate, when it may not be necessary in medical situations. Why is it important that such protocols be developed and who should be responsible for the development of such protocols?

Mr. AUBUCHON. Medicine attempts to be science or data driven as much as possible, and any physician wants to know when he or she should apply a particular therapy or when it's not appropriate. Although I believe I'm up to date on medical literature in terms of transfusion, when I speak with a surgeon or a physician about when to transfuse, I almost never have absolute data in my back pocket to say clearly this situation has been studied and I can show you precisely that you should take the following course of action. I usually have to refer to studies that are similar and deal with patients who are in a similar situation, and we have to make our best guess jointly.

Sometimes we guess wrong. The physician in charge of the patient does not want to avoid transfusing a blood component and risk a very serious outcome when the risk of transfusion is so low. If I go to a physician and say, if you don't transfuse this patient, he will do fine, and the surgeon may ask me what is the risk he will have a heart attack, and I will say it's probably very low. He says, one in a thousand, one in 10,000, what's the risk in AIDS, one in a million.

Given those choices, the surgeon is going to transfuse. This will make the blood supply safer. The surgeon is going to move into that direction. So we need more data in order to establish a scientific basis for transfusion medicine.

Mr. STRICKLAND. I think what you're describing is the practice of the art of medicine versus the science of medicine, and that's why I believe medical decisions need to be made by persons who are trained physicians, not only in this situation but across the delivery of our medical services.

In recent times, medical science has made great advances. And I'm wondering, in your judgment, are we approaching the point where blood substitutes may be practical as a way of increasing our supply and, if so, would you estimate when such practices may become cost-effective so that they could effectively alleviate concern about shortages?

Mr. AUBUCHON. I gave an hour-long lecture last week on that topic with 60 slides. I won't go into that detail for the subcommittee this morning.

I do not believe that blood substitutes are going to make a major impact in the near future. There are artificial blood-carrying solutions for fluorocarbons which may be used in some surgical situations to allow hemodilution immediately before surgery. However, for most patients, they are likely to save less than a unit of blood. The hemoglobin-based oxygen carrying solutions have a little further to go, I believe, before they are potentially licensable by the FDA.

The problem is that their source of blood is going to be primarily human blood. There is not much outdated blood today, and with loss of hemoglobin in the preparation, there will not be a lot of this hemoglobin-based oxygen carrier solution available. It will also be extremely expensive. So I do not see these, quote, unquote, blood substitutes playing a major role in transfusion therapy in the near future.

Mr. STRICKLAND. Thank you.

And, Dr. Heinrich, getting to this issue of preventing individuals who may have spent 6 months in the UK from donating blood because of the fear of the human form of the mad cow disease and given Dr. AuBuchon's contention that sometimes we focus on the least effective ways of increasing safety and neglecting others, looking at the loss that we would experience in the blood supply as a result of that decision, do you think it's justified and should we rethink whether or not that's a good practice?

Ms. HEINRICH. From the data that GAO collected, we found that there's an estimate that we would lose about 2.2 percent of units. It's our understanding that the various science advisory committees through FDA and the Public Health Service have said that, in terms of the science, we don't have all of the facts yet in terms of the possible transmission of a new variant CJD. And in terms of the timeframes, I think that the thinking was that 6 months is reasonable in terms of the kind of time, amount of time that one would have to have been in the UK.

I think that the Department is also going to be continually monitoring this decision. They're going to be looking at this on a regular basis, to see if, in fact, there's a problem with the supply or if there's anything new that comes up in terms of science.

Mr. STRICKLAND. Mr. Chairman, could I ask just one quick follow-up with Dr. AuBuchon? Is that an example of where we may be focusing on an issue that has very minimal risk and thereby

perhaps not focusing or neglecting to focus on things that could be done that would have much greater impact on the supply?

Mr. AUBUCHON. Precisely. The risk of transmission of CJD through the blood supply is clearly there. It's a potential possibility. It's my diligent effort to find it amongst individuals who have come down with new variant CJD and were prior blood donors. No cases of transmission have been found. Yet every year in this country data from the FDA and data reported to the New York State Department of Health document that we kill 2 dozen patients by giving them the wrong unit of blood, yet there's no discussion of that.

Mr. STRICKLAND. Thank you. Thank you, Mr. Chairman.

Mr. UPTON. Thank you, Mr. Strickland.

As I listen to the testimony—first of all, I appreciate again your testimony. And I just—the first question off the top of my head here, Ms. Sullivan, is, as you all through the NBDRC begin to collect monthly data next year, I would appreciate it if you could supply this committee with your results on a timely basis so we can continue to monitor this. If that would be possible, it would be terrific.

Ms. SULLIVAN. Certainly.

Mr. UPTON. I'm a blood donor. But I will confess it has been a little—when I get over this cold, I've already instructed my staff to sign me up in Michigan.

Dr. Heinrich, I listened to your testimony. You indicated that there was not a crisis, we are not in a crisis mode now, but in fact we are below a comfort level in many regions of the country, and in some cases, I would suspect that it's less than a day supply; is that right? How do those two statements comport instead of conflict?

Ms. HEINRICH. What we did is we looked at the overall numbers and found that, indeed, the decrease has been primarily in the autologous and directed donations, so that the community supply for blood overall, the decrease has been about 2.2 percent. We have heard again anecdotally that there are some regional shortages at some times of the year and certainly for certain blood types, the rare types O and B.

But on the other side of the equation is the fact that the ability of our major blood banking systems, the ability to shift blood from areas, regions where there are surpluses to areas where there is a need, seems to have made our system run rather efficiently to meet the demands.

Mr. UPTON. I know Richard Burr, who is the vice chairman of this subcommittee, represents North Carolina; and I believe a number of counties in his district are flooded.

Ms. HEINRICH. Yes.

Mr. UPTON. And I heard a report earlier this week on the news that, in fact, those areas impacted by the flooding—I suspect they would include New Jersey and some other places I've seen as well—have real trouble. And you believe then at this point from your overview that, in fact, those areas are covered sufficiently in terms of supply from other parts of the country?

Ms. HEINRICH. Our information would say that these national systems are able to accommodate regions when there is this kind of shortage.

Mr. UPTON. Mr. Roslewicz, what is the shelf life of a pint of blood after it's given until it has to be disposed?

Mr. BILBRAY. Whole blood.

Mr. ROSLEWICZ. Whole blood? I would have to defer to a doctor. I don't know the answer to that question.

Mr. UPTON. Dr. AuBuchon.

Mr. AUBUCHON. Whole blood itself can be stored for up to 35 days. Most units of whole blood are separated into red cells and the plasm. The red cells can be kept for 42 days in the liquid state.

Mr. UPTON. The question, now that we have that answer, is, you indicated in your testimony that in terms of safety, in essence, only about 14 percent of the errors were reported in the first 30 days, which means that 85 percent are reported after 30 days; is that right?

Mr. ROSLEWICZ. That's correct. As a matter of fact, another 13 percent are reported 6 months or later into years. So you have—there's a lot of—and it raises the question of, when you get a report that is a year old, sort of like getting an audit that is a year old, what good is it if you haven't had it when the incident happened; at least as early as possible, in order to make sure that the blood establishment took the proper actions to correct the problem.

That's one of the reasons why I think it's important that they get these reports more timely, so that they can in fact make sure that these blood establishments are acting appropriately. There are close to about 3,000 of them out there. Any one of these 3,000 institutions could have some kind of an error or accident and it could happen daily. Without knowing exactly what the accident was and what actions were taken to correct it, it becomes questionable when a report comes in a year later as to the value of that.

I realize in their proposal that they issued in September the FDA is recommending a 45-day maximum reporting period. That's something that FDA proposed—we did not give them what we thought was a reasonable period of time. But the issue you're raising about the shelf life is certainly something I think FDA needs to consider when they're making a determination.

Mr. UPTON. Do you know, though, if that consideration is going to be taken into effect with their proposed regs that they're planning to issue in 1901? Will they be looking at some gauge or standard to shorten that timeframe in terms of the error rate?

Mr. ROSLEWICZ. I hope they would do that. I haven't talked to them specifically about how they came up with the 45 days. It was something we did not do as part of the audit that we are testifying on today.

Mr. UPTON. Okay.

Mr. ROSLEWICZ. So I'm not sure as to what their basis was for the 45 days.

Mr. UPTON. Mr. Bilbray?

Mr. BILBRAY. Yes, Mr. Chairman.

Ms. Sullivan, speaking to the FDA on the process—and I guess we were just talking about them trying to get their reports and their status-front loaded so you can respond to them. You know, I

look at 6 years being called expedited by the FDA and, you know, you kind of say, well, they were busy doing other things. And I guess, Dr. AuBuchon, it was probably because they've been blocking this licensing of blood substitutes as it goes through the process.

I want to know when we get into this kind of a situation where we are being projected with a 2.2 reduction, do we have any strategy or is there any program being brainstormed to how they respond to get the public to respond to the crisis, if the crisis is created? And, Doctor, if you want to answer that, I'm sorry, I directed that to Miss Sullivan, but for any panelist.

Ms. HEINRICH. The Department of Health and Human Services, the HHS, has recommendations.

First of all, they feel that it's very important to increase the monitoring, and I think we've heard that that is ongoing. There are recommendations to increase donations from the existing donor pool. There are recommendations to increase the donor pool since only 5 percent of those eligible are donating now. There are recommendations to improve donor relations, to develop public service announcements and to do studies so that we better understand the incentives for giving blood.

And another one of their recommendations, there are a few others, but another one that I think people feel is very important is to address the economic issues that are facing our blood collection centers.

Mr. BILBRAY. My biggest concern is that if we really do have a plan that can be initiated as quickly as possible and to raise the public awareness—I mean, obviously, we could have—I know a lot of people would love to see Congress and the administration laid out on a gurney donating blood, and maybe more than we prefer, but that kind of public awareness, the ability to kick in that kind of program high enough, has anybody talked about that kind of high-profile response?

Ms. SULLIVAN. Certainly. Within the private sector, the American Association of Blood Banks, also America's Blood Centers, and in fact a lot of the individual blood centers themselves have such plans, but resources are very limited. Obviously, education recruitment campaigns are very important. Plans have been developed particularly targeted to the younger generations, which is a considerable concern with respect to generating and encouraging new blood donors. And what is essentially needed are additional resources to support these education and recruitment campaigns.

In addition, there are—there has been a lot of discussion of research activities, additional data collection activities that need to be undertaken to reduce the knowledge gap. Certainly research involving today's eligible blood donors, who gives blood, who doesn't give blood, why they don't give blood, how incentives factor into their blood donation decision, and then certainly the application of appropriate interventions and the effect of these interventions,these are all issues that we would all love to tackle if the resources were available.

Mr. BILBRAY. I would just ask, when you say resources, that we traditionally around here always talk spending more money on a new program rather than tapping into resources that are out there

already. The public relations and the public information—the public awareness potential that exists in this city and the ability for, you know, representatives from the city to go throughout the entire Nation on a "weekend" to raise that awareness, but that kind of coordinated effort, that, you know, popularizing, the whole issue has never been one—you see the President in foreign countries, but you don't see him on the in the West Wing giving blood. It may be one of those things that we talk about as a way—let's use this crisis as a way of raising it.

The trouble is, we've got the problem, and, Dr. AuBuchon, we expose the risk of expanding the universe of blood donors. Is there—and my question is, is that a higher risk or a lower risk than utilizing those who have been in the United Kingdom and maintaining that pool?

Mr. AUBUCHON. You raise a good question, because whenever we defer a donor for whatever reason, that donor ultimately has to be replaced, if the supply is going to be maintained. And particularly when we are talking about deferring a relatively large proportion, say 2 percent of the donating population, we will have to replace them to some extent by new donors.

New donors are known to be the riskiest donors, because they have not been previously tested for infectious disease markers, and their reasons for donating may not be as altruistic as the return repeat donor.

We would like to see the donors that we have donate more frequently, but we realize there are economic pressures, social pressures and the like that not everyone is going to donate every 8 weeks. So we have to balance the risk involved in every decision.

Mr. UPTON. Excuse me just 1 second here. We have a series of votes. We have only about 4 minutes to go. I'm not one of those folks to miss votes. We will temporarily stop the proceedings, and we will come back at quarter of.

[Brief recess.]

Mr. UPTON. I don't have to set the clock. We've got lively debate on the House floor. And we have a markup that's going on in another subcommittee, so members will probably be in and out.

I have a couple more questions that I would like to ask.

One, there's been a lot of attention with regard to this mad cow disease, and with the new proposal that's on the table, which is going to be implemented, a 6-month exclusion over a period of, what, 16 years, I guess it is. The estimate has been 2.2 percent in terms of the drop-off of donors. Do all of you agree that that is probably about right?

Ms. HEINRICH. When GAO did its data collection, we tried to verify the numbers of people that go to the UK in any year. And in terms of the numbers of people—and this was the American Red Cross survey that gave us the estimate of 2.2, that this new regulation would affect about 2.2 percent of the supply. We think that that's pretty reasonable.

What you don't know, though, is whether people, as this is publicized, how people will really respond to this. Will it increase people's concern and, therefore, they will not donate as they have in the past?

Mr. UPTON. One of the—Ms. Sullivan.

Ms. SULLIVAN. If I could also add.

Mr. UPTON. Let me just clarify, too. When did that—when does that new regulation hit? Is it soon?

Ms. HEINRICH. Now.

Mr. UPTON. It's now. And when did it take effect?

Mr. AUBUCHON. Now.

Ms. SULLIVAN. As soon as they can begin.

Mr. UPTON. August 17. Okay. Go ahead. I'm sorry to interrupt.

Ms. SULLIVAN. The Red Cross data, the 2.2 percent primarily applies to whole blood donations. But it's also important to realize that apheresis—there also will be a hit on apheresis donations. Nine million platelets are transfused in this country each year approximately and, of those, about ⅔ are collected by platelet phoresis. These donors actually donate, for the most part, more frequently and I have heard the figure, an average of 10 to 12 times per year. So the deferral could in fact hit that group even harder than the whole blood donor. So this is also something to consider.

And also we can't really take into account without any data at this point, the effect, the indirect effect or the self-deferral of donors who hear that they're deferring donors who have traveled to the UK, don't completely understand the deferral guidance, and they simply don't show up at the blood center because they assume that they landed in London 1 day, they may be deferred as well. So there will be probably an indirect effect as well.

Mr. UPTON. Now, your studies, when they commence next year, how quickly will you be able to ascertain whether that 2.2 percent figure was correct, do you think?

Ms. SULLIVAN. Well, we are hoping to be including some blood centers in our blood center sample that will be beginning some blood centers that will initiate the deferral or implement the deferral very soon, like before the end of the year.

Mr. UPTON. Before the end of 1999 or before 2000?

Ms. SULLIVAN. Before the end of 1999. It will take some other blood centers longer to implement the deferral. They have to make changes in their SOPs, in their blood donor forms, their donation records. So they won't all begin essentially immediately or even within the next 30 days or so. But we will try and include some blood centers in our sample that are coming on-line early with the implementation of that deferral and try and get data as soon as we can.

But it will be pretty limited. It will probably be 6 months or so before we have a sense.

In addition, those data will need to be compared with data from the previous year, from the period when the deferral was not in effect by month. So we will need to go back retrospectively and collect some additional monthly data probably from last year for comparison.

Mr. UPTON. Dr. Heinrich, you indicated in your report that—I mean, this is fairly well-known, that O and the B donors or that blood supply is the shortest. I happen to be A. My wife would—I'm not going to get into that. Why is that? Is there any reason why O and B are traditionally on the short end of the stick?

Ms. HEINRICH. I would actually defer to Dr. AuBuchon on this.

Mr. AUBUCHON. There are several reasons for that.

First of all, group O red cells can be transfused to any patient regardless of their ABO group. So in situations where we need to transfuse emergently, we don't have time to determine the ABO group. Or in some particular circumstances, such as in neonatal intensive care units, group O is the preferred type of blood to transfuse. That places a heavier burden on group O donors, which I happen to be one. And blood centers frequently call them to donate.

Group B is in shorter supply than one might imagine, primarily because group B is more commonly seen in African Americans than in Caucasians. About 20 percent of African Americans are group B and only about 9 percent of Caucasians are group B. For whatever reason, the donation message is not received as well in minority communities. We are not as successful in recruiting blood donors from minority communities. So we are undercollecting group B in comparison to our use of group B.

Mr. UPTON. On page 2 of the GAO report, it states that about 4 percent of the allogenic blood supply expired without being transfused. Why would it have expired before it was shipped, do you know? Do you know the reason behind that?

Ms. HEINRICH. Why?

Mr. UPTON. Why would the shelf—I presume it's because it was there too long, right?

Ms. HEINRICH. I think that that would be the usual. Would you have anything more to say with that?

Mr. AUBUCHON. Yes, Mr. Chairman. About half to two-thirds of those expiring units are group AB, which, although it's the rarest type of blood, can only be given to group AB recipients, and since there are so few of those and their needs can be taken care of by any other blood group, the AB blood is more likely to outdate.

The remainder are primarily group A, which, for the same reason, are usually only for group A recipients. So it's not a matter of logistics or having a better system to move the blood around. It's primarily this blood is just not needed.

Ms. HEINRICH. The demand.

Mr. UPTON. I understand. Thank you for that clarification.

The GAO criticized the National Blood Data Research Center projection that the demand would outstrip available supply next year because the projection relied on the study that overstated the decline in blood supply. However, GAO noted that the supply of the imported blood decreased—allogenic and imported blood decreased 2.1 percent. The community supply decreased by 2 percent, and that same portion of losses in autologous and directed donations would have to be replaced by units from the allogenic supply.

Given those decreases and the expected loss of 2.2 percent because of the mad cow, isn't it still possible, do you think, that the demand could exceed supply next year?

Ms. HEINRICH. I think that the supply and demand of the blood system is very dynamic. And, as we've heard, recently some blood centers have said that their donations are up. We have to remember that this is data from 1997. So there are a number of unknowns on the supply side and, as we discussed, there are also a number of unknowns on the demand side.

Mr. UPTON. Ms. Sullivan, would you like to answer that? Or Dr. AuBuchon?

Ms. SULLIVAN. We certainly maintain that a nationwide shortage could occur as early as next year, and we base that on the data that we collected.

I would like to make a couple of points. To paint a picture of the U.S. blood supply that does not fully include autologous and directed donations, as the GAO has suggested, because they are pulling the curve down essentially faster than it should be, simply doesn't tell the whole story, and that's why we felt they needed to be included.

Second, we think that it is clear, regardless of how you cut the numbers, that donations—if donations continue to decrease and usage is increasing, as it's likely to do, then the lines will eventually intersect, and whether it is next year or 5 years from now, we still need to take the same steps, we believe, to monitor the blood supply and avoid the situation.

And we—as I announced today, we are taking steps to collect more recent data as quickly as we can, data from 1998 and 1999, that will enable us to refine our estimate of the available supply for 2000.

Mr. AUBUCHON. Red cell use at our hospital had remained constant or slightly declined each year over the past 6 years. On average, about half a percent declined per year. I might like to take credit for that for working with our clinicians about better blood usage, but I'm not sure that really I can. However, in this year, our red cell usage has gone up 5 percent, and that's without the addition of any new clinical programs, without closure of any hospitals in the area, for reasons that we can't define. We are doing more surgeries, and it relates—our increased usage of red cells relates to that, but the reason we are seeing more patients coming to us, we don't know.

This is what is concerning to me knowing that the supply of blood is limited and may be headed downward, and it may indeed be that our usage is finally going upwards. We suppressed the usage in the mid-'80's, wringing some unnecessary transfusion out of the system. That change occurred because of some concern about HIV transmission. HIV certainly was not good, but the outcome in terms of becoming more conservative in blood transfusion was good, was useful.

I think we have done about all that we can do for the near term in that, and as the population continues to get older, we will have more demand on medical services and more need for transfusion.

Mr. UPTON. You know, as a layperson looking at the blood givers and the different things that are out there to try and remind and encourage, it's the public service announcements on radio and TV, and it's different competitions—our church does a little bulletin thing down in the basement: Next Monday, it's going to be the day.

And I know this week, when I was back in Michigan, I watched—Western Michigan University plays their big rival—which is in Kalamazoo, which is, their big rival is the Central Michigan University, so they have an annual blood drive fight. The winner, whichever campus turns in more blood gets a nice award at halftime of the game, and it's traditional.

As you've sort of looked at other communities across the country that often may be in a shortage of supply, what other things do you

think have worked effectively with the Red Cross and other groups in terms of, A, getting the message out before its dire straits like, you know, we are shipping people home from the hospital, whatever it might be? Or what other types of events have you seen that have been successful in raising the awareness of a community to let them know, in fact, there is a shortage and for folks to really come out and volunteer and donate a pint of blood?

Ms. HEINRICH. I'm sure others would like to contribute to the answer to this question.

From our data gathering, I think that's an area that we don't know a great deal about, that we really feel that we found that the experts are saying that they need more information about how to effectively put forward campaigns. And I think that there's also an interest now in finding out how to target particular populations that would be a good and dependable donor pool, if you will.

I think the other part of this is that the blood centers don't have incentives to collect more blood than they can use, and I think the balance that each center will try to achieve between blood collection, blood collection from a new pool and what they project their demand to be is a dynamic process that we don't know a great deal about.

Mr. UPTON. Are there some areas of the country that are traditionally more short than others in terms of having supply, and what are those? Where have they not done as good a job in other parts of the country by region?

Ms. HEINRICH. Our information says that New York, New York City, Miami or southern Florida, Los Angeles, San Francisco, seem to have chronic shortages. You probably want to add to that.

Mr. UPTON. Will your studies—in fact, as you do your monthly studies, will it look at region by region?

Ms. SULLIVAN. Yes. We are selecting the sample so that it will be representative by region, by size of blood center and numerous other factors so that we will be able to analyze any potential shortages by region of the country.

Mr. UPTON. Dr. AuBuchon.

Mr. AUBUCHON. If I can just offer the comment. I'm not a specialist in donor recruitment, but I have worked in blood centers in the past. I don't think there's a magic bullet to donor recruitment. There's no one single thing that will work in all communities or with all potential donors. The bottom line is that it requires people to go out and talk to people. It requires public knowledge about the importance of blood donation, which has to begin with the childhood years and working up to the time when someone can be a donor. And it requires enough organizational skill and manpower to pull together a blood drive.

I think we may be beginning to see the result of the constraints on health care spending as it's being trickling down to the blood centers. Hospitals have certainly seen difficult financial times over the last decade. They've placed pressure on all of their suppliers, including blood centers, to reduce costs.

Blood centers have attempted to do that. They've also been faced with increasing demand for new tests and quality assurance approaches, regulatory requirements and the like. So they're being hit

from that side as well. And there just isn't—there aren't as many resources as there were in blood centers as there were in the past.

I would think that recognition of the special nature of blood would be helpful and that there is an unusual commodity, it's donated. There's no payment for whole blood donation. The collection is handled by a not-for-profit blood center, community blood center or a large organization like the Red Cross, so not-for-a-profit blood center, without great resources, and the reimbursement is coming through a system that does not recognize blood as an individual cost item and yet the public is wanting more, more out of that system. So it's a difficult situation.

Mr. UPTON. Did either you or your organization, Ms. Sullivan, Dr. AuBuchon, provide comments to the FDA with regard to the new regulations that are supposed to be out?

Ms. SULLIVAN. Certainly the American Association of Blood Banks, which my company is a subsidiary of.

Mr. UPTON. It was awhile ago, you know; 1996 was when they solicited the comments.

Mr. AUBUCHON. You're speaking of comments on error and accident reporting?

Mr. UPTON. Yes.

Mr. AUBUCHON. Yes, I did personally.

Mr. UPTON. Would you be able to provide us your comments to the subcommittee?

Mr. AUBUCHON. I will try to find them in my files, yes.

Mr. UPTON. You've gotten a new computer since then, so you have got to find them.

All of us appreciate your testimony and your willingness to come up here today, sort of kicking off our series of hearings on this very important topic, and we appreciate that, providing us information that will certainly be used for questions, the FDA and others as they come up.

And if you have additional comments or thoughts, please feel free to pass them along to any members of the subcommittee and the staff. We clearly are working very closely together.

So thanks very much. You're excused. Have a nice day.

[Whereupon, at 12:10 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

AMERICAN
ASSOCIATION
OF BLOOD BANKS

2606 '97 DEC 22 P3:42

December 22, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

Re: FDA Docket No. 97N-0242: Biological Products; Reporting of Errors and Accidents in Manufacturing; Proposed Rule - AABB Written Comments

To Whom It May Concern:

The American Association of Blood Banks (AABB) appreciates the opportunity to submit written comments to the Food and Drug Administration (FDA) on its proposed rule to expand the scope of error and accident reporting requirements to include unlicensed blood establishments and transfusion services (hereinafter referred to as the FDA's proposed rule or proposal). The FDA is also proposing to alter existing regulations that currently require licensed manufacturers of biological products, to include blood and blood components, to report errors and accidents in manufacturing that may affect the safety, purity or potency of a product. AABB is the professional society for 8,500 individuals involved in blood banking and transfusion medicine. AABB also represents more than 2,200 institutional members including community and Red Cross blood collection centers, hospital based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components. AABB members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. Throughout its 50-year history, the AABB's highest priority has been to maintain and enhance the safety of the nation's blood supply.

Summary of Position

The following summarizes AABB's position on the FDA's proposed rule.

1. AABB opposes the information collection requirement **as currently proposed.**

2. AABB, however, supports the goal of identifying errors and accidents. The AABB recognizes in its own quality program the importance of a process to capture, assess,

97N-0242 C45

8101 Glenbrook Road • Bethesda, MD 20814-2749 • Phone: (301) 907-6977 • Fax: (301) 907-6895
Web Site: http://www.aabb.org • E-mail: aabb@aabb.org

investigate, and monitor events that deviate from accepted policy or procedure or that fail to meet applicable regulations and requirements.[1]

3. AABB offers and recommends for consideration an alternative model for the collection and analysis of error and accident reports.

4. AABB questions the utility of the proposal given a lack of details and information on how the FDA will analyze and use error and accident report information, on the development of a standardized and uniform data collection process, and on the specific format for the filing of information. AABB, however, supports development and implementation of a standardized and uniform data collection process. Additionally, whatever error and accident reporting program is ultimately implemented by FDA as a result of the proposed rule, it should be the single source for reporting all errors and accidents, adverse events, etc. for all blood products, all medical devices and all drugs. All other reporting programs, voluntary or mandatory, should be terminated.

5. There is a lack of clarity, specifically with regard to definitional issues. There has been no effort to comprehensively define the terms "errors" and "accidents" to ensure a uniform standard for reporting. Any regulatory action in this area should resolve ambiguities and establish a clear understanding of the terms errors and accidents. FDA should identify or define differing levels of severity with respect to errors and accidents and then adjust mandatory reporting requirements to include only the more severe errors and accidents. Less severe events should be assigned to internal QA for assessment and corrective action. AABB presents several examples of FDA defined errors or accidents which, in fact are neither errors nor accidents, and should not be reported. These examples are more effectively handled under an existing organizational Quality Assurance Program (QA) and associated Standard Operating Procedures (SOPs).

6. AABB strongly supports the use of automated data collection techniques, when and where appropriate, and other forms of information technology.

7. The AABB is concerned that the FDA may not have met its statutory obligations under the Paperwork Reduction Act of 1995. This issue was addressed in detail in AABB's written comments with the Office of Management and Budget (OMB). Those written comments are incorporated by reference herein and a copy is attached.

Background

FDA's Proposal

The AABB files these comments in response to the FDA's proposed rule. The FDA proposes to expand the scope of error and accident reporting requirements to include unlicensed blood

[1] Quality Program Implementation. AABB Association Bulletin #97-4. August 1, 1997.

establishments and transfusion services. The FDA is also proposing to alter existing regulations that currently require licensed manufacturers of biological products to report errors and accidents in manufacturing that may affect the safety, purity or potency of a product. The AABB estimates that more than 50 percent of its institutional members are not currently required to report, but will be required to do so if this regulation is enacted as proposed.

Specifically, the FDA's proposal:

- Further defines the terms "error," "accident" and "available for distribution;"
- Requires errors and accidents to be reported as soon as possible but not to exceed 45 calendar days;
- Requires that error and accident reports be submitted for products that have been made available for distribution; and
- Amends the current Good Manufacturing Practice (cGMP) regulations for blood and blood components to require error and accident reporting by unlicensed registered blood establishments and transfusion services that are currently reporting on a voluntary basis. The FDA notes at the present, these entities are requested to submit such reports voluntarily, but FDA estimates that only about one percent are doing so, and even these entities may not be submitting all the reports that would be required under the proposed rule. Thus, according to FDA, this reporting requirement would involve a new routine activity for the great majority of unlicensed blood establishments and transfusion services.

FDA stated that any final rule that it issues on the basis of this proposed rule will become effective 180 days after publication in the *Federal Register*.

Discussion

There are significant problematical issues associated with the proposal. AABB will address each of these issues below in the context of AABB's summary points 1 - 7.

AABB opposes the reporting requirement **as proposed**. AABB, however, supports the goal of error and accident reporting. AABB recognizes specifically the value of error and accident reporting in fulfilling FDA's mandate to protect the public health by reviewing the safety and efficacy of blood and blood components as highlighted in the proposed rule and below.

FDA Goal: In general, protecting the public health by reviewing the safety and efficacy of blood and blood components; and specifically, in addition to expediting reporting, enhancing the ability to identify potential quality assurance problems and facilitating a rapid response where public health may be at risk.

Discussion of AABB summary points 1, 2, and 3.

Introduction

The FDA's stated goal reflects the desire to implement a mandatory error and accident reporting requirement that will enable: (1) blood facilities to use error and accident reporting to improve system performance by making system corrections related to the underlying causes of the reported errors and accidents; and (2) FDA to track trends in blood processing that might indicate a threat to the public health and necessitate a rapid response. In its proposal, the FDA cites a 1995 Office of Inspector General (OIG) report[2] noting that its proposal is, in part, a response to the OIG report. The report also noted that the "FDA envisions that the error and accident reports submitted by blood establishments can be used to identify trends and develop appropriate 'early warning' guidance to the field offices and the blood industry."

Other Points of View

Having a system in place in which errors and accidents are reported to the agency responsible for enforcement against those reporting the errors does not necessarily assure, nor instill, confidence that all error and accident data will be reported; and therefore, that FDA's goal will be achieved. Donald M. Berwick, M.D., M.P.P., argues[3] in the *New England Journal of Medicine* that, to have continuous improvement in the health care arena, "fear" should be precluded from controlling the atmosphere and the data. He notes that when these types of regulatory activities dominate, they have an unfavorable effect on quality as they are solely based on what he calls "the theory of bad apples." This theory argues that quality is best achieved by discovering bad apples and removing them from the lot. Some measure their success under this theory by "counting heads on platters." This "bad apples" approach could result in the concealment of errors and accidents due to fear of retaliation for reporting. Dr. Berwick notes, among other things, that the emphasis should be on learning (and thus improvement), not defense (reporting something and then consuming resources defending one's self). He agrees that it is absolutely necessary for regulators to perform their oversight function and concludes that regulators who willingly learn and respect modern principles of quality improvement can have a helpful role. He states: "They can do so as . . . partners . . . in developing sound measurement tools that represent common values and are for use primarily by the producers [health care professionals] themselves; by aggregating data centrally to help [health] care givers learn from each other; by providing technical support and training in methods of quality improvement . . ."

Dr. Berwick's arguments are strongly supported by Howard F. Taswell, M.D., et. al., [4] in discussing errors in transfusion medicine. Dr. Taswell notes, among other things, that widely accepted current techniques of total quality management and continuous improvement should be

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[2] Reporting Process for Blood Establishments to Notify the Food and Drug Administration of Errors and Accidents Affecting Blood. Office of Inspector General, Department of Health and Human Services. May 1995.

[3] Berwick, DM, MD, MPP. Continuous Improvement as an Ideal in Health Care. SOUNDING BOARD: The New England Journal of Medicine. Vol. 320, No. 1, January 5, 1989.

[4] Taswell, HF, MD, et al. Errors in Transfusion Medicine: Detection, Analysis, Frequency, and Prevention. Archives of Pathology and Laboratory Medicine. Volume 118, April, 1994.

effective in bringing about a reduction of errors in transfusion medicine. He suggests that preventive efforts should emphasize the process, not the individual. He identified the fundamental cause of errors as usually inherent to the system.

AABB Concerns

The AABB is concerned that with the FDA reporting system currently in place and the FDA's proposed expansion of that reporting system, the principles identified by Dr. Berwick will negate any chance of achieving the stated goals. Put simply, facilities that must report errors and accidents to the agency charged with enforcing infractions of the rules have a strong disincentive to report; i.e., fear of further regulatory enforcement action. Moreover, in evaluating FDA's proposal, it is apparent that the proposed rule does not suggest use of collected information for any sort of "trend analysis." In fact, FDA currently maintains a database of error and accident reports and only compiles quarterly and annual summaries. No effort is made to analyze the information for the benefit of the public or the community.

Implementation of a reporting program for errors and accidents should emphasize quality systems and the prevention through system corrections of the underlying causes. AABB's implementation of a quality program,[5] released in August of this year, emphasizes an approach to quality based on prevention not detection. The intent of a quality program is to ensure that quality principles are applied consistently throughout the various operational areas within an organization, to include errors and accidents.

Alternative Model

H. S. Kaplan, MD; J. B. Battles, PhD; T. W. Vander Schaaf, PhD; C. E. Shea, PhD; and S. Q. Mercer, MT(ASCP)SBB are studying the identification and classification of causes of events (errors and accidents) in transfusion medicine under a grant from the National Heart Blood and Lung Institute at the National Institutes of Health. The Medical Event Reporting System for Transfusion Medicine (MERS-TM) was established to explore and develop a standard and uniform method of classifying root causes of reported errors. Their research recognizes that current reporting efforts concentrate on describing what occurred with only limited, if any, attention to why it happened. The lack of a practical uniform system for the capture and causal analysis of transfusion events hampers the ability to understand and better manage error, particularly in the context of the human operator as part of a system of transfusion safety.

Dr. Kaplan, et al, emphasize that studies of safety incidents in other error-critical fields such as commercial aviation, have shown the near-miss events to be very similar to those associated with full-blown disasters.[6] Formal reporting systems have been established in aviation,[7] nuclear

[5] Quality Program Implementation. AABB Association Bulletin #97-4. August 1, 1997.
[6] Nagel ID. Human Error in Aviation Operations. In: Wiener EL, ed. Human Factors in Aviation. San Diego: Academic Press, Inc., 1988.
[7] National Aeronautics and Space Administration Science and Technical Information Branch. The Development of the NASA Aviation Safety Reporting System. Moffett Field, CA. Ames Research Center, and Mountain View, CA: Battelle's Columbus Laboratories. 1986 (NASA Reference Publication 1114).

power,[8] and the petrochemical industry.[9] These systems capture events and provide a resource for their study in order to prevent, or, at a minimum, better manage error when it occurs. The aviation reporting system, though funded by the Federal Aviation Administration which regulates aviation, is in fact operated by the National Aeronautical Space Administration (NASA Aviation Safety Reporting System). This was intentionally done so that those being regulated in aviation do not report directly to their regulators but rather to a third party to encourage reporting.

Dr. Kaplan notes that in designing and implementing MERS-TM, a concerted effort was made to take lessons learned about near-miss reporting systems from industries such as aviation, nuclear power, and the petrochemical industry and apply them to the medical domain. The key attributes of MERS-TM are: (1) no-fault reporting; (2) integration with quality assurance activities of local blood centers and hospital-based transfusion services; (3) the capability to deal with a high volume of reports; and (4) to provide a consistent method of classification and investigation that can be used by existing quality assurance personnel without extensive additional training.

A near miss reporting system that identifies and classifies the causes of events can be a powerful tool in understanding how transfusion medicine operations are actually functioning, Dr. Kaplan concluded. He noted that **capturing precursor or near-miss information critical to blood safety, as opposed to less critical information** to blood safety, can facilitate correcting problems before they turn into major misadventures. One should anticipate a significant increase in events reported when true no-fault, no harm reporting is put into place.

Given the existence of alternative models for error and accident reporting, especially the MERS-TM currently under study, FDA has failed to explain the basis for its current proposal or that it compared alternative models. It is entirely possible that alternative models, such as the MERS-TM may also prove more efficient from an administrative perspective as well. MERS-TM already has public support as evidenced by the NHLBI grant. This pilot is being implemented in three blood centers and three hospital transfusion centers. Organizations represented in the development process include the AABB, the American Red Cross, Blood Systems, Inc., and America's Blood Centers. The FDA has been involved and supportive of the development process of MERS-TM. At a minimum, FDA should delay its initiative until the MERS-TM results can be fully reviewed and translated into available options for expanded error and accident reporting.

- **Whether the proposed information collection is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.**

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[8] Ives G. Near Miss Reporting Pitfalls for Nuclear Plants. In: Van Der Schaaf, TW, Lucas DA, Hale AR, eds. Near Miss Reporting as a Safety Tool. Oxford, Butterworth and Heinemann, 1991:51-56.

[9] Van der Schaaf TW, Lucas DA, Hale AR (eds). Near Miss Reporting as a Safety Tool. Oxford, Butterworth and Heinemann; 1991; and Van der Schaaf TW. Near Miss Reporting in the Chemical Process Industry (Dissertation). Eindhoven, The Netherlands. Eindhoven University of Technology; 1992, 113p.

Discussion of AABB summary point 4.

The practical utility of the current proposal is highly questionable. FDA has neither explained in any detail, nor documented in any way, how it will specifically collect, input, maintain, and analyze the information and then, more importantly, how it will use the information. FDA has not discussed the development and implementation of a standardized and uniform data collection process (manual or electronic) consistent with standard practices and procedures related to data collection, input, retrieval and analysis (trend analysis). Further, the FDA has not addressed a specific format (manual or electronic form or both) for the filing of information.

AABB recommends development and implementation of a standardized and uniform data collection process (manual or electronic) consistent with standard practices and procedures related to data collection, input, retrieval and analysis (trend analysis). AABB further recommends that a form be developed and proposed for comment before the proposed rule can go into effect, notwithstanding FDA's "recommended essential information," and an effective date of 180 days after publication of the final rule in the *Federal Register*.

As to how the information, once collected, will be used, AABB is suggesting that the FDA first explain in detail how it will use this information. AABB asks that the FDA respond to its failure to date, to address what the OIG Report identified as FDA's vision that the error and accident reports submitted by blood establishments be used to identify trends and develop appropriate early warning guidance to the field offices and the blood industry. This is the very essential part of any proposed error and accident reporting system because, as discussed above in reference to a quality program, some sort of trend analysis would be very critical to improving blood safety overall. FDA already collects error and accident information from registered facilities, combines the error and accident data by event and publishes quarterly and annual reports. No attempt is made, however, to evaluate the data or use it for forecasting trends. Error and accident data that is not evaluated or used for forecasting trends is of limited value to anyone.

Finally, AABB recommends that whatever error and accident reporting program is ultimately implemented by FDA as a result of the proposed rule, it should be the single source for reporting all errors and accidents, adverse events, etc. for all blood products, all medical devices and all drugs. All other reporting programs, voluntary or mandatory, should be dispensed with.

- **Ways to enhance the quality, utility, and clarity of the information to be collected; the definitional issue.**

Discussion of AABB summary point 5.

The information to be collected lacks clarity. While providing definitions (previously existing definitions of "error," and "accident."), and also providing examples, it is still not clear as to what constitutes an error or accident. FDA in its most recent annual report[10] on error and accident

[10] ERROR AND ACCIDENT REPORTS - ANNUAL SUMMARY FOR FY-96. Food and Drug Administration. December 19, 1996.

reporting notes that 22 percent of reports "did not appear to meet the threshold for reporting." In other words, 22 percent of the errors and accidents reported did not fit the FDA definition of a reportable error or accident and should not have been reported. This would indicate that reporting entities do not have a clear understanding of what events require reporting and what events do not require reporting.[11]

Additionally, at the AABB's October Annual Meeting session on "Ask the FDA Inspector," several questions were asked regarding clarification of the terms "errors and accidents." In fact, the FDA was asked specifically why the FDA doesn't publish a list of reportable errors apart from the existing quarterly and annual error and accident summaries. Reliance on these FDA summaries and that blood centers modify what they report after reviewing and analyzing these summaries does not necessarily solve the definitional problem of error and accident. In fact, given that individual blood centers would more than likely come to different conclusions on what to report, the result could be even more confusing.

Specific Comments

Concerning FDA's second category of events to be reported defined as "an unexpected or unforeseeable event," as opposed to the first category of a deviation from cGMP, AABB would strongly recommend that the FDA **not** require reporting for both an autologous unit labeled with incorrect information provided by the donor or for a unit of blood or blood components which becomes broken/damaged during shipment. In the case of the former, AABB questions how an incorrectly labeled autologous unit affects the quality of product in any way. If it is given to the donor, there is really no "event" to report. If the donor cannot be identified, it is destroyed and there is no event. In the case of the latter, if the unit is damaged or broken it is destroyed and once again, there is no event to report. In either case (autologous or damaged/broken), internal QAs, clearly documented in internal SOPs, will be more than sufficient for dealing with these occurrences. It is an unnecessary consumption of both industry and FDA resources to require reporting of these occurrences.

In the proposed rule under "Format for Reporting," the FDA has recommended to manufacturers of blood or blood components certain essential information that should be submitted in the report. This information should include, among other things, "the final disposition of the blood product." AABB would recommend that if the product **has been** subject to recall, then the recall mechanism should be the instrument for reporting the final disposition. Requiring the double reporting of the final disposition of the same product under both error and accident reporting and recall would be redundant and wasteful of both FDA and industry resources. A significant amount of industry time and resources are required to determine the final disposition of product, particularly when a number of different blood products are involved, and may in fact delay reporting under the error and accident 45-day reporting requirement.

[11] At the AABB Ad Hoc FDA Liaison Committee meeting on December 5, 1997, FDA reported that the proper reporting of errors and accidents has improved over the last year and that in 1997, less than 10 percent have not met the reporting threshold.

As to the format for reporting, AABB would strongly recommend that while there may in fact not be a specific form available now, that FDA should at least provide for an appropriate ordering of the information to be reported. If the order of the information is the same for all reports, then the FDA can locate more easily, as can others, any particular piece or section of information. Additionally, AABB would be willing to work with the FDA in the development of a format for reporting.

A further request for clarification concerning error and accident reporting involves the term "made available for distribution." The AABB strongly believes there is a clear distinction between the term "made available for distribution" and the term or concept of a product being "actually delivered." First, AABB, consistent with the previously discussed alternative model and reporting near-miss events only, would not consider the former a near-miss event and therefore not reportable, while the latter could be considered a near-miss Error and accident reporting should only be required for the latter while an organization's QA and associated SOPs could address the former.

Moreover, the release criteria for product available for distribution differs between a blood bank and a hospital transfusion service. For a hospital, a product is not made available until it is released from the transfusion service for transfusion to a specific patient. In particular, a hospital transfusion service which performs compatibility testing is making a product available for a specific patient. For example, if a unit of Fresh Frozen Plasma (FFP) breaks in the waterbath, a transfusion service would not necessarily consider this a reportable error or accident although, based on the proposed rule, FDA would. The hospital transfusion service has a procedure under its QA and outlined in its SOPs that requires it to perform a final inspection and add a patient ID label to the unit after it is removed from the water bath. If breakage is discovered prior to or during the final inspection, no patient ID label would be added, it would not be released for transfusion, it would not be considered available for distribution and, would in fact, be destroyed. Yet FDA would consider the product available for distribution from the time it is labeled with its ABO and it is still in the freezer available for distribution. There is no justifiable reason for requiring an error or accident report in a situation such as this.

Another example would be a unit that has been issued/released for a patient, kept out of the blood bank for more than 30 minutes, is not used, is returned to the blood bank, and then in accordance with SOPs, is destroyed. A transfusion service would not necessarily consider this a reportable error or accident although, based on the proposed rule, FDA would. Once again, there is no justifiable reason for requiring an error or accident report in a situation such as this.

Both examples described above would be more effectively handled under an existing QA and SOPs associated with the program. Since the existence of both the QA and SOPs effectively identify and destroy the product in both situations, why should an error or accident report be required. Internal organizational controls have effectively prevented any error or accident. Thus a report should not be required. Only in those cases where the product was actually distributed or made available to a patient should they be reportable.

FDA should identify differing levels of severity with respect to errors and accidents (a specific, delineated list). Although it is important to identify and correct all errors and accidents, not all errors and accidents have the severe consequences that underlie the concerns motivating an expanded reporting requirement.[12] This is especially true in the context of post-donation information received from donors. The less severe errors and accidents should continue to be resolved internally within each facility as part of the QA. Mandatory reporting requirements should be limited to the reporting of severe errors and accidents. The level of severity that would trigger the differing reporting requirements should be carefully evaluated and established (as suggested in the MERS-TM System) based on the nature of the potential adverse effects. A blood or transfusion center's internal quality assurance system(s) could detect and address directly errors and accidents of a less severe nature. The FDA would inspect for system consistency within QA.

- **Ways to minimize the burden of the information collection on respondents, including the use of automated data collection techniques, when appropriate, and other forms of information technology.**

Discussion of AABB summary point 6.

AABB strongly supports the use of automated data collection techniques, when and where appropriate. AABB believes that this information technology concept may be premature given that many blood and blood component facilities lack current information technology resources. However, AABB would be willing to work with FDA to develop such an information technology approach to information collection in conjunction with the development and implementation of the format (form). Obviously, by developing both the form and appropriate related information technology collection, each would complement the other and contribute to an operationally straightforward system.

AABB recommends the establishment of an automated error and accident reporting system using INTERNET technology. A suggested system model could work in the following manner though it is not AABB's intent to discuss a complete and detailed model here but rather just to make a suggestion and indicate a direction. Each licensed facility would be assigned a confidential PIN number. A third party collector under contract with the FDA would provide a web site to collect error and accident data and use the PIN number to validate the report. The third party collector would acknowledge receipt of the data, assign it an accession number, indicate who it is forwarded to and when. The acknowledgment data could be automatically returned to the reporting facility. All data would have to be encrypted. In INTERNET terms, this web site would be a front end to an error and accident data base. This would expedite the process of error

[12] For example, transfusing a unit of platelets at 1 am which officially expired at midnight is not the same level of severity and therefore should not be reportable as transfusing those same platelets to an unintended recipient (even if no adverse consequences result) and should be reportable. The former "violates" an arbitrary (albeit relevant and important) rule whereas the latter shows evidence of a system breakdown that risks violating a "biologic rule" (potential for administering the incorrect blood type to a recipient). The former presents a risk of harm that is minimal, compared to the latter where the risk of harm is far greater.

and accident reporting for both the FDA and industry and would result in considerable savings in people hours for both the FDA and industry.

For those without INTERNET access, an identical paper form would have to be available to be completed and faxed to the third party collector. The third party collector could then input the data into the same system as facilities transmitting via the INTERNET.

- **The accuracy of FDA's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used.**

Discussion of AABB summary point 7.

AABB written comments to the OMB are incorporated by reference herein and a copy is attached.

Conclusion

If FDA is willing to develop and implement an error and accident reporting program that truly enhances safety by identification of trends and establishing subsequent prevention initiatives, not individual event identification and enforcement, AABB would be very supportive of such a program and would be willing to work with both FDA and AABB members to implement such a program. In particular, AABB would be willing to have individuals who work in transfusion services and understand the complex medical decision making issues associated with transfusion services actively participate in the error and accident program implementation. Additionally, AABB is in the initial stages of organizing a national conference for next summer to examine systems necessary to ensure the appropriate reporting of errors and accidents to both member internal quality assurance programs and to the FDA.

Once again, AABB appreciates the opportunity to comment on the error and accident reporting proposed rule.

Sincerely,

Edward L. Snyder

Edward L. Snyder, MD
President

Attachment

BLOOD SAFETY AND AVAILABILITY

WEDNESDAY, OCTOBER 6, 1999

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

The subcommittee met, pursuant to notice, at 10:30 a.m., in room 2322, Rayburn House Office Building, Hon. Fred Upton (chairman) presiding.

Members present: Representatives Upton, Burr, Bilbray, Bryant, Bliley (ex officio) and DeGette.

Staff present: Alan Slobodin, majority counsel; Anthony Habib, legislative clerk; and Chris Knauer, minority counsel.

Mr. UPTON. Okay. Good morning. This morning the subcommittee continues its oversight hearings on the safety and availability of the U.S. blood supply, and knowing that the chairman of the full committee, also a member of this committee, is here and knowing that he needs to be on the floor soon for the important debate on the Patients' Bill of Rights, I will yield for an opening statement to the chairman.

Mr. Bliley.

Chairman BLILEY. Mr. Chairman, I want to thank you for these continued hearings concerning the safety and availability of the Nation's blood supply. I particularly want to welcome Dr. David Satcher and the other witnesses for the Department of Health and Human Services. As we learned at the previous hearing, the U.S. blood supply is tightening and will get even tighter. We need more blood. We also recognize that the U.S. blood supply has never been safer. Let me repeat that. It has never been safer.

New technological advances can make the blood supply even safer, but we still can do more to reduce the risk. Errors and accidents in the blood supply, especially transfusion errors, remain a safety problem that can be reduced. In fact, the risk of a fatal transfusion from a transfusion error is about the same risk as getting a transfusion with the AIDS virus. One study, based on reports to the FDA, from 1990 to 1992 found that incompatible red blood cell transfusion continued to be the primary cause of preventable transfusion deaths and concluded that one-third of the deaths could have been prevented by following proper procedures.

As we have learned, a well-designed reporting system is an effective safety management tool. For example, in the field of domestic airline safety, aviation reporting systems have helped contribute to a safety record of no fatalities in 1998. Unfortunately, the present FDA reporting system for errors and accidents at the blood supply

has several weaknesses. Some of these were identified by reports by the HHS Inspector General's Office and the General Accounting Office. Since the IG's Office issued recommendations 4½ years ago, the weakness remains uncorrected, and FDA does not expect to publish a final rule on error and accident reporting until 2001.

The American people should not have to wait until 2001 to have a stronger blood supply safety system. We can make getting a blood transfusion much more safe. There is an alternative reporting system with promising results that exists, and the FDA participated in its design. The alternative model is called the medical event reporting system for transfusion medicine, which was developed by Dr. Harold Kaplan and his team at the University of Texas. This reporting system is supported by a research grant funded by the National Heart, Lung, Blood Institute.

Through this committee's investigation of blood safety, we have learned about the exciting possibilities of this new reporting system and brought this matter to the attention of Dr. Satcher. I am pleased that Dr. Satcher has indicated that he is taking action to see if it can be implemented. At the appropriate time, I intend to ask Dr. Satcher about how the Department can assume direct control over blood reporting and accident reporting, expedite a new policy and consider the medical event reporting system for transfusion medicine as the new reporting system for blood errors and accidents.

Improving the reporting system is just one area this subcommittee is looking at to protect the Nation's blood supply. We want to be supportive of Dr. Satcher's efforts to increase blood donations. I believe the subcommittee and Dr. Satcher can work together to give the American people the blood they need with absolutely the most safety possible.

And I thank you, Mr. Chairman, and regret that I am not going to be able to stay to hear the testimony of the witnesses.

Mr. UPTON. Well, I would note to all the folks that are here, not only are we very busy on the House floor, on votes that will commence in just a couple of minutes, but all of our subcommittees are meeting as well. Some of us are on another committee, as I serve on the Education Committee, and we are marking up Title I of the Elementary and Secondary Education Act. So you will see a lot of moving chairs as we work through this hearing this morning.

We do welcome today's witness, Dr. David Satcher, who is the Assistant Secretary for Public Health, the U.S. Surgeon General and the Blood Safety Director, and we look forward to learning more about the views of HHS on the blood supply, the UK donor exclusion policy, strategies to increase the blood supply, error and accident reporting, and the HHS blood oversight system.

At our previous hearing on September 23, we heard testimony that suggested that we are below the comfort level in some areas of our blood supply. The GAO testified that the blood supply as a whole is not in crisis, but there is a cause for concern about shortages of certain blood types or in certain regions. GAO confirmed that the available data showed that the blood supply has tightened, even though the blood supply has declined more slowly than assumed in the projections. The National Blood Data Resource Center, NBDRC, testified that if rates of overall blood collection and

transfusion that occurred between 1994 and 1997 continue, the U.S. may experience a national blood shortage as early as next year. Dr. James AuBuchon of the Dartmouth Medical School testified that given the demographics of our population, the blood supply situation is only going to get worse, and that he did not expect significant reductions in blood usage.

At the same time our blood supply is tightening, HHS made a major policy change that could further reduce the blood supply. On August 17, 1999, FDA directed that individuals who had spent a total of 6 months or more in the United Kingdom between 1980 and the end of 1996 be prohibited from donating blood because of concerns over the theoretical risk of spreading a new variant human form of mad cow disease. This new donor exclusion policy has been estimated to reduce the blood supply by 2.2 percent. At the September subcommittee hearing, the GAO testified that this estimate appeared to be reasonable.

At today's hearing, I would like to examine the strategies that Dr. Satcher and HHS are taking and considering to offset the shortages that may result from the U.K. donor policy.

We will also follow up on a blood safety issue from the last hearing: error and accident reporting. On May 31, 1995, the Office of Inspector General, Department of Health and Human Services, IG, issued a report that concluded that the FDA could improve the safety of the blood supply by doing a better job of collecting data on errors and accidents made by hospitals and blood banks. The audit found that the FDA was not insisting that hospitals and blood banks submit error reports in a timely fashion, and that the FDA does not get these reports at all from unlicensed facilities that handle about 10 percent of the blood used in the United States.

The IG made several important recommendations to address the issue, with which the FDA agreed. Yet here it is 4 years later, and the FDA has yet to issue a final regulation extending the reporting requirement to unlicensed facilities and requiring more timely reporting on the part of all of its facilities. The FDA has indicated that the final rule will not see the light of day until February of 2001, and this in spite of the fact that the Commissioner of the FDA has stated that blood safety is one of the agency's top priorities.

One last issue we will want to discuss at the hearing is how well the new HHS blood oversight system is working. In July 1995, the Institute of Medicine issued a report that concluded that there was a failure of leadership from the Public Health Service agencies that may have delayed effective action against AIDS-contaminated blood products. To address this problem, the report recommended that HHS reorganize its oversight of blood issues by establishing a blood safety director, a blood safety council and an expert panel. Starting in October of that year, HHS Secretary Donna Shalala instituted a number of changes, such as establishing the blood safety director as the Assistant Secretary of Health. Four years have nearly passed now since the HHS oversight system was established. It is certainly appropriate for this subcommittee to review what has been accomplished and what remains to be done in the stewardship of the blood supply.

In addition to Dr. Satcher, I have also invited Secretary Shalala and FDA Commissioner Henney for this hearing. I had hoped, given the importance that both the Secretary and the FDA Commissioner have placed on blood safety, that they might have been able to join us today. Had they appeared with Dr. Satcher, it would have provided an even more powerful public statement from the administration about the importance of blood donations and blood safety. Since I intend this subcommittee to continue its oversight of the blood supply throughout this Congress, perhaps there will be another opportunity for these folks to appear before us.

During this oversight hearing on blood safety and availability, the subcommittee will probably identify some areas where more could be done. I appreciate the difficulty of Dr. Satcher's task. I am strongly supportive of his goal and work to increase blood donations, and I am going to be playing my role by donating blood in Michigan next week.

Again, the policy challenges facing the blood supply have changed in recent years, but some things about the blood supply have not changed. There is no substitute for blood, and we need blood donations. As Douglas Starr, the author of the book, "Blood," observed, "Blood is a precious and dangerous medicine. We must be careful how we use it."

And I would yield for an opening statement to the vice chairman of the subcommittee, Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman. You stimulate me to look at my pocket and see if my due date is here for the next donation, and I am sure that it is.

Let me take this opportunity to welcome the Surgeon General and to express the subcommittee's thanks for his diligence on this issue. I think it's safe to say that as we sit here today, not only is the blood supply safer, as you say in your testimony, but we also discover new health risks and technology changes when we're able to detect more things and also to check the blood supply.

I think the challenge for us, though we can always find fault with Congress and with agencies, is to make a commitment that we will make sure that the government oversight and the policies we set in the future are as seamless as the technology and the health risks that we will face in the future; that it won't take an oversight committee of Congress or a delay from an agency to change the policy to reflect the safeguards that the American people need.

I'm confident that we have the right formula in those agencies and the Surgeon General and in this Congress that we can accomplish this with the highest degree of confidence. I look forward to working with you, Mr. Chairman, and with the Surgeon General to make sure that seamless world is one that we can achieve.

I thank you.

Mr. UPTON. Mr. Bilbray.

Mr. BILBRAY. Yes, Mr. Chairman. Mr. Chairman, I would like to echo Chairman Bliley's statement. I think a lot of us, as we approach these situations where we see that there's improvement can be done, we sort of forget about highlighting how much success we've had in the past. Let me just say as somebody who's had 25 years involvement in different public health issues and environ-

mental health issues, we need to be reminded that the air today is cleaner than it has ever been in the history of the United States; that our water is cleaner than it's ever been in the history of the United States; our drinking water is safer than it's ever been in the history of the United States. There is less risk from hazardous waste today than there has ever been in the near past, and the fact is, our blood supply is safer than it has ever been in the history of this country.

So I think starting from that basis, that we're not coming from a crisis of how terrible things are, but the fact that things are as good as they have been in the past, that we need to move forward and continue the process of improvement, continue to refine the safeguards, and I think that what we're looking for here now is how we can we do that fine-tuning to continue the evolution toward a safer, more healthy society for all citizens. And I appreciate the fact that we are trying to work together here in a bipartisan way with the administration and the Congress, and I look forward to us taking that next step. And there may not be a huge leap, but it's those small, little steps that have added up in the past, and those steps are the important steps that we need to make for the future.

I yield back, Mr. Chairman.

Mr. UPTON. Thank you.

Those of you all who heard those buzzers, it means we do have a vote on the floor. We'll temporarily adjourn. We will come back at about 11 o'clock.

[Brief recess.]

Mr. UPTON. It must be 11 o'clock. We are going to keep the record open for any opening statements that other members may make. So I make unanimous consent that the record be open for any opening statements, and at this point we'll proceed with the opening statement of Dr. Satcher.

As you know, it is customary of this subcommittee to take testimony under oath. Do you have any objection? Are you planning to have counsel with you or others?

Mr. SATCHER. No. I would like for the colleagues that I might call upon in the question period to stand with me and take the oath.

Mr. UPTON. If you could so identify them and have them maybe join with you, that would be perfect.

Mr. SATCHER. There will be three. Dr. Kathy Zoon is the Director of the Center for Biologics Evaluation and Research; and with her is Dr. Jay Epstein, who is Director of the Office of Blood Research and Review in the same center; and Dr. Steven Masiello, who is the head of the Office of Compliance and Biologics Quality. They might well be called during the question-and-answer period.

Mr. UPTON. If you all would raise your right hand.

[Witnesses sworn.]

Mr. UPTON. You are now under oath, and again, we welcome you to this subcommittee, and you may proceed with your opening statement. Certainly, as a matter of courtesy, your statement in its entirety is made part of the record, and the time is now yours.

TESTIMONY OF DAVID SATCHER, ASSISTANT SECRETARY FOR HEALTH AND SURGEON GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY KATHRYN ZOON, DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, STEVEN A. MASIELLO, DIRECTOR, OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, AND JAY S. EPSTEIN, DIRECTOR, OFFICE OF BLOOD AND RESEARCH REVIEW, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION

Mr. SATCHER. Thank you, Mr. Chairman and members of the Subcommittee on Oversight and Investigation of the Committee on Commerce. Thank you for inviting me to discuss the safety and availability of the blood supply. This is really a critical issue, and we appreciate this opportunity.

Our Nation's blood supply is safer than it ever has been and is getting safer as we speak. Dr. AuBuchon, who testified before you last month, reported that just 2 years ago the risk of hepatitis C from blood transfusions was about 1 in 100,000 transfusions, or about 120 cases a year. He also reported that the risk of HIV was about 1 in 500,000 transfusions, or about 24 cases per year. We have made tremendous progress, especially when you reflect on the fact that it was not that long ago that the risk of hepatitis C was at least 50 times greater.

One of my most memorable experiences as Director of the CDC, of course, was meeting with the National Hemophiliac Foundation a few years ago and revisiting their experience in the early to mid-1980's when over that half of that population was infected with HIV. We have come a long way, but the issue of the safety of the blood supply is still a very critical issue.

We have recently introduced the nucleic acid test for hepatitis C and HIV into development. Most of the older tests which produce the results that Dr. AuBuchon described detect antibodies to these viruses, but in contrast, nucleic acid tests detect the viruses themselves. For this reason, nucleic acid tests may help us to close the so-called window period between the time an infectious agent appears in the blood and the time that infections can be detected.

As you know, currently nucleic acid tests are investigational and are being evaluated widely using pools of donated blood. Even more sensitive nucleic acid tests performed on single units are under development. Collectively these advances should reduce the risk of transfusion-transmitted hepatitis C and HIV by a large order of magnitude and possibly even more.

I want to say a word about what I think we've accomplished in terms of blood safety since we reorganized our strategy for protecting the blood supply. First, we have prioritized blood safety within the Department. Our efforts to increase the safety of the blood supply began in the earliest days of this administration. In July 1993, Secretary Shalala commissioned the Institute of Medicine to prepare a report on the introduction of HIV into the blood supply. She did this, as she said at the time, to ensure the safety of the Nation's blood supply against new challenges in future.

The Institute of Medicine released its report in July 1995. On the same date that it was released, the Secretary directed Dr. Lee,

then the Assistant Secretary of Health and senior member of the Department, to review it. In October of that year, in testimony before Congress, the Secretary announced her concurrence with this report, and I must say I was then Director of the CDC, and I was involved in all of these deliberations. She also announced that she had designated the Assistant Secretary for Health to be the blood safety director for the Department. In addition, she announced the establishment of two high-level committees on blood safety and availability, one internal and one external to the Department.

The Secretary concluded her testimony by saying blood and blood products will always be capable of transmitting diseases, and their use will never be completely free of risk. But for everyone who relies on blood and blood products to sustain life, the Federal Government will do everything in its power to reduce risk and to assure availability.

We are implementing the Secretary's policy in three ways: No. 1, working for the timely introduction of new technologies such as the nucleic acid testing; two, a proactive response to the threats posed by emerging and reemerging infectious diseases such as transmissible spongiform encephalopathies; and three, increased attention to quality assurance, such as an emphasis on current, good manufacturing practice requirements.

We believe that these three initiatives will permit us to achieve the degree of blood safety that the American people demand without compromising the blood availability that the American people need.

What is our blood action plan? I feel it's important to stress in light of earlier discussions by the committee the commitment of the Food and Drug Administration to increasing effectiveness of regulation of the blood industry. The concrete expression of this commitment is the Blood Action Plan which was initiated in July 1997. The Blood Action Plan is one of the FDA's responses to the 1995 Institute of Medicine report and also to several congressional oversight reports since that time.

The Blood Action Plan establishes a comprehensive review of all blood-related regulations. Most of this review has been completed. In May and August of this year, the FDA published direct final rules and companion proposed final rules that updated technical standards for blood and blood products. In August of this year, FDA proposed two additional rules, one on testing blood donors for infectious diseases and another on donor notification. But also in July of this year, FDA proposed an important consumer safety initiative, a tracking system for plasma derivatives from manufacturer through the distribution network to the end user, that will ensure prompt notification when indicated.

Progress has been made in improving the responsiveness of the agency. Under the Blood Action Plan, FDA is harmonizing its new biologics license application for blood products with its new drug applications. In addition, I think it's important to note that the Food and Drug Administration is working with the CDC and NIH representatives and have formed an emerging infectious disease committee that has developed plans for responding to emerging infections that threaten the blood supply.

I do want to point out, Mr. Chairman, that I think there are global implications to the safety of our blood supply, and as you probably remember, a few years ago when I was Director of CDC, we proposed a global system of surveillance and response for emerging infectious diseases, and that proposal was approved, and we are now in the process working with our G-8 partners and others of implementing such a system.

FDA has also recognized its field inspection programs and has reorganized these programs, and as a result, there has been considerable progress toward bringing the blood and blood product industries into full compliance with current good manufacturing practice requirements.

In the past, we have talked about the hepatitis C look-back program, and in the interest of time, I will only mention the Department's initiative to notify all individuals who may have inadvertently been exposed to hepatitis C through blood transfusions. FDA has moved rapidly to issue guidance on this initiative and is moving rapidly as well to issue a final rule on this matter. I think the role of the CDC and the FDA in collaboration with the Agency for Health Care Policy and Research will allow us to implement an effective program and to evaluate that program as it goes forward. So we're committing to not only implementing this look-back, but being able to tell you how effective this program is being throughout the country.

One of the major issues that you have discussed recently and that we have been concerned about is the defense against the transmissible spongiform encephalopathies. Over the past 4 years, the Department has substantially updated its policies regarding TSEs, if you will. These include Creutzfeldt-Jakob disease, or CJD, and this new variant CJD, the human form of mad cow disease, if you will. Animal experiments indicate that both are potentially transmissible by blood transfusion, but it's important to point out that no actual case of this has been thus far observed in humans.

This surveillance system that we have in place through the CDC really goes back to 1979, and we have been monitoring very closely for the occurrence of CJD and any form of it. So we're very confident about the data.

Extensive epidemiologic data has permitted us to revise some precautions against CJD. However, new and disturbing information about this new variant CJD has recently become available. We have learned that the prions of new variant CJD are quite different from classic CJD in many ways, but let me say that this may explain why the clinical manifestation of the two diseases tend to be so different. We have learned that the new variant CJD forms deposits in peripheral tissues, like lymph nodes and the spleen and the tonsils, and there is some preliminary evidence in transgenic mice that suggests a role for certain blood cells in the pathogenesis of this disease, and I think you can see, therefore, why, even though there's no evidence that this is transmitted in the blood, we have not reached the level of comfort that would prevent us from taking action.

We've learned that the risk of new variant CJD is uniformly distributed throughout the United Kingdom. In fact, the only definable risks of new variant CJD at present are long-term residence

in the United Kingdom and the methionine homozygosity at codon 129 of the prion protein gene.

The first critical piece of information we currently lack is the length of the incubation period between exposure to the agent of a new variant CJD and the onset of the symptoms. This is a really critical issue. I think if we were to assume that the incubation period in humans were the same as in cows, we would assume that it was about 5 years, and therefore, we would expect no more than about 500 victims. Even that assumption is open to some question. However, the incubation period in humans could be as much as 40 years, and that means that we could have as many as 500,000 victims of this new variant CJD.

I think the other critical piece of information we currently lack is whether this new variant CJD is, in fact, transmitted by a blood transfusion in man. So far there is no evidence that this has occurred, and as you probably know, we have had no evidence that CJD itself has been transmitted through the blood and humans. And without going into a lot of detail, we have followed the evolution of this, especially looking at the hemophiliac population, persons with thalassemia, persons with sickle cell disease, all people who receive a lot of transfusions, and there's no evidence today that that population is at any greater risk for CJD than any others. So we are pretty comfortable, even though not comfortable to stop monitoring this very carefully, but we have no evidence to date that CJD itself is transmitted through blood transfusions.

The Food and Drug Administration's Transmissible Spongiform Encephalopathy Advisory Committee made recommendations on June 2 of this year regarding donor deferral based on a period of residence or travel in the United Kingdom to the blood safety committee which I chair, and we voted unanimously to support that, and it was really out of that committee that we recommended that persons who had spent up to 6 months in the United Kingdom between the years of 1980 and 1996 be deferred from blood transfusions. There is, as you know, some disagreement with that, but I do want to point out that we felt that if we were going to err, we should err on the side of being very cautious.

We were concerned about the impact that this would have on the blood supply. According to our data and our estimates, this could potentially reduce the blood supply by 2.2 percent, but it would, on the other hand, take care of 87 percent of the days of risk that we would experience from that group of people. So we felt that this was the right decision. However, the main point I want to make today is that this is a decision that we will continue to revisit at least every 6 months. So as we speak, we are evaluating the impact that this decision is having.

The next point I want to make is a word about the availability of blood and what we're trying to do to assure that blood availability is enhanced in this country. At the June 8 meeting of the Blood Safety Committee, I did appoint an Interagency working group to make recommendations to me about ways that we could enhance the blood supply, and they made their recommendations, which I have accepted, and there are five areas of recommendation.

One is, of course, that we do a better job of monitoring the blood supply, and we have committed up to $300,000 in the current fiscal

year from NHLBI to purchase this information from the National Blood Data Resource Center. So we are going to be monitoring much more carefully the blood supply and seeing what's happening to donations.

We're also going to do more to encourage the public to donate blood. I was very happy to hear about your commitment and others on the panel. I hope to do a much better job as Surgeon General of communicating to the American people in general the importance of donating blood, as well as donating organs. A lot of lives can be saved, and we're going to make that a much greater part of our deliberations.

The NIH has committed $1.8 million in the current fiscal year to research strategies that can be used to enhance donation.

The third thing that this committee recommended and we accepted was that we needed to work on improving the relationship between donors and the blood establishment. There are donors who complain about the experiences that they have when they go to donate blood. So we're going to see how we can really improve that relationship in many ways.

We also are going to remove unnecessary restrictions to donations. This is a very important recommendation because we believe that there is much more blood available than we're receiving because of some unnecessary restriction. So we are going to review the current donor deferral policies, particularly in light of emerging technologies, such as nucleic acid testing. FDA's decision to reassess donations by individuals with hemochromatosis that was announced on August 10 by Commissioner Henney is only one of several responses to this issue that we are now considering.

And finally, we're going to address economic concerns of the blood industry as it relates to blood donations. What I didn't say, which I should mention because I don't know how many people are aware, that about 60 percent of the people in the population are really eligible for blood donation, and yet only about 5 percent are donating. The other thing, of course, is that of the people who donate, many of those persons could donate many more times a year than they are. Most of them donate once a year. So we are working on those two things at the same time.

The other Departmental initiatives in blood safety which I'll mention just briefly as I close is to look at the issue of accidents and errors associated with blood administration, which Congressman Bliley mentioned. FDA has long recognized the importance of reporting investigation and correction of errors and accidents. The FDA has already used information learned from the errors and accident reports to identify areas where clinical practice and government regulations could be improved, and FDA issued a proposed rule in 1997 to require unlicensed, as well as licensed, institutions to file these reports, and they quantified a time period in which they should be filed. However, the final rule of this matter has yet to be issued.

It is important to emphasize that the error and accident reporting required under this rule serves not to alert the FDA to emergencies, but to provide an additional layer of data for quality assurance for longer-term safety monitoring, audits and to help support for target inspections. The major proactive approach to assuring

high quality and compliance with the regulations of the blood industry is, in fact, FDA's regular inspection process. In fact, the vigorous and rigorous FDA inspection program has led in recent years to a number of major enforcement actions to help assure the safety of the blood.

Mr. Chairman, I would like to join your fellow committee members who have thanked you for holding this hearing because you have raised awareness of an essential layer of the blood safety system. I want to assure you that none of us are waiting for the time required to issue a final rule to address this important matter. As you know, on August 13 of this year I had directed the Advisory Committee on Blood Safety and Availability to place this matter on their agenda. This is a very talented advisory committee, very diverse in terms of its expertise, and they will be looking critically at this matter. This meeting in which they will discuss this issue is scheduled for late January of 2000, and preparation for it is already under way.

Congressman Bliley mentioned Dr. Harold Kaplan, professor of transfusion medicine, who has been awarded a research grant by the National Heart, Lung, and Blood Institute to study transfusion errors and how it might be reduced. The Department will promptly consider any recommendations that arise from this meeting. We will not wait until 2001 to respond. We will move as expeditiously as possible to put in place recommendations to enhance or reduce errors and accidents, and we'd be delighted to inform of you our response to these recommendations.

Thank you.

[The prepared statement of David Satcher follows:]

PREPARED STATEMENT OF DAVID SATCHER, ASSISTANT SECRETARY FOR HEALTH AND SURGEON GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, Members of the Committee: Thank you for your invitation to discuss the safety and availability of the blood supply.

I. RECENT ADVANCES IN BLOOD SAFETY

Our nation's blood supply is safer than it ever has been, and it is getting safer even as we speak. Dr. AuBuchon, who testified before you last month, reported just two years ago that the risk of hepatitis C from blood transfusion was about one in one hundred thousand transfusions, or about 120 cases per year. He also reported that the risk of HIV was about one in five hundred thousand transfusions, or about 24 cases per year.

Since then, nucleic acid tests for hepatitis C and HIV have been developed. Most older tests, which produced the results Dr. AuBuchon described, detect antibodies to these viruses. In contrast, nucleic acid tests detect the viruses themselves. For this reason, nucleic acid tests may help us close the so-called "window period" between the time an infectious agent appears in the blood and the time that infection can be detected.

Currently, nucleic acid tests are investigational, and are being evaluated widely using pools of donated blood. Even more sensitive nucleic acid tests performed on single units are under development. Collectively, these advances should reduce the risk of transfusion-transmitted hepatitis C and HIV by an order of magnitude, and possibly even more.

II. DEPARTMENT ACCOMPLISHMENTS IN BLOOD SAFETY

A. Prioritization of Blood Safety Within the Department

Our efforts to increase the safety of the blood supply began in the earliest days of this Administration. In July 1993, Secretary Shalala commissioned the Institute of Medicine to prepare a report on the introduction of HIV into the blood supply.

She did this, as she said at the time, "...to insure the safety of the Nation's blood supply against new challenges in the future."

The Institute of Medicine released its report in July 1995. On the day it was released, the Secretary directed Dr. Lee, then the Assistant Secretary for Health, and senior members of the Department to review it. In October of that year, in testimony before Congress, the Secretary announced her concurrence with the report. She also announced that she had designated the Assistant Secretary for Health to be the Blood Safety Director for the Department. In addition, she announced the establishment of two high-level committees on blood safety and availability, one internal and one external to the Department. The Secretary concluded her testimony by saying

> Blood and blood products will always be capable of transmitting disease, and their use will never be completely free of risk. But for everyone who relies on blood and blood products to sustain life, the Federal Government will do everything in its power to reduce risk and assure availability.

We are implementing the Secretary's policy by:

1. Timely introduction of new technologies, such as nucleic acid testing;
2. Proactive response to the threats posed by emerging and re-emerging infectious diseases, such as transmissible spongiform encephalopathies; and
3. Increased attention to quality assurance, such as emphasis on current Good Manufacturing Practice requirements.

We believe that these three initiatives will permit us to achieve the degree of blood safety that the American people demand without compromising the blood availability that the American people need.

B. Blood Action Plan

I feel it is important to stress, in light of earlier discussion by this Committee, the commitment of the Food and Drug Administration to increasing the effectiveness of regulation of the blood industry. The concrete expression of this commitment is the Blood Action Plan, which was initiated in July 1997. The Blood Action Plan is one of FDA's responses to the 1995 Institute of Medicine report, and also to several congressional oversight reports since that time.

The Blood Action Plan established a comprehensive review of all blood-related regulation. Most of this review has been completed. In May and August of this year, FDA published Direct Final Rules, and companion Proposed Final Rules, that updated technical standards for blood and blood products. In August of this year, FDA proposed two additional rules, one on testing blood donors for infectious diseases, and another on donor notification. Also, in August 1999, FDA proposed an important consumer safety initiative: a tracking system for plasma derivatives from manufacturer through the distribution network to the end user that will insure prompt notification when indicated.

Progress has also been made in improving responsiveness of the Agency. Under the Blood Action Plan, FDA is harmonizing its new Biologics License Application for blood products with its New Drug Application. In addition, FDA, CDC, and NIH representatives have formed an Emerging Infectious Diseases Committee that has developed plans for responding to emerging infections that threaten the blood supply. FDA has also reorganized its field inspection programs. As a result, there has been considerable progress towards bringing the blood and blood products industries into full compliance with current Good Manufacturing Practice requirements.

C. Hepatitis C Lookback

In the interest of time, I will only briefly mention the Department's initiative to notify all individuals who may have been inadvertently exposed to hepatitis C through blood transfusion. FDA has moved rapidly to issue Guidances on this initiative, and it is moving rapidly as well to issue a Final Rule on this matter. As part of this effort, CDC is coordinating a Hepatitis C Public Information Campaign and, in collaboration with FDA and the Agency for Health Care Policy Research, will carefully evaluate both the targeted and the general notification efforts.

D. Defense Against Transmissible Spongiform Encephalopathies

Over the past four years, the Department has substantially updated its policies regarding the transmissible spongiform encephalopathies. These include Creutzfeldt-Jakob disease, or CJD, and new variant CJD, the human form of "mad cow" disease. Animal experiments indicate that both are potentially transmissible by blood transfusion, but no actual case of this has so far been observed in humans.

Extensive epidemiologic data has permitted us to revise some precautions against CJD. However, new and disturbing information about new variant CJD has recently become available. We have learned that the prion of new variant CJD is different

from the prion of classic CJD. This may explain why the clinical manifestations of the two diseases are so different. We have learned that the prion of new variant CJD forms deposits in peripheral tissues, and there is some preliminary evidence in transgenic mice that suggests a role for certain blood cells in the pathogenesis of this disease. We have learned that blood from rodents experimentally infected with Mad Cow Disease can, under some circumstances, transmit it to other rodents. We have learned that the risk of new variant CJD is uniformly distributed throughout the United Kingdom. In fact, the only definable risks of new variant CJD at present are long-term residence in the United Kingdom, and methionine homozygosity at codon 129 of the PRNP gene."

The first critical piece of information we currently lack is the length of the incubation period between exposure to the agent of new variant CJD and the onset of symptoms. In cows it is five years. If it is also five years in people, there may be no more than 500 victims of this disease. However, if the incubation period is up to forty years, there could be more than 500,000 victims of new variant CJD.

The other critical piece of information we currently lack is whether new variant CJD is in fact transmitted by blood transfusion in man. No such instance has yet been identified, but the possibility has not been excluded. Some have suggested that we take no action until the first case of transfusion-transmitted new variant CJD is documented. However, by that time, how many others might be irreversibly infected with a uniformly fatal disease that destroys the brains of its victims in the prime of their lives? We have chosen to reduce this risk by the limited methods now available to us, and not wait until the answer reveals itself.

In formulating our policies, we have repeatedly invited comment from scientists, the blood industry, and the public on their perception of the risk to blood safety posed by new variant CJD to blood safety, the impact of any measures we might take to reduce that risk, and what we could do to minimize that impact. As we expected, the advice varied. For this reason, we followed the process established by Secretary Shalala in 1995, which was to bring this matter promptly to the highest level of the Department. The Food and Drug Administration's Transmissible Spongiform Encephalopathy Advisory Committee made their final recommendation on June 2 of this year regarding donor deferral based on a period of residence or travel in the United Kingdom; the Blood Safety Committee, which I chair, met on June 8. The Blood Safety Committee's recommendation was unanimous in favor of this precautionary measure. FDA announced this recommendation at its Blood Products Advisory Committee meeting on June 17, and FDA's Guidance to Industry was issued on August 16.

III. DEPARTMENT ACTIONS TO ASSURE THE AVAILABILITY OF BLOOD

At the June 8 meeting of the Blood Safety Committee, I appointed an Interagency Working Group to identify strategies to increase the blood supply. I received their report on August 10, and discussed it at the August 26 meeting of the Advisory Committee on Blood Safety and Availability. I concur with each of their recommendations, both for the short and the long term, and I have directed the appropriate agencies to implement these recommendations as soon as possible. Much of this implementation has already occurred.

A. Monitor the Blood Supply

The first recommendation of the Interagency Working Group was to institute prospective monitoring of the blood supply. The NIH has committed up to $300,000 in the current fiscal year to purchase this data from the National Blood Data Resource Center, beginning as soon as possible, and perhaps even this month. Plans for long-term management of this activity are currently under review.

B. Encourage the Public to Donate (And to Continue Donating)

The second recommendation was to increase suitable donations. As the General Accounting Office report to your Committee pointed out, there are plenty of eligible donors; we simply need to find more effective ways to encourage them to donate. The NIH has committed $1.8 million dollars in the current fiscal year to research in this area.

C. Improve Relations Between Donors and Blood Establishments

The third recommendation was to improve relationships between donors and blood centers. While much of this task is the industry's, the Department will consider steps that it can take. For example, there may be ways to make required donor questionnaires less burdensome without making them less effective.

D. Remove Unnecessary Restrictions to Donation

The fourth recommendation was to review current donor deferral policies, particularly in light of emerging technologies such as nucleic acid testing. FDA's decision to reassess donations by individuals with hemochromatosis that was announced on August 10 by Commissioner Henney is only one of several responses under active consideration by FDA.

E. Address Economic Concerns of the Blood Industry

The fifth and final recommendation was to address economic pressures on the blood industry that may limit its performance. The Advisory Committee on Blood Safety and Availability reviewed this issue at its August 27 meeting. The Committee's recommendations are currently under review within the Department.

IV. OTHER DEPARTMENTAL INITIATIVES IN BLOOD SAFETY

Another issue that both we and you have under active review is accident and error associated with blood administration. FDA has long recognized the importance of reporting, investigation, and correction of errors and accidents. FDA has already used information learned from error and accident reports to identify areas where clinical practice and government regulation could be improved. FDA did issue a Proposed Rule in 1997 to require unlicensed as well as licensed institutions to file these reports, and to quantify the time period in which they should be filed. However, a Final Rule on these matters has not yet been issued.

It is important to emphasize that the error and accident reporting required under this rule serves not to alert the FDA to emergencies, but to provide an additional layer of data for quality assurance, longer-term safety monitoring, audits, and to help target inspections. The major proactive approach to assuring high quality and compliance with regulations in the blood industry is FDA's regular inspection process. In fact, the vigorous FDA inspection program has led, in recent years, to a number of major enforcement actions which have helped assure blood safety.

Mr. Chairman, I would like to join your fellow Committee members who have thanked you for holding this hearing, because you have raised awareness of an essential layer of the blood safety system. I want to assure you that none of us are waiting for the time required to issue a final rule to address this important matter. As you know, on August 13 of this year I had directed the Advisory Committee on Blood Safety and Availability to place this matter on their agenda. This meeting is scheduled for late January 2000, and preparations for it are already under way. One of the invited speakers will be Dr. Harold Kaplan, the Professor of Transfusion Medicine at Columbia University, who has been awarded a research grant by the National Heart, Lung, and Blood Institute to study transfusion error and how it might be reduced. The Department will promptly consider any recommendations that arise from this meeting, and I would be delighted to inform you of our response to these recommendations as soon as it is formulated.

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

Mr. UPTON. Well, thank you very much for your testimony, and again, I apologize for Members who are not here, but we do have a number of activities going on in committee that require all of our attention.

As I indicated in my opening statement, I am planning to donate blood next week, and I am going to be donating it through my local Red Cross facility back in Michigan. We don't have votes on Monday, and I know that the Red Cross, of course, complies with all the regulations. They are, in fact, licensed. They have inspections. They have prompt reporting of any error and accident rates, and all of us want very much to know and be assured that, in fact, all of the blood supply, 100 percent, is sufficient in terms of its level and that it is safe.

And one of the concerns that I know Chairman Bliley raised earlier and all of us share is that, in fact, we're not perhaps at that 100 percent level. And you referenced the regulations that were put out for comment back in 1997—a good year for the Michigan Wolverines, national champs, and we're looking to repeat again this year—but you know, 10 percent of the blood collected, in fact, goes

to unlicensed facilities that, as I understand it, are inspected maybe not more than once every 1 or 2 years. The definition of prompt reporting of errors and accident rates—it's all relative. Who knows what it is. In fact, furthermore, we learned that there are a number of blood transfusion centers that have no oversight by the FDA at all but, in fact, are overseen by HCFA. Is that right?

Mr. SATCHER. Well, there are some programs that come under HCFA because they are funded through Medicare and Medicaid, so that is true.

Mr. UPTON. But there's a mishmash of stuff that does not sort of bring the full regulatory oversight to 100 percent of the blood supply; is that not right?

Mr. SATCHER. I would say that's correct, and I think that that's what we're looking to correct.

Mr. UPTON. Well, Chairman Bliley indicated earlier today when he was here at the committee that one-third of the transfusion-related deaths could have been prevented by eliminating human errors in the processing of blood. Unfortunately, the FDA has yet to implement the regulations providing for more timely reporting and more comprehensive reporting of the error and accident rates as recommended by both the GAO and the Inspector General, and there are a lot of us that are not happy about waiting until the year 2001. That's a long time away.

Chairman Bliley raised earlier today that as the airline industry is required to promptly report all of the problems that may happen in the air. They have learned from those mistakes, and we had a 100 percent safety record, as I recall, this last year, no deaths. That has not been the case with blood safety. A question that I have for you, particularly as you look to the meeting that you referenced in January coming up a couple of months from now, would you be willing as the blood safety director to assume control over the policy of error and accident reporting, to put the medical event reporting system for transfusion medicine before that meeting and report back to this subcommittee next March or so on whether or not you can implement the error and accident reporting initiative way before they might otherwise come to it in 2001? Would that be something you'd be willing to discuss and put on the agenda?

Mr. SATCHER. Yeah. In essence, in our mind that's what I've done. My intent is that——

Mr. UPTON. In other words, we want someplace where the buck's going to stop, and we don't want to wait a couple more.

Mr. SATCHER. I take responsibility for blood safety and availability. I think my role as Assistant Secretary for Health puts me in charge of the Blood Safety and Availability Committee in the Department. We have an outside advisory council to whom we take issues so we can get the kind of input that we need to make the right decisions. So I take that responsibility very seriously, and I have talked with Commissioner Henney, and she is well aware that we're going to move forward when we get the information we need to deal with errors and accidents. We are not waiting until the year 2001.

Mr. UPTON. You think that you can implement a system that, in fact, will be in place way before 2001 so, in fact, 100 percent of the

blood collected will be regulated and we can be assured that it's safe?

Mr. SATCHER. I don't want to preempt the committee.

Mr. UPTON. You've got a couple of——

Mr. SATCHER. I don't want to preempt the January meeting. I can tell you what I think, but it wouldn't be fair for me to say to an advisory council, I want you to put this on your agenda, I want you to bring the best minds in the country to testify, and then when we finish that meeting, we're going to make a decision about how rapidly we can move, and I will report back to you. It is my intent to move as rapidly as possible, yes, but I do want to go through the process. I wish it would have happened faster, but this is where we are. We have set in this place, this process of bringing it before a very outstanding advisory council. Dr. Harold Kaplan will be there to testify, and we're going to move as rapidly as possible following that.

Mr. UPTON. Well, we'd like to light the fire underneath that meeting to be sure that it comes into place because we don't want to wait. We raised this at our hearing we had back in September. From 1997 to 2001 is too long. I don't know of any regulation in this administration or the last couple that has waited and languished that long on an issue that everyone, everyone will acknowledge is one of the most important things that we need to assure the American public that it is safe, particularly when we see the evidence that as much as 10 percent has regulation that's pretty lax. Every year or 2 someone might come by and inspect the records versus accurate and prompt reporting of any error or accident. If other agencies are able to do it, there's no reason why we can't try to expect the same for something just as vital as this one. Your leadership will be most appreciated in crossing that touchdown line.

Mr. SATCHER. I appreciate that. It's not my intent, and I try to avoid doing that, to make excuses for what has not happened, but in fairness to FDA and others, I don't think they have just been sitting and waiting. I think we have made a tremendous progress in this area while dealing with hepatitis C issues and several other major issues in blood safety where we, as you have pointed out, have made tremendous progress in the last 2 or 3 years. So they have not just been waiting, and I think if you look at the data in terms of the number of deaths that have occurred from blood transfusions, they have been coming down rapidly. I think it's about, what, 45 to 50 per year now based on, you know, the blood itself that's being transfused.

We have made tremendous progress. We will not be satisfied until we have in place a system that is optimal for protecting the blood supply and the safety of the transfusion itself,but they have not just been sitting and waiting. They have been involved in a process that I would agree I think we can move more rapidly, and we're going to move more rapidly.

Mr. UPTON. So you are not happy about the delay either then?

Mr. SATCHER. I am not happy about the delay, but I also understand people have made a lot of progress in the system while we have been, as you say, waiting for the formal, the final rules.

Mr. UPTON. What would you say about the blood transfusion centers? Are their regulations that you would like to see come into place, put it under one body instead of others such as we have learned with HCFA?

Mr. SATCHER. Well, I think—again, I think that's what—I'd like to wait and see what works best. There is a reason for things being the way that they are in terms of efficiencies, and we're going to look at that. That is one of the issues that we will be looking at, but again, I get criticized when I don't allow the advisory council to advise us before we make decisions and commitments, and I don't want to be guilty of that, and I don't think it's the best way to run this operation. So I will listen very carefully to the input from that council and will act on the best information expeditiously. That I will promise you.

Mr. UPTON. Well, we look forward to hearing back.

At this point, I yield to the vice chairman Mr. Burr.

Mr. SATCHER. If you would like to hear more details from Dr. Zoon.

Mr. UPTON. I'm sort of watching the clock. I didn't set this little timer here. Do you want to respond to that now? That would be terrific.

Ms. ZOON. One thing I would like to ensure the committee is 100 percent of the blood is regulated. That 10 percent of the blood supply which is supplied by registered blood banks in lieu of the 90 percent that's under licensed banks is regulated by FDA. They are required to maintain error and accident reports in their blood banks, and those are inspected when the FDA goes in there. Their submission of the reports to the FDA is voluntary, but their need to follow GMPs and establish error and accident reports and follow up on those error and accidents is part of our requirement.

Mr. UPTON. My point is, though, the inspections may lapse for as long as 20 or 24 months before someone actually comes by to sort of leaf through the material. Though the definition is we'd like you to report it today when you have an accident, in fact that doesn't happen.

Ms. ZOON. And we agree with the committee, and it is being changed in the proposed rule to have those voluntary reports mandated, but if there are problems in a facility, our inspectors will follow up more frequently than the 1 or 2 years, depending on the nature of the violations in the blood bank.

Mr. UPTON. But, see, one of the points I would like to make is here we have a problem that's been identified and you admit is a problem, and we'd like to change it. Why is it that it takes years to get even that part of it in place? What would be the problem of just promulgating a final rule that just deals with that, which then gives us all a little breathing room in terms of the safety of the blood supply?

Ms. ZOON. Sir, we did propose the rule which includes the very blood banks that you have——

Mr. UPTON. I know that it is proposed, but it's not final.

Ms. ZOON. And the FDA has gotten the comments back. We had 97 comments back on the proposed rule, and many of these comments have been reviewed, categorized, and definitely we are moving forward on this rule. And clearly under Dr. Satcher's leader-

ship, we will move as expeditiously as possible to finalize this rule, again, being mindful of the PHS Blood Advisory Committee. But one thing I want to assure the committee, and this is very important, that error and accidents are just a very small part of the surveillance procedures that we use for blood banks. We have—as I mentioned, there are not only error and accidents. We have adverse reports. We also have fatality reports, and I think this is very important because this requires the institutions to report to the agency immediately and then follow it up with a report within 7 days, and that is for the fatalities.

In addition, we get annual reports. If there are medical device reports, they are also reported to the agency. In addition, we have guidances, inspection programs and recalls that we use as part of our compliance activities to ensure at least that this oversight of the blood safety program is dealt with, and while we recognize the importance of error and accidents as part of that, it is part of the bigger picture of the FDA surveillance of this system. And we treat this very seriously because we believe this is an important area of one of the five layers of blood safety.

Mr. UPTON. I would just like to say, I know that I am beyond my 5 minutes and I apologize to my friend and colleague Mr. Burr. But as I think about things, 1997 is a while ago, and to have only 97—I used to work at OMB, and I know what comments look like—and to have only 97 comments come in is not an inordinate number that someone can't begin to look through, even almost one a month, to try and get the darn thing done. To wait until 2001, I just think one death is too many. I would hate to welcome that family and say, if those regulations had only been in place like it was proposed, you know, years ago, we could have saved. I mean, it's just not acceptable. I don't know if you're able to do this, but can you share with this committee the 97 comments?

Ms. ZOON. Yes, yes.

Mr. UPTON. Can I get copies of the 97? I'll look through them myself.

Ms. ZOON. Yes.

Mr. UPTON. I look forward to doing that, but I don't think it will take years to finish that, particularly when I know that one of the top priorities of the Commissioner is blood safety. I mean, it doesn't seem like we're getting there—it's not right. The priority may not be there even though she is well-intended in stating such. I mean, we're just not seeing the results that we really ought to have. It's because of that stack of frustration that the chairman and others are looking at. Maybe we ought to transfer the authority to someone that we know is responsible and thoughtful and courageous and a good spokesperson in making sure that the job gets done.

Mr. SATCHER. As we speak, I take responsibility because in the Department I am responsible for the blood safety community. That includes FDA and NIH and CDC, and I have discussed this with Commissioner Henney, and we are going to move forward expeditiously. We are going to give time——

Mr. UPTON. Well, surprise us. Okay.

Mr. Burr.

Mr. BURR. I thank you, Mr. Chairman.

Dr. Zoon, if you would just stay at the table, and I thank you for being here. Few people do I hold in as high a regard at the FDA as I do you, and I thank you.

Just for the record let me say, Mr. Chairman, that if my memory serves me correctly, the time that it took to go from proposed to final rule on tobacco was 1 year with 1,000 comments. So clearly when an agency is focused on completion, I think that significant increases can be made in how expeditious we move from proposed to final.

Let me say that it's refreshing, Dr. Satcher, to hear you hold off and to say, I am going to wait for the advisory panel. Most people fold and go ahead and give the answer prior to getting the recommendation, and I commend you for doing it because that's the reason we have advisory panels, but they're overlooked in many cases.

I thought, as Fred talked about blood donations, about my last one. It was a very tough process to go through. It was lengthy. The process time seemed to be doubled, if not tripled. There were questions that I had no clue as to why they asked them, and there were stations that I had to stop at that really did give me the impression that a bureaucrat set the system up versus somebody who's in the business of blood collection, and I think that was exacerbated by the fact that when I asked the individuals why they were there, they couldn't answer me. So I commend you on the efforts to streamline the process because I think that we're always limited in the potential pool. That pool is one that fluctuates up and down in the frequency of their donations, and I think right now we're trending in a direction, myself included, where the 55-day period which I usually aspire to religiously has slipped and slipped and slipped because of the time that's needed to drop by.

Let me ask you a few questions relative to the blood collection. I think most banks have expressed increased difficulty with their collections. Do you believe it's today as easy for a blood bank to take one of the mobile units up to a factory, and collect blood as it was prior to our efforts?

Mr. SATCHER. That's a tough question. One of the reasons the blood supply is as safe as it is is that we have had to make the process tough in some ways, but I still believe, based on my own personal experience with donating blood, that it is fairly easy to collect blood. I think we have to look at that donor satisfaction issue, and I listed that as one of the five areas that we're going to be looking at. I believe that we can improve rather than just leave it like that on what we're doing now because I don't know if we have done what I would call the sort of quality-assurance-type strategies that we need to do to really make this process as efficient as possible.

Mr. BURR. How much will technology play a role in our ability to expedite that process and to raise the assurance of a clean blood system in the next several years?

Mr. SATCHER. Well, you know, obviously, as I mentioned, technology will play a role, no question about it. The nucleic acid testing will certainly mean that some of the donors that we now either say no to or defer, we can really, really test the blood and know fairly comfortably that it is safe. So technology will continue to play

a major role, but also in just a repetitive way in which we're able to assess it.

I mean, just to reflect on hepatitis C, we first discovered this virus in this country in 1988, and around July 1992, June, July, we had a screening test that allowed us to really adequately screen the blood for hepatitis C. The difference in term—and those are the figures that I gave you about the risk of 1 in 100,000 versus a risk of 1 in 200 of receiving hepatitis C through a blood transfusion. Technology is critical in this area. It is the area where we have to continue to invest in improving technology, but also improving the technology of the process of blood donation.

Mr. BURR. Now, nucleic acid is still an investigational drug; it has not gone through approval?

Mr. SATCHER. Right.

Mr. BURR. Let me ask you about another one, Dr. Zoon. Abbott Labs prism blood screening analyzer. It came before the FDA in a 510K in October 1997. It took 18 months to get that final 510K clearance. Now, there's a Federal statute under the FDA Modernization Act. We didn't meet it in this particular case, and I am not asking for specifics about this application. If I did that, I'd do it privately. But I guess my question to you is, how much better are we doing? Where are the priorities as it relates to how new technology expedites the process, and gives us a higher degree of assurance? We did it with nucleic acid, but not with this. What's the process we go through?

Ms. ZOON. As you say, sir, the FDA Modernization Act had a number of provisions in it that the agency is currently implementing. CBER has a number of devices related to biological products, and those that are involved in blood screening lie under CBER's purview. We recognize the importance of high performance in this area, and, in fact, in the past 9 months we have issued a device action plan at the Center for Biologics to deal with performance issues, inspections, communication and a variety of areas to affect devices, so that we are looking forward to improvements in this area and performance overall by focusing on this more.

Mr. BURR. What is the percentage of applications that actually fall within that 90-day statute; do you know?

Ms. ZOON. Well, there's a number of—there are—the Center for Devices and Radiological Health have by far the large majority of 510Ks. I don't have those numbers right here in my head, but we'd be happy to get back to you.

Mr. BURR. Get back with me if mine are wrong, and according to recently released data, the FDA's Division of Blood Applications took first action within 90 days as required by the statute and the FAD's own performance goals in 36 percent of the cases. Now, if, in fact, my information is wrong, please let me know, but I would tell you that if you are looking for an area that we can have an immediate impact, let us get closer to 100 than zero as it relates to that statutory deadline of action on applications.

Dr. Satcher, let me go somewhere that probably isn't directly relevant to this hearing, but I think that it's important. There is a huge debate that will continue for some time, and possibly action by HHS, as it relates to medical privacy. I've looked at your plan on the hepatitis C look-back. The way I envision some of the pro-

posals as it relates to medical privacy, some go as far as an opt-in, opt-out on a patient's basis as far as the sharing of their data. Opt-out, it can go nowhere. It can be used for nothing. It cannot go into research for the purposes of drug and device development. But more importantly, when you lose the ability to have a key to identify the individual, how could that affect the public health of this country, and what would it do specifically to the ability to look back, whether it's hepatitis C, or if it's something 10 years from now, or all of a sudden there is a need to address a public health issue with individuals?

Mr. SATCHER. I think it's a critical issue, let me just put it that way. I think balancing patients' rights to privacy with the public health needs for research and investigation is one of the critical issues that we face. Obviously, it relates even to HIV name reporting which is being debated right now. For a lot of reasons you could argue that we need to treat HIV the same as we've treated other sexually transmitted diseases.

I think we have not in this country arrived at a point that we have assured the population that there is not a risk of being identified. We have been through a difficult period, you know, Ricky Ray and other things I can remind you of, where people have actually suffered because of identity. So we're trying to overcome that. We're trying to overcome that fear, that distrust. We're trying to find ways to assure people that we can protect them while at the same time carrying out the public health needs to take control of an infectious disease epidemic like hepatitis C or HIV.

Mr. BURR. Do you agree that Congress could go so far in the privacy effort that they could eliminate the ability for you as a Surgeon General, or CDC, or for anybody whose core function it is, to address the public health of the American people, that we would have an inability to look back, an inability, once technology allows us to find a genetic trait that may or may not be treatable, but we owe it to look back and notify the individual? Could we go so far that we couldn't have the ability to do that?

Mr. SATCHER. We could, but I think we have this need and this obligation to also protect the rights of people from abuse, and whether that occurs on a Federal level or State level or local level. So I think we're trying to balance these, and I think that does require us to do some things that are not necessarily optimal at the time in terms of the public health needs, but I think we always have to keep the public health needs of the Nation in the forefront while trying also to protect individuals.

Mr. BURR. I would agree with you totally.

Let me ask you relative to the technology infusion into this specific area of blood safety, if we went too far on the privacy issue, what does that do to the marketplace as it relates to what effort companies are going to make to develop technological advances in blood detection or any other areas?

Mr. SATCHER. Well, obviously, it could affect the market in terms of depending on what specifically we did.

Mr. BURR. It's not a trick question. I am not trying to nail you on anything. I'm just trying to make everybody understand this is a much bigger issue.

Mr. SATCHER. It's a very important issue, there's no question about it, and I think the bottom line is—and it's not always easy to get to that bottom line—is that we've got to find a way to balance the public health needs on the one hand and the thing that we value so much in this country, the rights of individuals and the protection of individuals from abuse.

Mr. BURR. If you couldn't identify the individuals who were exposed to mad cow disease, to follow them for whatever period of time we need to, to secure their safety, how much of a health risk is that in the U.S., if we don't know that it can be transmitted?

Mr. SATCHER. I don't know the answer to that question because——

Mr. BURR. Nor do I.

Mr. SATCHER. As I have already said, if we don't even know yet whether or not it is possible for a new variant CJD to be transmitted in blood transfusions, we certainly don't know the risk that individuals provide to others in society. So we are still studying that issue very carefully. So I can't answer your question.

Mr. BURR. If it could be transmitted, though, it would be important that we would know who was exposed, wouldn't it?

Mr. SATCHER. Yeah, but also you have to understand that we—what we need to be able to do is to detect any risk to the public that is in the blood supply. Many times the individual him or herself will not know that they have the risk in their blood. So our concern right now is our own ability to detect as early as possible any threat to the safety of the blood supply, and that's our major struggle.

Mr. BURR. You have mentioned nucleic acid several times. How available is it to blood centers around the country?

Ms. ZOON. While it's under investigational development, it has broad use—many blood centers have and institutions have taken it on under the clinical investigation phase to get experience with it and have been involved in these clinical trials. So it has a very broad base. I can't give you the percentage of implementation of NAT testing, or nucleic acid testing, for blood. It varies based on the agent. HCV and HIV are the two primary agents, and we could get you the exact numbers of how the percentage of what blood banks are using the NAT test for HCV and the NAT test for HIV.

Mr. BURR. What I conclude from that answer is that if we looked at it on a percentage basis, it would be a very small percentage of the blood banks.

Ms. ZOON. No. Actually Dr. Epstein just handed me 92 to 98 percent of whole blood is already NAT-tested for HCV.

Mr. BURR. Okay. Mr. Chairman, I thank you for the time that you were able to give me and would encourage you to give up on Michigan this year. They have no prayer.

Mr. UPTON. I just wished we played North Carolina and North Carolina State or any other, Wake Forest, it doesn't matter. The gentleman's time has expired.

Mr. BURR. Mr. Chairman, can I make one correction? My crack staff behind me informed me that I needed to correct the record as it related to the comments on tobacco. There were 7,000 comments on tobacco, which probably makes my point even a little heavier.

Mr. UPTON. But the problem is 6,000 of them were yours.

Okay. I have a question with regard to the NAT testing. When I donate blood next week, I am going to ask about the NAT test. My sense is that it will be NAT-tested. Tell me exactly what happens. You said, what, 90 percent of the blood collected today is NAT-tested, nucleic-acid-tested?

Ms. ZOON. Yes. It's investigational, so these are being studied in 92 to 98 percent of whole blood, and this is for hepatitis C virus, so I just want to make sure that's clear.

Mr. UPTON. Will they test it right there at the site?

Ms. ZOON. Some blood banks will have their own laboratory. Others have centralized laboratories. I believe ARC has centralized laboratory testing.

Mr. UPTON. Okay. Part of the testimony that we heard in September was the concern that at some point next year, the trend lines will cross, and we will perhaps be in a real crisis as the number of donors and blood units has been on the decline, and the need for blood is increasing. And particularly with the new test that's now in place or the new question that if you have been in the UK from 1980 to 1996 for a period of more than 6 months during that period, you're asked to come back some other date, who knows when, but because of that decline, which is probably about as much as 2.2 percent, as I recall, that, in fact, the real comfort level for the blood supply, particularly in a number of regions around the country, could be in desperate need. Now, would you agree with that? Is your sense along the same lines?

Mr. SATCHER. It's a difficult question, but let me just say that there are several things happening at the same time, and the same day on which, of course, we acted on that proposal, which we will monitor every 6 months, we've also taken action relative to hemochromatosis. What impact will this have on the blood supply? It could increase the blood supply from 300,000 units to 3 million units of blood a year. And then the other things that we are doing in terms of enhancing the blood supply—and on the other end, I think there's also some ways to be more efficient with how we use blood that we collect, and so all of these things are happening at the same time.

We're going to be vigorous in our attempts to make sure that the blood supply continues to be adequate and it's enhanced, especially in the areas of plasma donation.

Mr. UPTON. I was a little surprised when the NBDRC testified, and I was a little surprised at that hearing that there was not a system now in place, at least monitored by the FDA or anybody else, that actually measures the units of blood on a monthly basis that are collected, and in fact, your statement as part of the record was that we are going to get data—and the NBDRC indicated they would share the data with this committee as well. I hope we don't have to pay $300,000 for it.

Mr. SATCHER. You've already paid $300,000.

Mr. UPTON. Yeah, maybe we did. But I was surprised, I guess, that we've spent a lot of money. Over the last couple of decades looking at some of these trend lines, and yet there is not one thing that has been collected at least on a national basis until beginning of next year. What's your comment with regard to that?

Ms. ZOON. Well, my only comment is that at this point in time, we recognize the need right now, especially with the current concerns regarding blood supply, to make sure that we have a vigorous program in the Department to look at this, and, in fact, this study is actually being funded by the National Heart, Lung, and Blood Institute and will be sharing the data with the FDA and the CDC and working with Dr. Satcher on the Blood Safety Committee to make sure that we use this information wisely to ensure an adequate blood supply.

So we have not done this, to my knowledge, on a monthly basis or contracted this information, but we have—there have been other studies looking at blood donations, and that will be important additional information, as we go forward, to look at what initiatives we may need to follow.

Mr. SATCHER. And I think there is—we think that there is a lot of potential in going back to donors like yourself, and I don't know how often you donate, but there are a lot of people who take very seriously the donation of blood. Many of them only donate once a year, and so we can be much more aggressive in terms of trying to encourage people to donate more, but also that pool of people who are eligible who don't donate, so we're going to be working in all of these areas.

Mr. UPTON. Well, that second category is going to be considerably larger than the first one, I imagine. Maybe we just ought to get for happenstance a show of hands in this room, how many folks here have donated blood ever, raise your hand. I'm pleasantly surprised. And how many people have donated in the last year? My hand is down, too, but it will change next week.

Mr. SATCHER. That's an important question, and how do we get to the 60 percent. You see, I didn't raise my hand for the last year.

Mr. UPTON. Because the camera was on you.

Mr. SATCHER. No, no, because I travel. In my position, I travel a lot, and there are a lot of places where we travel that you're not eligible——

Mr. UPTON. We'd like you travel to Michigan. You can do it with me on Monday.

Mr. SATCHER. No. I travel to places where if you travel there, you're not eligible to donate blood, sometimes for 3 years, and that's one of the ways we protect the safety of the blood supply.

Mr. UPTON. What are some of those countries? I will fill out the questionnaire when I am there on Monday, but what countries are——

Mr. SATCHER. Places that are high risk for malaria for example, sub-Saharan Africa, Southeast Asia, places where countries are still struggling with malaria, and hopefully we're going to solve that problem because the World Health Organization has made a real commitment to roll back malaria. But these are maybe 1 billion people in the world who are now at risk for malaria because of where they live. Generally, they are places where poverty is a major factor in terms of setting up the systems to prevent the spread of malaria and diseases like that. So if you travel to those areas, in order to optimally protect the safety of the blood supply, we ask people—we don't allow people to donate for quite a while.

Mr. UPTON. That's certainly a valid excuse. You don't need to submit anything in writing on that.

One of the things you indicated in your statement was that the NIH has been authorized to spend $1.8 million to enhance and improve the number of folks that donate blood. Has that ever been done before? Has NIH been given that authority before? Have there been times that they have had——

Mr. SATCHER. They have a priority. What I don't know is if they have ever done it before. I don't think so.

Mr. UPTON. Do you know if they have done that before?

Mr. SATCHER. It's new. As far—I'm always hesitant to say it's never been done before.

Mr. UPTON. Especially under oath.

Mr. SATCHER. Yeah, that's right. But as far as we know, it has not been done before.

Mr. UPTON. And do you know when their report is going to be due or submitted? Do you know when that will be? It won't be in time for your January meeting, will it, or it will be? Good, I see a nod.

Ms. ZOON. The money or the funding for the NBDRC is committed to produce monthly data is starting in October. So we should have our first report in November.

Mr. SATCHER. We don't know how much information we will have by then, so when we say monthly reports, some of those will be just process reports.

Mr. UPTON. I know that we asked for the same data, as I indicated a little earlier, so we are looking forward to seeing those trend lines particularly early next year when Congress comes back, after we finish at some point this year as well.

Well, I appreciate you both coming up today, and we may have additional questions that other members of the panel may wish to submit. If you could respond to those in a timely basis, that would be terrific.

We wish you well on your meeting. If you would like to take this gavel and rap some knuckles, it's yours, and you don't need——

Mr. SATCHER. We really appreciate your holding this hearing. I think it will help to move us forward. We appreciate your attention.

Mr. UPTON. We will be following it with rapt attention, I can assure you. Thank you very much. You are excused. Thank you.

[Whereupon, at 12:10 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON COMMERCE
October 21, 1999

The Honorable DAVID SATCHER
Assistant Secretary for Health and Surgeon General
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

DEAR DR. SATCHER: Thank you for your testimony on October 6, 1999 concerning the safety and availability of the U.S. blood supply. I appreciate your commitment and hard work for maintaining the safety and availability of the nation's blood supply. As a follow-up to the hearing, I would appreciate your response to a question concerning the Hepatitis C education program.

Hepatitis C virus (HCV) is the most common cause of post-transfusion hepatitis. Overall, HCV is responsible for 15 to 20 percent of all cases of acute hepatitis and is the most common cause of chronic liver disease. Prior to 1992, blood was not routinely tested for HCV prior to transfusion. FDA regulations now require testing of all blood for HCV. HCV has become a major public health concern, and public health agencies have engaged in an active search to identify patients exposed to HCV-infected blood. In August 1997, the Department of Health and Human Services recommended a look-back and public education campaign.

On March 5, 1998, you announced the HCV look back and education plan. You testified that HHS has "established a comprehensive plan to address this significant public health problem. It is our intention to reach effectively as many people at risk as we can." My understanding is that rather than running a national campaign informing people at risk about the need to get tested for Hepatitis C, the Centers for Disease Control (CDC) is pilot testing transit ads in the insides of buses and other public transportation only in the Washington, D.C. area and Chicago, September 1-October 31, 1999. This month, the Michigan Hepatitis C Coalition is kicking off a statewide education campaign, Hepatitis C Awareness Month. I understand as many as 168,000 Michigan residents already may be infected with Hepatitis C. These residents and many other Americans would benefit from the Hepatitis C public education program.

Given your commitment to a comprehensive campaign, when will the Hepatitis C public education program run nationally? In addition to providing a target date, please explain what information the CDC expects to gain from the pilot program and how this could affect the design and timing of the public education program.

I would appreciate your response by November 12, 1999, for purposes of completing the hearing record. Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Committee staff at (202) 225-2927.

Sincerely,

FRED UPTON, *Chairman*
Subcommittee on Oversight and Investigations

cc: The Honorable Tom Bliley, Chairman
The Honorable John D. Dingell, Ranking Member
The Honorable Ron Klink, Ranking Member Subcommittee on Oversight and Investigations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR HEALTH
SURGEON GENERAL
November 18, 1999

The Honorable FRED UPTON
Subcommittee on Oversight and Investigation
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, D.C. 20515-6115

DEAR MR. UPTON: I am happy to respond to your inquiry of October 21, 1999 regarding the Department of Health and Human Services' Hepatitis C Public Education Program.

This program, which I announced in Congressional testimony on March 5, 1998, has several components. These include education of healthcare professionals, education of the general public, and education of those at increased risk of hepatitis C virus (HCV) infection.

Our efforts to educate healthcare professionals began in 1997. Prior to this time, many physicians had little knowledge of HCV infection, and there were differences of opinion among experts about how best to manage this condition. For this reason, a Consensus Development Conference was convened by the National Institutes of Health (NIH) in March 1997. Following this Conference, the NIH issued *Management of Hepatitis C*, based on evidence presented at the Consensus Conference. In November 1997, The Centers for Disease Control and Prevention (CDC), in collaboration with the Hepatitis Foundation International, produced an interactive satellite conference on HCV infection for primary care physicians, *Hepatitis C: Diagnosis, Clinical Management, Prevention*. The audiotape and other materials from this teleconference were mailed to 250,000 primary care physicians (family practitioners, internists, pediatricians, surgeons, and obstetrician-gynecologists) during the summer of 1998.

In July 1998, CDC convened a meeting of consultants to develop updated recommendations for the prevention and control of HCV infection and HCV-related chronic liver disease, including identification of persons at risk because of prior blood transfusion. In October 1998, *Recommendations for Prevention and Control of*

Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Liver Disease was published as a supplement to Morbidity and Mortality Weekly Report. This supplement was mailed to both primary and specialty care physicians throughout the country. These publications provided a framework for developing health education messages concerning HCV screening, counseling, and prevention to the public.

Initial public education activities begin in 1997 with the development of health communications materials on hepatitis C, risk factors for HCV infection, and HCV testing. These materials were developed by the CDC and the American Liver Foundation, the Hepatitis Foundation International, and the National Association of City and County Health Officials, with support from cooperative agreements funded by CDC. In early 1998, CDC began routine updates of information about HCV prevention, testing, and control on its website and on its Hepatitis Information Line.

Development of national public education activities to encourage HCV testing of persons at risk because of prior blood transfusion began in February 1999. Contracts were funded for the development of public advertising and patient information brochures. Focus groups of individuals who had received transfusions were used in the development of these materials. On May 5, 1999, CDC hosted a press briefing about HCV at the National Press Club; this event was attended by over 100 media representatives. Public transit advertisements based on these materials were run in Washington, D.C. and Chicago in September and October, 1999, at a cost of $70,000. The impact of this pilot program on the number of inquiries to the CDC Hepatitis Information Line, a manned hepatitis C hotline, and to the CDC hepatitis web site is currently being analyzed.

CDC plans to expand this effort nationwide by making these materials available to national voluntary health organizations for distribution. In addition, through the CDC Foundation, partnerships are being developed for cosponsorship of an expanded national public advertising campaign that is to begin in early 2000.

Also in early 2000, CDC plans to bring together national professional and voluntary health organizations whose patients have a high likelihood of having received a transfusion before July 1992 (e.g., premature infants, persons who had heart surgery, women who had caesarean sections). The purpose of this meeting is to encourage these organizations to make their membership aware of the need for HCV testing for certain transfusion recipients and to share the materials developed by CDC.

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

Sincerely yours,

DAVID SATCHER, *M.D., Ph.D.*
Assistant Secretary for Health and Surgeon General

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON COMMERCE
November 1, 1999

The Honorable DAVID SATCHER
Assistant Secretary for Health and Surgeon General
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

DEAR DR. SATCHER: Thank you for your testimony on October 6, 1999 concerning the safety and availability of the U.S. blood supply. As a follow-up to the hearing, I would appreciate your responses to the following questions:

1. The FDA, NIH, and U.S. Army held a September 27-28, 1999 Workshop on "Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes." Given the potential shortages which could occur—either regionally or nationally—in the blood supply, some observers believe that oxygen therapeutics could provide a safe, effective, and readily available alternative to blood donations. What specific actions and timelines for implementation resulted from this Workshop?

2. The General Accounting Office (GAO) indicated that "one alternative being explored for handling issues of blood shortages and blood safety is the development of blood substitutes." The goal is to develop substitutes for red blood cells that are safe, do not require cross-matching or typing, have a longer shelf-life, are readily available in large quantities, and deliver oxygen therapeutically and quickly to tissues and organs. Given the potential of these alternative agents, what criteria would be considered for expedited review of their use for specific applications which could relieve shortages, either regionally or nationally, if and when they occur? If the criteria were satisfied, what steps would be taken to expedite review?

3. As indicated by the GAO, the U.S. imports approximately 2% of its blood supply. Given the potential for shortages in the U.S. supply, how can HHS assure that any increased imports of blood will have the same level of quality—particularly considering donor exclusions like the ban on individuals who have resided in the U.K. for a cumulative 6 months or more between 1980 and 1996?

I would appreciate your response by November 15, 1999, for purposes of completing the hearing record. Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Committee staff at (202) 225-2927.

Sincerely,

FRED UPTON, *Chairman*
Subcommittee on Oversight and Investigations

cc: The Honorable Tom Bliley, Chairman
The Honorable John D. Dingell, Ranking Member
The Honorable Ron Klink, Ranking Member Subcommittee on Oversight and Investigations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR HEALTH
SURGEON GENERAL
November 18, 1999

The Honorable FRED UPTON
Subcommittee on Oversight and Investigation
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, D.C. 20515-6115

DEAR CONGRESSMAN UPTON: I am writing in response to your letter to me dated November 1, 1999 concerning the development of oxygen-carrying therapeutics as possible blood substitutes in light of possible blood shortages. At this time the approval of any such product is not imminent, since no candidate product has yet been shown to be safe and effective for a well-defined clinical indication. By way of clarification, it needs to be understood that oxygen-carrying therapeutics may not actually substitute for use of blood products. For example, products with a short duration of action in the body may prove useful as volume replacement solutions, but only as a temporary therapy until blood is available. Also, even if oxygen-carrying therapeutics can substitute for use of some blood components such as red cells, they cannot be expected to substitute for use of all blood components due to the complex nature or blood.

FDA has been very active in its interactions with the industry that is developing oxygen-carrying therapeutics both through public discussions and regular meetings at the request of product sponsors. At these meetings, sponsors are given the opportunity to express their views and discuss their data. FDA understands industry's concerns about the often-difficult clinical studies that are necessary to validate these products. At the same time, FDA is appropriately concerned about the need for careful studies to establish the safety of oxygen-carrying therapeutics. As you know, there have been enormous strides made in recent years to make the United States blood supply highly safe. If a product is to be used as a substitute for blood, there should be assurance that it is at least as safe as blood. Studies to substantiate safety comparable to blood products necessarily are large, difficult and expensive.

The following remarks address your specific questions as numbered in your letter:

1. You asked what specific actions and timelines for implementation resulted from FDA's recent "Workshop on Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes." As a result of the valuable discussions from both industry representatives and academic researchers who are prominent in the field, FDA will develop an industry guidance document on the design of clinical trials to validate indications for oxygen-carrying therapeutics. According to established "Good Guidance Practices" the guidance will be distributed initially as a draft for comment, and then finalized for implementation after review of public comments. In this policy document FDA will address the various possible indications for these products and provide guidance an the data needed to validate different claims. FDA's Center for Biologics Evaluation and Research expects to develop the draft guidance by the end of Spring 2000. In the interim, FDA will continue to make its current thinking known through public statements and in meetings with product sponsors.

2. You have asked what criteria would be considered for expedited review of these products. FDA is committed to a rapid approval of any product that addresses a significant unmet medical need such as novel use in a serious or life-threatening condition. Under the FDA Modernization Act of 1997, criteria for fast track approval were well defined. In particular, accelerated marketing approval can be granted to appli-

cable drugs that have an effect on a surrogate marker that is reasonably likely to predict clinical benefit, As yet, such surrogate markers have not been established for validation of oxygen-carrying therapeutics. Nevertheless, FDA is working cooperatively with product sponsors to clarify the requirements for validation and thereby facilitate product development. For some indications, e.g., trauma, the endpoint of mortality is of overwhelming interest and it is possible that a surrogate may not be useful.

3. You have asked how DHHS can assure that any increased importation of blood will maintain the U.S. standards for quality. As you know, FDA allows blood products to be imported under certain conditions. However, the blood that is imported for distribution in the U.S. is collected and processed only in FDA-licensed facilities. As such, the facilities are required to meet all of our standards including those for donor suitability, product testing, and good manufacturing practice. To insure compliance, U.S.-licensed foreign facilities are inspected according to the same standards as facilities located within our borders. Blood products that are not collected in licensed facilities may be imported for further processing solely for export under appropriate circumstances and conditions as determined by FDA. Such imported blood cannot be distributed for human use in the U.S., and the final manufactured product can only be exported. Therefore, the safety or availability of blood products in the U.S. would not be affected.

I hope that these remarks adequately address your stated concerns. Please feel free to contact this office if you have additional comments.

Sincerely yours,

DAVID SATCHER, *M.D., Ph.D.*
Assistant Secretary for Health and Surgeon General

DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
November 23, 1999

The Honorable FRED UPTON
Chairman
Subcommittee on Oversight and Investigations
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6116

DEAR MR. CHAIRMAN: The Food and Drug Administration (FDA or Agency) appreciated the opportunity to accompany Dr. David Satcher, Assistant Secretary of Health and Surgeon General, at the October 6 hearing to discuss the present state of blood safety and availability. FDA appreciates and shares your concern about the safety of the blood supply. During the October 6 hearing Dr. Kathryn C. Zoon, Director, Center for Biologics Evaluation and Research (CBER), was requested to provide written answers to several questions for the hearing record. The questions and answers are provided below and the corrected transcript is enclosed. In addition, to assist the Committee in its consideration of blood safety issues, a more detailed explanation of certain aspects of FDA's blood safety program is provided.

Error and Accident Reports

FDA is committed to finalizing the proposed rule on error and accident. FDA appreciates the concern expressed by you about the lack of required error and accident reporting for registered, but unlicensed blood banks. A more detailed explanation of the error and accident reporting function and its applicability to blood safety is provided below for your information.

Error and accident reports are one of several safety layers FDA utilizes in monitoring the safety of the blood supply. FDA uses error and accident reports primarily to identify systemic problems for the entire industry. Inspections are the most important tool used to monitor industry compliance. Prior to inspection, and on an ongoing basis, FDA reviews previous inspection reports, fatality reports, adverse experience reports, medical device reports, annual reports and error and accident reports. During inspection, FDA reviews these reports to determine if the firm appropriately investigated the incident and implemented corrective action.

There is, at times, a public misconception that recalls and withdrawals of products are dependent on the filing of error and accident reports to the Agency or that such actions are somehow delayed by the classification of such reports. This is not accurate. Blood establishments are required to take corrective actions immediately, independent of the reporting process. Blood establishments are ultimately responsible for the products they distribute. FDA monitors industry compliance with

standards but cannot function as the quality assurance unit for each manufacturer. It is the manufacturer's responsibility to comply with rigorous standards that are necessary to protect the blood supply. The error and accident reports constitute one facet of the system of overlapping surveillance. Primarily, these serve as one source of information on industry performance. The most critical problems that result in a fatality are brought to FDA's attention in a short time and investigated. As noted at the hearing, fatalities are required to be reported to FDA within seven days (21 CFR § 606.170(b)).

The requirement for blood establishments to file error and accident reports cannot itself provide an assurance that blood will be safe. The majority of errors or accidents are not life threatening and are detected and reported retrospectively during quality assurance activities or audits (21 C.F.R. § 211.180 (e) and 21 C.F.R. § 820.22 requires that audits be performed on at least an annual basis). The detection of errors and accidents allows firms to investigate and correct any deficiency in the system so that future errors can be prevented. On an industry wide basis, the actual reporting to FDA of errors and accidents enhances FDA's oversight. These reports assist the Agency to identify the need to develop new policy, to revise existing policy, to provide training to industry and FDA inspection personnel and to revise compliance programs as appropriate.

Licensed Blood Banks and Unlicensed Blood Banks (Registered)

During the hearing on October 6 and the two other hearings held on blood safety and availability, licensed and unlicensed blood banks were discussed. To assist the Committee, the following information may be helpful.

All blood banks are registered with FDA and are assigned registration numbers. The Public Health Service Act requires a firm to have a license in order to introduce biological products such as blood and blood products into interstate commerce. This is in addition to being registered with FDA. Although there are two types of facilities, there is no difference in the inspectional coverage or requirements to follow current good manufacturing practices (cGMPs) for licensed versus unlicensed blood banks. Routinely, all blood banks are inspected once every two years. Inspectional frequency of individual blood banks is increased, however, when there is a recent violative history.

Transfusion Services

A number of questions were also raised during the hearing concerning transfusion services and we wanted to provide additional information for the Committee. Transfusion services routinely perform blood typing and crossmatching. Transfusion services do not collect blood or manufacture components. While the majority of transfusion services are inspected by the Health Care Financing Administration (HCFA), some transfusion services that perform some further manufacturing of blood products such as washing, freezing, deglycerolyzing, or irradiating are inspected by FDA. Because the Veteran's Affairs and military transfusion services are not regulated by HCFA, these facilities are also inspected by FDA.

Transfusion services that are inspected by HCFA are usually small hospital or outpatient center blood banks that only perform blood typing, crossmatching and issue blood. As of November 1, 1999, the number of transfusion services, which do not collect blood or manufacture blood components, and are regulated by HCFA is about 5000. FDA's and HCFA's coverage and responsibilities for these facilities is discussed in the 1980 Memorandum of Understanding between FDA and HCFA, a copy of which is enclosed as Tab A.

Fatality Reports

In the hearings held by the Committee there was uncertainty concerning the number and types of fatalities. As noted at the hearing, fatalities are required to be reported to FDA within seven days (21 CFR § 606.170(b)). We are happy to provide the following information for clarification.

The total number of fatalities reported to FDA in the last 3 years is:

FY 1999	64
FY 1998	85
January to September 1997	57

Of these fatalities, the following numbers and percentages refer to fatalities that occurred as a result of an individual receiving the wrong unit of blood:

FY 1999	7 (11%)
FY 1998	11 (13%)
January to September 1997	14 (25%)

These errors have been attributed to either laboratory staff or other persons outside the blood bank (usually nurses and medical staff in the OR, ER, ICU, or patient units), in the following numbers:

	Lab	Other
FY 1999	4	3
FY 1998	6	5
January-September 1997	8	6

Please note that CBER changed its reporting interval in October 1997 to reflect the fiscal year used throughout the Government.

A small number of the laboratory errors are caused by laboratory personnel, usually phlebotomists, who do not work directly in the blood bank but who obtain blood specimens from patients for the blood bank to use in crossmatching. Errors caused by nurses and medical staff outside the blood bank can occur when a unit that has been correctly processed and labeled is given to the wrong patient. As mentioned above, please note that the number of fatalities caused by patients receiving the wrong unit of blood has decreased over the past 3 years.

Questions/Answers from October 6 Hearing

Question: (Chairman Fred Upton) Could FDA provide the 97 docket comments received commenting on the 1997 proposed Error and Accident Rule?

FDA has provided these comments previously to the Committee. All of the docket comments were provided electronically to Mr. Alan Slobodin, Committee Counsel, over several days, from September 26 through September 29.

Question: (Mr. Richard Burr) According to his information, only 36% of device applications filed with CBER had a first action within the statutory deadline of 90 days.

Please find enclosed at Tab B a chart entitled, CBER's Device Review Performance, which details FY99 and FY98 device review data for a number of categories. CBER is committed to improving its performance in this area. As was explained by Dr. Kathryn Zoon at the hearing, CBER has made considerable progress in improving device review times. Performance has been of concern in the past and in response to that concern, CBER held a stakeholders meeting in December 1998 specifically to discuss CBER's review of medical devices. One result of that meeting was the development of the CBER Device Action Plan (DAP). This DAP is provided at Tab C. The plan also can be found on FDA's website at www.fda.gov/cber.

The plan went into effect on April 20, 1999. Since then, CBER has received 17 device submissions. Of these 17, 11 have had a first action completed on time while the remaining 6 submissions are pending and CBER anticipates completing the first action within the due date.

In conjunction with the DAP, CBER also has conducted a number of activities that relate to the implementation of the Food and Drug Administration Modernization Act device provisions. These include the following:

CBER is working along with CDRH on device standards development and guidances for In vitro Diagnostics.

CBER established a "Device Information" section on its home page that includes:
- The Device Action Plan
- A list of medical devices regulated by CBER
- Device Approval Information
- FDAMA Guidances, Information on Preparation Device Marketing Submissions, & Intercenter Agreement between CBER and CDRH

In July 1999, CBER established mechanisms to meet the time periods specified in FDAMA for the review of applications and submissions.

CBER conducted scientific training to improve the skills of product reviewers; many product reviewers also took courses sponsored by CDRH.

CBER and the Health Industry Manufacturers Association (HIMA) cosponsored a Vendor's Day for CBER staff to allow biological device manufacturers to demonstrate new biological devices and describe how they work.

A CBER sponsored public meeting and teleconference was held on November 15, 1999, with device stakeholders on the development of regulations and guidance documents.

Question: (Mr. Richard Burr) Why did it take 18 months for the Abbott Prism screening test to receive 510k clearance?

The original submission for this device came to FDA in October 1997, and the review was completed in November 1998. At that time, a period of 1 year for a blood device review was not uncommon in CBER and reflected the resource limitations in this program.

Question: (Mr. Richard Burr) What percentage of facilities are using nucleic acid testing (NAT) for its blood donations?

Information on implementation of NAT was provided to FDA in August and October by the American Association of Blood Banks based on a survey of blood centers and hospitals. As of October 1999, of the blood centers that collect approximately 92% of whole blood in the United States, close to 100% were using NAT for Hepatitis C Virus (HCV) screening. As of August 1999, approximately 65%-78% of these same centers were using NAT for HIV. Of hospitals that collect about 8% of the blood supply in the United States, approximately 10% (51 out of 500 hospitals surveyed) were using NAT for HCV screening. These 51 hospitals account for about 90% of hospital collections, so another 7% of the blood supply was being screened by NAT for HCV. As of August 1999, the Department of Defense (DOD) had not yet implemented NAT testing. DOD collections represent about 1% of the blood supply. Since the test is not yet approved, all use is being conducted as part of clinical trials for the investigational product. Part of the 8% of blood that is collected by hospital blood banks is autologous blood, to be used by the donor only, and presents no additional risk of infection to the donor/recipient.

We hope this information is useful and responds to your questions. We will be glad to answer any other questions you have.

Sincerely

MELINDA PLAISIER
Associate Commissioner for Legislation

Enclosures

cc: The Honorable Ron Klink
Ranking Member
Subcommittee on Oversight and Investigations
House of Representatives

The Honorable Tom Bliley
Chairman, Committee on Commerce
House of Representatives

The Honorable John Dingell
Ranking Member
Committee on Commerce
House of Representatives

Tab A

SUBJECT: MOU with Health Care Financing Administration Concerning Blood-Banking and Transfusion Programs (FDA 225-80-4000)

MEMORANDUM OF UNDERSTANDING

Between The

HEALTH CARE FINANCING ADMINISTRATION

And The

FOOD AND DRUG ADMINISTRATION

I. Purpose and Background:

Since 1966, hospitals and independent laboratories participating in the program of Health Insurance for the Aged and Disabled established by Title XVIII of the Social Security Act (Medicare), have been surveyed by HHS, most recently including the Health Care Financing Administration (HCFA), for compliance with the applicable provisions of the Medicare statute and regulations. These regulations include requirements affecting the blood banking and transfusion services of hospitals and independent laboratories. (Hospitals accredited by the Joint Commission on the Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA) are deemed under the Medicare Act and regulations to meet most of the Medicare requirements.)

Since 1973, the Food and Drug Administration (FDA) has concurrently conducted administrative inspections of blood banks and transfusion services engaged in the collection, processing, storage, compatibility testing, or distribution of blood and blood components under the drug provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the biological products provisions of the Public Health Service Act (42 U.S.C 262).

Most nongovernmental hospitals and independent laboratories with blood-banking or transfusion service capabilities approved by the Medicare program are also subject to inspection by FDA. In early 1979, HCFA and FDA proposed to coordinate all Federally authorized inspections of hospital blood banks and transfusion services in order to minimize duplication of effort and to reduce the burden on affected facilities. This Memorandum of Understanding finalizes the

consolidation within HCFA of all responsibilities for the inspection and surveying of approximately 3,000 transfusion services. However, other blood establishments, as defined below, will remain subject to inspection under the Public Health Service (PHS)/FDA program, and will also be subject to HCFA requirements if they choose to participate in the Medicare Program.

PHS/FDA and HCFA shall continue to act under existing delegations of authority, and no transfer of statutory functions or authority is made here. HCFA shall, however, conform many of its program requirements for the survey of blood banks and transfusion services to those issued by PHS/FDA. This includes the adoption of certain of the PHS/FDA regulations applicable to blood and blood component products set forth at 21 CFR Part 606.

Additionally, PHS/FDA shall no longer inspect on a routine basis clinical laboratories or portions thereof which perform tests such as hepatitis tests, serum protein electrophoresis, or quantitative immunoglobulin determinations in support of the preparation of biological products by a firm registered with PHS/FDA, if the clinical laboratory is approved under the HCFA program.

II. Substance of Agreement:

A. Definitions

For the purpose of this agreement, the following definitions apply:

1. A "transfusion service" is a facility, which is part of either a hospital or an independent clinical laboratory, and which performs compatibility tests for, but is not engaged in the routine collection or processing of, blood or plasma (except recovered plasma or red blood cells) except for therapeutic collections, and the hospital or the independent testing laboratory is approved by HCFA for participation in the Medicare program.

2. A "blood establishment" is any other facility or portions of a facility registered as such with FDA pursuant to 21 U.S.C. Part 510 and 21 CFR Part 607. Blood establishments include hospital and non- hospital blood banks, plasmapheresis centers, and the clinical laboratories performing required testing for these establishments.

B. Transfusion service survey and approval.

HCFA shall be responsible for:

1. Surveying hospitals and independent laboratories, including the transfusion service, and applying the Medicare conditions of participation and conditions for coverage through the Medicare survey, certification, and facility approval process, including the utilization of HCFA's system of Medicare State survey agency agreements;

2. Approving and disppproving hospitals and independent laboratories for purposes of Medicare.

3. Surveying the transfusion service of hospitals and independent laboratories in conjunction with PHS/FDA, when such a survey is appropriate to certify and document any alleged significant deficiency or deficiencies, which would, if confirmed to be present, adversely affect the health and safety of patients.

4. Conducting special surveys of the transfusion services of hospitals and independent laboratories concerning administrative, procedural, licensure, technical certification or related matters as needed, or when requested by PHS/FDA or others, as appropriate.

5. Conducting enforcement activities, such as the investigation and referral of cases to the Inspector General of the Department of Health and Human Services for further action.

6. Negotiating, approving, and administering agreements with the Medicare State survey agencies; and

7. Applying the administrative review and hearing provisions applicable to hospitals and independent laboratories under Medicare.

C. Survey of good manufacturing practices in facilities performing emergency blood collections only

HCFA shall survey the procedures related to the collection and processing (including labeling) of blood and blood components for transfusion at transfusion services in hospitals and independent clinical laboratories participating in the Medicare program. These facilities will not be registered as blood

establishments with PHS/FDA.

D. Development of technical and scientific standards

PHS/FDA shall be responsible for the promulgation and interpretation of technical and scientific standards relating to transfusion services and blood establishments and for responding to inquiries concerning these standards except as indicated in paragraph E below. HCFA shall undertake to adopt these standards for use in the Medicare program.

E. Application of personnel and proficiency testing standards

For purposes of the Medicare program, the HCFA standards for personnel (42 CFR 405. 1028(d), (g), and (i) for hospitals and 42 CFR 405.1310 through 405.1315 for independent clinical laboratories) and proficiency testing (42 CFR 405.1314(a)) shall apply. For purposes of the PHS/FDA program, the PHS/FDA standards for personnel (21 CFR 600.10 for licensed establishments and 21 CFR 606.20 of registered blood establishments) shall apply to registered licensed and unlicensed blood establishments.

F. Special investigations of clinical laboratories

PHS/FDA shall no longer routinely inspect clinical laboratories or portions thereof which perform hepatitis tests or other laboratory procedures for registered blood establishments when the laboratory is surveyed by and meets the requirements of the HCFA program. When a special investigation is required by PHS/FDA to document the presence of any alleged significant deficiency or deficiencies which would, if confirmed, adversely affect the safety or efficacy of products, or the safety or health of donors, the investigation by FDA will be coordinated with regional HCFA personnel.

G. Adverse transfusion reaction reporting

The provisions of 21 CFR 606.170(b) require that fatal transfusion reactions related to the administration of blood or blood components be reported as soon as possible to PHS/FDA. PHS/FDA evaluates these reports and, when indicated, may undertake special investigations to determine whether remedial action has been or needs to be undertaken by the blood establishment.

PHS/FDA shall continue to receive these reports from blood banks and transfusion services in hospitals and independent

laboratories participating in the Medicare program. Those reports received by FDA from transfusion services will be transmitted to HCFA for evaluation and followup under that program. In addition PHS/FDA shall transmit to HCFA those reports which involve fatalities resulting from errors and accidents in areas of a hospital unrelated to the collection or processing of blood or blood components.

H. Research and development

1. PHS/FDA shall be responsible for conducting studies related to the technical and scientific aspects of the administration and regulation of transfusion services and blood establishments, including studies for standards' development, improved quality control practices and testing, and evaluation methodologies.

2. HCFA shall be responsible for conducting studies pertaining to the Medicare coverage and amount of reimbursement to hospitals and independent laboratories stemming from the activities of their transfusion services and blood banks, the survey and approval of such services, the appropriate utilization of services, and the related administrative processes.

I. Training

1. PHS/FDA shall furnish technical assistance to HCFA for the training of laboratory surveyors of the Medicare State survey agencies and other HCFA survey personnel with respect to the technical and scientific standards applicable to transfusion services and blood banks.

2. HCFA, in conjunction with PHS/FDA, shall be responsible for training laboratory surveyors of the Medicare State survey agencies and HCFA personnel concerning blood banking administration and procedure.

J. Amendments

This agreement may be modified at any time in writing by the Assistant Secretary for Health, the Commissioner of Food and Drugs, and the Administrator of the Health Care Financing Administration, or their authorized delegates. PHS/FDA and HCFA shall review this memorandum of understanding within 2 years after its effective date. Either party in the interim has a right to an earlier review of this agreement or any of its provisions.

K. Resolution of differences

In any case in which PHS/FDA and HCFA find that the resolution of significant differences with respect to this agreement cannot be achieved, the matter will be referred by the Assistant Secretary for Health, the Commissioner of Food and Drugs, and the Administrator, HCFA, to the Undersecretary or the Secretary for decision.

For the Public Health Service:

By: [signature]

Assistant Secretary for Health ~~and Surgeon General~~, Public Health Service.

Date: 10/15/79

For the Health Care Financing Administration:

By: [signature]

Administrator, Health Care Financing Administration.

Date: 1/5/80

For the Food and Drug Administration:

By: [signature]

Associate Commissioner for Regulatory Affairs, Food and Drug Administration.

Approved:

By: [signature]

Secretary of the Department of Health, Education, and Welfare.

Date: JAN 21 1980

GUIDE	7155e.03

Amendment:

Sections II.A.1. and II.C. have been amended and all references to Department of Health, Education and Welfare and HEW changed to Health and Human Services and HHS, respectively as provided in approvals shown below:

APPROVED AND ACCEPTED FOR THE HEALTH CARE FINANCING ADMINISTRATION	APPROVED AND ACCEPTED FOR THE PUBLIC HEALTH SERVICE	APPROVED AND ACCEPTED BY THE FOOD AND DRUG ADMINISTRATION
By: [signature]	By: [signature]	By: [signature]
Acting Deputy Director, Health Standards & Quality	Assistant Secretary for Health	Joseph P. Hile Associate Commissioner for Regulatory Affairs
Title: Bureau, HCFA	Title:	Title:
Date: February 3, 1983	Date: MAY 4 1983	Date: MAR 14 1983

Approved

By: [signature]

Title: Secretary of the Department of Health and Human Services

Date: 6-6-83

Tab B

CBER's DEVICE REVIEW PERFORMANCE

The following table summarizes CBER's recent performance in review of device applications related to manufacture of blood products. Data are summarized for FY1998 and FY1999. Most noteworthy are the dramatic improvements in meeting review timelines for traditional 510(k)'s, and for PLA supplements (PLS) both in the cateogory of blood grouping reagents and infectious disease test kits. These categories represent the vast majority of all submissions.

		FY 1998 Cohort			FY 1999 Cohort		
	Review timelines	Total Submissions Received / Completed	% On Time Based on First Action	Average FDA Review Time based on Completion	Total Submissions Received / Completed	% On Time Based on First Action **	Average FDA Review Time based on Completion
Traditional 510(k)	90 days	28 / 27	30%	128	26 / 11	64%	80
Abbreviated 510(k)	90 Days	1 / 1	100%	39	7 / 3	83%	71
Special 510(k)	30 days	3 / 3	100%	22	4 / 2	65%	40
PMA	12 months	1 / 0	0%	Pending	1 / 0	100%	Pending
PMS	6 months	9 / 7	67%	130	1 / 0	Pending	Pending
PLA Test Kit	12 months	6 / 6*	100%	3	5 / 1*	100%	3
PLS Test Kit	6 or 12 months	31 / 18	30%	6	36 / 15	64%	5
PLA Blood Grouping	12 months	3 / 3*	100%	3	3 / 3*	100%	2
PLS Blood Grouping	6 or 12 months	36 / 20	42%	8	39 / 32	69%	5

* includes corporate name changes
** some first actions pending
as of October 8, 1999

Of particular note, in December 1998, CBER held a stakeholders meeting specifically to discuss CBER's review of medical devices. One result of that meeting was the CBER Device Action Plan went into effect on April 20, 1999. Since then we have received 17 device submissions. Among these, 11 have had a 1st action completed on time. The remaining 6 submissions are still pending, however, we anticipate completing the first action within the due date.

CBER also has made considerable progress in reducing backlogged submissions. By definition, a backlogged submission is one that has gone beyond its specified review time for any reason during any review cycle. A submission then remains on backlog status until it is completed (even if later review cycles are completed on time). The following table demonstrates CBER's progress in eliminating backlogged applications:

	1996	1997	1998	1999
Backlog	72%	80%	68%	17%*

*There are currently 72 submissions that have not been completed. Of these 12 are in backlog status (17%).

Tab C

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

DEVICE ACTION PLAN

The Center for Biologics Evaluation and Research (CBER) regulates medical devices related to licensed blood and cellular products by applying appropriate medical device laws and regulations. The medical devices regulated by CBER are intimately associated with the blood collection and processing procedures as well as the cellular therapies regulated by CBER. CBER has developed specific expertise in blood, blood products and cellular therapies and the integral association of certain medical devices with those biological products supports the regulation of those devices by CBER.

During Fiscal Year 1998, CBER received eight Pre-Market Applications (PMA) applications/supplements and thirty-four 510(k) submissions. It completed reviews of four PMA applications/supplements and sixty-one 510(k) submissions. In addition to these medical device submissions, CBER also receives and reviews blood donor screening tests for licensure under section 351 of the Public Health Service Act.

Recently the FDA Modernization Act of 1997 enacted several significant changes in the regulation of medical devices. In addition, the Center for Devices and Radiological Health (CDRH) has embarked on reengineering initiatives to streamline the regulatory process for medical devices. During recent 406(b) Stakeholders public meetings, certain concerns have been stated by industry representatives regarding CBER's commitment to implement the FDAMA law and to consistently apply CDRH policy and procedures to the regulation of medical devices at CBER. Commenters also expressed an interest in CBER's improving its medical device review performance and its communication with industry.

The Center has developed a Device Action Plan in order to facilitate the implementation of the device provisions of FDAMA and to assure consistency of policy and procedures between CBER and CDRH. It will assess any differences that may exist and determine if those differences are justified in the interests of public health. This plan addresses areas of cooperation, coordination and communication between CBER and CDRH to assure harmonized activities. It focuses on Center review practices and performance goals under a managed review process. The plan also includes ongoing outreach activities to maintain input and feedback from industry and the public.

The attached Device Action Plan lays out general principles, and will require further development by CBER and CDRH to work out specific details. Close cooperation among the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health and the Office of Regulatory Affairs will be necessary for implementation.

Kathryn C. Zoon, Ph.D.
Director, Center for Biologics
Evaluation and Research

Elizabeth D. Jacobson, Ph.D.
Acting Director, Center for Devices
and Radiological Health

Dennis E. Baker
Associate Commissioner for
Regulatory Affairs

Jane E. Henney, M.D.
Commissioner of Food and Drugs

DATE: April 26, 1999

U.S. Food and Drug Administration

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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The attached Device Action Plan lays out general principles, and will require further development by CBER and CDRH to work out specific details. Close cooperation among the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health and the Office of Regulatory Affairs will be necessary for implementation.

Signed Plan - *(PDF)*

Six Month Report - *10/29/1999*

ISSUE	**Compliance and Team Biologics Issues**
CURRENT STATUS	In some instances industry and FDA staff may lack clear guidance on the application of certain GMP's and compliance policy to devices regulated by CBER.
PROPOSED SOLUTION	Implement a transparent process for consistently applying regulatory and administrative requirements to the review, inspection and compliance follow-up for device products regulated by CBER.
NECESSARY STEPS	a. The ORA/CBER/CDRH/CDER GMP group will complete their document clarifying applicability of stability/ and sterility requirements to CBER regulated IVDs (Revised: April 1, 2000). Guidance and training will be prepared for FDA and Industry to implement decisions (Revised: April 1, 2000). b. A working group from the Team Biologics Operations group (which includes CBER), with additional staff from CDER and CDRH, chaired by ORA/Office of Enforcement, will: 1. Determine whether there are licensed biological products where we could apply device methods and therefore lighten the inspection load (e.g., tines, pre-filled syringes, and injectors) (Revised: April 1, 2000). 2. Determine whether any differences from CDRH policies are justified and beneficial (Revised: April 1, 2000). 3. Make Recommendations to the full Operations Group (Revised: April 1, 2000). c. The Team Biologics Operations Group will review those recommendations and implement those they believe are appropriate (Revised: April 1, 2000). d. The Device Action Plan Compliance and Team Biologics Working Group will determine what training and guidance needs to be prepared to implement the recommendations approved under section C. above (Revised: April 1, 2000). e. The training and guidance will be developed and disseminated to CBER, CDRH, ORA and State counterparts (April 1, 2000).

TIMEFRAME	a. White paper completed by April 1, 2000 (Revised). Guidance and training completed by April 1, 2000 (Revised). b. Completed by April 1, 2000 (Revised). c. Completed by April 1, 2000 (Revised). d. Completed by April 1, 2000 (Revised). e. Completed by April 1, 2000.
OUTCOME	a. The clear articulation of the applicability of requirements for CBER regulated products and the development of associated guidance and training. b. The assurance of consistent application of regulatory and administrative requirements to the review, inspection, and compliance follow-up for device products regulated by CBER. c. The enhancement of communication with device manufacturers of CBER products.

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ISSUE	**ENHANCING COMMUNICATION WITH INDUSTRY AND WITHIN FDA**
CURRENT STATUS	Rapid changes in device regulation under FDAMA and reinvention of procedures for device review have increased the need for communication between industry, review staff and policy staff.
PROPOSED SOLUTION	a. Systematically assess the current status of communications between the Center staff and the industry. b. Assess how regulatory changes are communicated to the device manufacturer. c. Develop communication methods for FDA review and policy staff to improve device regulation and review.
NECESSARY STEPS	a. Review transcripts of Open Public Meeting on Device Action Plan and summary minutes of 406(b) stakeholder meetings to identify major issues communicated by the device industry on the way CBER does business (June 1999). b. Identify contacts in the biologics device community and establish liaison

	and other types of meetings to facilitate communication between CBER and the device industry (July 1999). c. Hold internal and external stakeholder meetings to solicit input on ways to improve communications with the device industry that will contribute to more timely, effective and consistent reviews (June 1999). d. Hold annual internal assessment meetings to include representatives of CBER and CDRH (April 2000).
TIMEFRAME	Step a and c will be completed by June 1999. Step b will be completed by July 1999. Step d will be completed by April 2000.
OUTCOME	a. Keep device manufacturers engaged in the CBER processes that affect the review and approval of their products. b. CBER review and policy staff will take ownership in the plan to improve communications with Industry. c. Device manufacturers and CBER review and policy staff will develop an ongoing effective communication process that will improve device regulation and review.

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ISSUE	**COORDINATION WITH THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)**
CURRENT STATUS	Informal, ad hoc communications and consultations as necessary on specific issues. Intercenter Agreement (1991). Reports of instances of inconsistent application of policies. FDAMA device policies and procedural guidance developed at CDRH.
PROPOSED SOLUTION	a. Formalize intercenter communications, consultations and training activities. b. Review, revise and update intercenter agreement as necessary.
NECESSARY STEPS	a. Assign a CBER/CDRH task force to review, revise and update the intercenter agreement (June 30, 1999). b. Assign CBER staff liaisons to appropriate CDRH reengineering work groups (May 2, 1999). c. Publish a FR notice to clarify the applicability of FDAMA regulations and guidances to medical devices regulated by CBER (May 2, 1999).

	d. Develop a CBER device training plan in coordination with CDRH training initiatives and workshops for FDAMA policies and procedures (May 2, 1999). e. Create a device section on the CBER Home Page web site and cross link to CDRH Home Page (May 2, 1999). f. Mutually develop and review appropriate guidance documents (Ongoing). g. Periodic review of product jurisdictional issues by a CBER/CDRH oversight committee (Ongoing).
TIMEFRAME	All steps will be initiated by April 2, 1999. Step a will assign a task force by June 30, 1999. Steps b, c, d, and e will be completed by May 2, 1999. Steps f and g will be ongoing.
OUTCOME	Both Centers will engage in cooperative training, coordinated communications and consultations to achieve a consistent, seamless application of medical device laws and regulations.

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ISSUE	**IMPROVEMENT OF DEVICE REVIEW PERFORMANCE**
CURRENT STATUS	Not meeting GPRA review expectations or legal non-PDUFA deadlines. Processing, management, workload, and staffing issues contribute to problem. Problems are recognized within and outside CBER.
PROPOSED SOLUTION	a. Define review expectations for second half of FY 99 and FY 2000 and 2001. b. Identify and resolve processing, workload, and management problems.
NECESSARY STEPS	a. Define problem by analyzing issues of backlog, numbers of review cycles, review time, and resource staffing for FY 96-98 (June 1). Determine workload distribution, complexity, scientific staffing and operating dollar needs (July 1, 1999). Develop review expectations for FY 99, FY 2000, and FY 2001 using FDAMA criteria (August 1, 1999). b. Analyze application processing for delays and implement improved processing (June 1, 1999). Develop business practices model and initiate improved practices, including streamlining procedures (October 1, 1999). Clarify expectations of reviewers, project managers, committee chairs and managers within managed review process harmonized with other applications (August 1, 1999). Develop training plan for all staff (June 1, 1999). Hold staff go-away to communicate goals and develop participation (July 1, 1999).

	c. Identify and initiate needed organization changes (July 1, 1999). d. Identify and implement workload reduction measures such as guidance development. Harmonize with CDRH where possible (October 1, 1999). e. Identify necessary CBER laboratory testing standards and initiate laboratory projects (October 1, 1999).
TIMEFRAME	All steps initiated by February 1, 1999. Step a will be completed by August 1, step c by July 1, and steps b, d, and e by October 1, 1999.
OUTCOME	A more closely managed review process with clearly defined expectations resulting in a higher percentage of deadlines met without negative impact on review quality.

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U.S. Food and Drug Administration

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Device Action Plan - Six Month Report

October 29, 1999

OVERVIEW

The Device Action Plan (DAP) was initiated on April 26, 1999 in response to stakeholders concerns solicited under FDAMA 1997 and internal discussions at the Center for Biologics Evaluation and Research (CBER). The intent of the **DAP** is to develop clear policies and procedures to facilitate consistency of application of medical device laws and regulations, cooperation between CBER, the Center for Devices and Radiological Health (CDRH), the Office of Regulatory Affairs (ORA), and the Office of Chief Counsel (OCC) in regulating medical devices and communicating to the industry and the public regarding medical device issues. The **DAP** will also effect an improvement in the review performance by CBER staff.

A Core Team was formed consisting of CBER representatives from the Office of the Center Director and each of the following offices: Office of Blood Research and Review (OBRR), the Office of Therapeutic Research and Review (OTRR), the Office of Vaccine Research and Review (OVRR), the Office of Compliance and Biologics Quality (OCBQ), and the Office of Communications and Manufacturers Assistance (OCTMA). In addition the Core Team has representatives from CDRH, ORA, and OCC. The **DAP** identifies four key issue areas. Action Item Working Groups were formed around these issues. The Working Group members meet on a routine basis to implement the action items. The Working Group leaders report monthly to the Core Team. The Core Team meets monthly to oversee general progress of the **DAP**, identify unresolved issues and refocus activities.

SIGNIFICANT ACCOMPLISHMENTS

- **SIGNIFICANT IMPROVEMENTS IN REVIEW TIMES**
  During the past six months CBER backlog status of device reviews has been reduced from 68% to 17%. Additionally, we currently have no overdue submissions. CBER has received 17 device submissions since April 26, 1999. Eleven have had a first action completed on time, the remaining six submissions are still pending, however we anticipate completing the first actions within the due date.

- **OBRR OFFICE GO-AWAY TO SET PRIORITIES**
  In May 1999, OBRR managers had a two-day go-away. They reviewed the organization and critical issues affecting OBRR's ability to fulfill its mission. The OBRR managers committed to 1) down delegation of responsibilities, 2) prioritization of work, and 3) immediate attention to recruitment and hiring.

- **OBRR REORGANIZATION**
  OBRR is operating under a new organizational structure as of October 1, 1999. The new structure allows OBRR to review device submissions more efficiently and to address emerging diseases

affecting the blood supply.

- **OBRR MANAGED REVIEW PILOT PROGRAM FOLLOWING ANALYSIS OF BUSINESS PRACTICES**
  On August 1, 1999 OBRR initiated the Streamline Application Review Process as a six-month pilot project. This project will achieve the following outcomes: 1) implementation of the Regulatory Project Management concept under OBRR SOP's, 2) integrating the scientific and regulatory reviews within each division, 3) more effective and timely reviews.

- **DEVICE REVIEWER TRAINING FOR CBER**
  "Overview of Medical Devices" training was developed and presented to CBER medical device reviewers in September 1999. Both CBER and CDRH senior staff made presentations. Approximately 70 CBER staff completed this training, which provided an overview of device regulations, application processes and compliance issues. Participants provided evaluations of the training including suggestions for training and workshops on more advanced and specific topics.

- **IDENTIFICATION OF LABORATORY TESTING STANDARDS**
  A task group identified necessary laboratory testing standards and laboratory projects to facilitate the improvements of device review performance.

- **FORMATION OF INTERCENTER AGREEMENT WORKING GROUP**
  This Working Group has met with senior management from CBER and CDRH and is pursuing a revision of the agreement to clarify jurisdictional designations.

- **CREATION OF A CBER DEVICE WEB PAGE**
  There is now an external web page for device actions and issues, http://www.fda.gov/cber/dap/device.htm. This page includes the Device Action Plan and links to other device issues, such as approvals, products, CDRH guidance's, CDRH/CBER intercenter agreement and premarket information. The page is updated as information changes. Significant accomplishments from the Device Action Plan will be posted.

- **PUBLICATION OF FR NOTICE**
  FDA Modernization Act of 1997; List of Documents Issued by the FDA that Apply to Medical Devices Regulated by the CBER (April 26, 1999).

- **ASSIGNMENT OF CBER STAFF AS LIAISON TO SIX CDRH RE-ENGINEERING GROUPS**

- **COORDINATION WITH THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**
  CBER staff participates in training programs provided by CDRH including regulatory and FDAMA reengineering issues on a routine basis. CBER is also working with CDRH on the redesign of their reviewer training. Once completed, this will be a training mechanism for CBER regulatory project managers involved in the review of device applications.

- **OPEN PUBLIC MEETING ON DEVELOPMENT OF GUIDANCE DOCUMENTS FOR MEDICAL DEVICES REGULATED BY CBER**
  This meeting, scheduled for November 15, 1999 is being held in response to issues raised by CBER's stakeholders at the April 18, 1999 FDAMA meetings, regarding input to the development of regulations and guidance documents for medical devices regulated by CBER. The industry will be

given the opportunity to present their views and suggested input to their roles in guidance document development.

- **REVIEW OF STAKEHOLDERS CONCERNS**
  Transcripts of Open Public Meetings and minutes of 406b meetings were reviewed to identify major issues communicated by the device industry.

- **OUTREACH ACTIVITIES**
  CBER staff participated in meetings with RAPS, HIMA, IVD Roundtable, and AABB to further communicate with the device industry.

- **VENDOR DAY**
  CBER's first "Vendor Day" was held on October 4, 1999. Seven manufacturers participated, sharing their products with CBER employees. This program was well received by both the staff and the industry, with proposed plans to hold this program on an annual basis.

- **COMPLIANCE AND TEAM BIOLOGICS ISSUES**
  Several working groups have been assembled with participation from CBER, CDRH, ORA, and CDER. The mission of these working groups is to prepare clear guidance on the application of certain GMP's and compliance policy to devices regulated by CBER. The work of these groups is expected to be finalized concurrently with the training, which is scheduled for April 2000.

BLOOD SAFETY AND AVAILABILITY

TUESDAY, OCTOBER 19, 1999

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

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 2322, Rayburn House Office Building, Hon. Fred Upton (chairman) presiding.

Members present: Representatives Upton, Whitfield, Ganske, Bryant, Bliley (ex officio), and Green.

Also present: Representative Combest.

Staff present: Alan Slobodin, majority counsel; Anthony Habib, legislative clerk; Chris Knauer, minority counsel; and Brendan Kelsey, minority clerk.

Mr. UPTON. Good morning. Those bells, by the way, indicate we are going into recess for a short while. I think we are not expecting a vote for about an hour or so.

This morning the subcommittee continues its oversight hearings on the safety and availability of the United States blood supply. At previous hearings we have heard from the GAO that the blood shortage situation was overstated. Today we will hear a much different story from the blood collection side. Today's testimony and reports from around the country indicate that our blood supply is below comfort level in many regions. More current information than that reviewed by the GAO suggests overall trends threaten the blood supply. For example, the American Red Cross will tell us that in the last 2 years, while they have seen blood collections increase by 8 percent, blood distribution to hospitals has increased even more, 11 percent.

In August 1999, survey of members of America's Blood Centers showed a 7 percent increase in demand over August 1998. The Midwest has historically been the blood basket for the rest of the country. I understand from America's blood centers that some blood centers in the Midwest that have never or rarely gone on emergency appeal went on an emergency appeal this year, 1999.

This past summer, my home State of Michigan, the American Red Cross declared a blood alert in Michigan because of decreased donor turnout. The southeastern Michigan region of the Red Cross had less than 1 day's supply of blood in its inventory.

One of the themes we will hear at this hearing is that national leadership is needed to support national blood donations. For the past month this subcommittee has held hearings on the safety and availability of the blood supply. I anticipate chairing further hear-

ings on blood-related issues throughout this Congress. Last week in my home community, I donated blood and I urge others to donate blood as well. We will hear from one family today on how that blood donation truly is the gift of life.

Without a significant effort to increase blood donations, our blood supply will gradually be outstripped by increased need. More Americans are living longer and require more operations and more blood transfusions. New safety requirements, new donor exclusion rules, and increased costs are pressuring the blood supply. Although we have heard differing assessments about the degree of seriousness of blood shortages, everyone is in agreement that action must be taken.

To that end, at the October 6 hearing, Surgeon General David Satcher outlined a 5-point strategy for increasing the blood supply. As I indicated at that hearing, I will be supportive of Dr. Satcher's efforts to increase blood donations.

This subcommittee and I will also point out ways to improve blood safety and availability. For example, Chairman Bliley and I are pushing to get improved blood safety reporting now. I look forward to the witnesses' testimony and am particularly interested in hearing about the blood banks' view on Dr. Satcher's plans and how they plan to increase donations.

As we have learned, the U.S. blood supply is indeed fragile. This subcommittee will continue to monitor the situation, keep the blood supply on our radar screen, and support volunteer blood donations.

And, in addition, I guess you could somewhat say, putting my money where my mouth is on this issue, in addition to personally donating blood this last week, I have joined the Congressional Honorary Host Committee for National Volunteer Blood Donor Month 2000. I want to encourage all members and staff in this Congress to participate in the Year 2000 Fight for Life on Capitol Hill, a friendly contest between Republican and Democrats, to see who donates more blood.

[The prepared statement of Hon. Fred Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

This morning the Subcommittee continues its oversight hearings on the safety and availability of the U.S. blood supply. At previous hearings, we heard from the GAO that the blood shortage situation was overstated. Today we will hear a much different story from the blood collection side.

Today's testimony and reports from around the country indicate that our blood supply is below comfort level in many regions. More current information than that reviewed by the GAO suggests overall trends threaten the blood supply. For example, the American Red Cross will tell us that in the last two years while they have seen blood collections increase by 8%, blood distribution to hospitals has increased by 11%. An August 1999 survey of members of America's Blood Centers showed a 7% increase in demand over August 1998.

The Midwest has historically been the bloodbasket for the rest of the country. I understand from America's Blood Centers that some blood centers in the Midwest that had never or rarely gone on emergency appeal, went on emergency appeal in 1999.

This past summer in my home state of Michigan, the American Red Cross declared a blood alert in Michigan because of decreased donor turnout. The southeastern Michigan region of the Red Cross had less than a one-day supply of blood in inventory.

One of the themes we will hear at this hearing is the need for national leadership to support volunteer blood donations. I am delighted to provide some of this national leadership. For the past month, the Subcommittee has held hearings on the safety

and availability of the blood supply. I anticipate chairing further hearings on blood-related issues throughout this Congress. Last week in Benton Harbor, I donated blood. I urge others to donate blood. We will hear from one family today on how that blood donation truly is the gift of life.

Without a significant effort to increase blood donations, our blood supply will gradually be outstripped by increased need. More Americans are living longer and require more operations and more blood transfusions. New safety requirements, new donor exclusion rules, and increased costs are pressuring the blood supply. Although we have heard differing assessments about the degree of seriousness of blood shortages, everyone is in agreement that action must be taken. To that end, at the October 6 hearing, Surgeon General David Satcher outlined a five-point strategy for increasing the blood supply. As I indicated at that hearing, I will be supportive of Dr. Satcher's efforts to increase blood donations. The Subcommittee and I will also point out ways to improve blood safety and availability. For example, Chairman Bliley and I are pushing to get improved blood safety reporting now.

I look forward to the witnesses' testimony. I am particularly interested in hearing about the blood banks' views on Dr. Satcher's plans and how they plan to increase donations.

As I have learned, the U.S. blood supply is fragile. This Subcommittee will continue to monitor the situation, keep the blood supply on our radar screen, and to support voluntary blood donation.

And I am putting my money where my mouth is on this issue. In addition to personally donating blood, I have joined the Congressional Honorary Host Committee for National Volunteer Blood Donor Month 2000. I want to encourage all Members of Congress and their staff to participate in the year 2000 Fight for Life on Capitol Hill, a friendly contest between Republican and Democrats to see who donates the most.

Mr. UPTON. Mr. Chairman.

Chairman BLILEY. Thank you, Mr. Chairman, for these continued hearings concerning the safety and availability of the Nation's blood supply. I also want to thank you, Mr. Chairman, for your hard work in bringing attention to the U.S. blood supply and to thank you for stepping up to the plate and donating blood. I hope maybe it will slow you down a step or two on the tennis court when we next play.

The blood supply, you know, ladies and gentlemen, is like an insurance policy. You don't think much about it until you need it. But most of us or our loved ones at some point in our lives will need blood.

Today's testimony paints a troubling picture about whether we will have the blood we need. It is a more troubling picture about the blood supply than what we heard from the GAO at the September 23 hearing. On the front lines of blood collection in the United States, these blood centers represented before this subcommittee are seeing evidence of a blood system struggling to meet demand. For example, the American Red Cross will tell us that in the last 2 years, while they have seen blood collections increase by 8 percent, blood distribution has increased by 11 percent. Other testimony will show that some blood centers which usually do not resort to emergency appeals for donations during the year are making several such appeals this year.

With the challenge to meet increased demand for blood products, today's witnesses are calling for national leadership to support volunteer blood donation. This committee, through these hearings on the blood supply, has stepped up to the plate to provide some of this leadership. We are pushing for more blood donations and for more safety of the blood supply. For example, on the blood safety front, I have pushed for a new reporting system for blood errors now, rather than wait for FDA to take at least 6 years to imple-

ment recommendations from the HHS Inspector General to repair its flawed reporting system.

I am pleased that at the last hearing, Surgeon General David Satcher was not only receptive to my request to implement a new reporting system for transfusion errors that will improve blood safety, but he announced that an outside HHS advisory committee will meet on this matter in January. I am optimistic that we can improve the safety of the blood supply just as we have done with the commercial airline safety and nuclear power.

Fred Upton and I will continue to push for improvements and quick action on the U.S. blood supply.

Mr. Chairman, I join your call to the American people for more blood donations. Just one pint of blood can save several people's lives. Thank you.

Mr. UPTON. Mr. Chairman, if I had known that by donating blood we could get a 12-0 score a couple days later, I would do it every week.

Chairman BLILEY. Then you better cut it off.

Mr. UPTON. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. I do want to thank you for holding this hearing and also for the work that you do in this area, and also as I listened to our full committee chairman, Mr. Bliley, I want to thank him also for his sponsorship of legislation in regard especially to the safety of our blood supply.

Certainly the two issues that are important—and I am not going to go on and on because I am anxious to hear the very competent and qualified testimony from the panel that we have, panel of witnesses that we have today—but certainly what concerns all of us across this country is the two issues of supply: the amount of supply, the abundance of supply, and the safety of that supply. And certainly it is our responsibility as Members of Congress to, and particularly this committee and this subcommittee, to help oversee those two very important issues.

So I think we are doing our job today as we have been in past hearings. I appreciate very much the testimony that we have had in the past, and certainly I think we are going to hear a little different version or story today. But I do appreciate our Surgeon General, Mr. Satcher, and some of the things he is recommending regarding the blood supply and safety issues.

But again, I look forward to the testimony, not only listening to it, but also perhaps getting to read some of it. As those of you who have been in Washington know, sometimes the pulls and tugs of other committees come into play, and I have another subcommittee involving the Food and Drug Administration going on that will be starting at about 10 o'clock, so I am going to try to be shuffling back and forth between the two committees.

Again, with that, I would yield back my time.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Mr. Chairman, for scheduling this important hearing.

There are several important issues to be discussed before this Committee today. Most importantly, however, is to examine recent trends that indicate that blood do-

nations in this country are on the decline, and what that means for our nation's health care establishment.

This trend, combined with the rise in demand for blood, due to an aging population and increased surgical procedures, is a real threat to our nation's health infrastructure and one that deserves the close scrutiny of this Committee.

We should examine carefully all the options to addressing this situation, including the controversial proposal to allow the distribution of blood units that are gathered through the treatment of patients who suffer from hemochromatosis.

We must insure that we first remove any and all financial incentive for donation before a policy like this is implemented, so as to remove the temptation for these patients to mislead hospital officials about their medical histories when they go in to give blood.

Additionally, we must ensure that we act to protect the safety of the blood supply by supporting new rules designed to exclude donors who may have encountered previously unknown or unsuspected risk factors.

An example of this would be the FDA's new donor exclusion policy concerning individuals who spent six months or more in the United Kingdom between 1980-1996. Because of the uncertainty surrounding how the so-called "mad cow disease" may or may not be spread, this action is an important step that will give us time to determine the seriousness of the threat while avoiding endangering the blood supply and those who depend on it.

Again, Mr. Chairman, thank you for holding this hearing and I look forward to the testimony of the witnesses here today.

Mr. UPTON. Thank you. I would let everyone know here that we have a number of subcommittees that are meeting this morning, so we are all juggling our time constraints. We welcome everyone here. I would ask that the witnesses come to the table: Ms. Jacqueline Fredrick, CEO of the American Red Cross Biomedical Services; Dr. Celso Bianco, President of America's Blood Centers; Mr. and Mrs. Craig Sperry from the America's Blood Centers; and Dr. Susan Wilkinson, Deputy Director of the Clinical and Technical Services of Hoxworth Blood Center in Cincinnati, Ohio.

Let me just say, I don't know whether you knew our normal practice before this subcommittee, but we take testimony under oath. Do any of you have objection to that?

Hearing none, committee and House rules allow you to be represented by counsel. Do any of you need to be represented—feel the need to be represented by counsel?

If not, if you would stand and raise your right hands.

[Witnesses sworn.]

Mr. UPTON. You are now under oath. For the purposes of introduction, I would like to introduce and recognize my friend and colleague from Texas, the chairman of the House Agriculture Committee, Mr. Larry Combest.

Mr. COMBEST. Mr. Chairman, thank you very much for letting me come to introduce three of my constituents and three of your witnesses today with what is, I think, a very personal and heartfelt story. Craig, Jennifer, and Kirkland Sperry are from Canyon, Texas, in my district. I think that this is one of those great stories that had a wonderfully happy ending. That happy ending happens to be with us here today. But I think that Kirkland's father, Craig, best summed it up, and you will hear their full account, when he said that a person totally unbeknown to them was willing to give an hour of their time to allow blood to be—to donate blood in a very critical moment. That blood supply, literally one pint, saved Kirkland's life. I think it points out something we take for granted many, many times.

Thank goodness, Kirkland is here. The Sperrys took their time to be here, and I appreciate very much, Mr. Chairman, your allowing me to come and introduce them.

Mr. UPTON. We appreciate your time as well. Since you are here, maybe we will start with the Sperrys, with their testimony. I want you to know we appreciate all of you sending your testimony in advance. It is made part of the record in its entirety. We would like you to limit your remarks, if you can, to about 5 minutes. I will set this very sophisticated timer. It has probably never been tested on eggs before, but I suspect it works. If you can limit your remarks to about 5 minutes, that will be terrific. We will all listen for that familiar chime at the end. We recognize the Sperrys first. Thank you for coming here this morning.

TESTIMONY OF CRAIG AND JENNIFER SPERRY, C/O AMERICA'S BLOOD CENTERS; SUSAN L. WILKINSON, DEPUTY DIRECTOR, CLINICAL AND TECHNICAL SERVICES, HOXWORTH BLOOD CENTER; JACQUELYN FREDRICK, CHIEF OPERATING OFFICER, AMERICAN RED CROSS BIOMEDICAL SERVICES, NATIONAL HEADQUARTERS; AND CELSO BIANCO, PRESIDENT, AMERICA'S BLOOD CENTERS

Mrs. SPERRY. Thank you for allowing us to be here. This is just a story that I am sure us, as well as other parents, or hopefully not many parents, have had to go through, the experience of having to have a pint of blood save your child's life.

When Kirkland was born, he was diagnosed with a cardiac condition and a seizure disorder. We thought that that was the end of our problems, as you would think. But when he was 2 months old, he developed the RSV virus, respiratory syncytial virus, and he progressed through that very well as far as being in the hospital.

Then one night when we were about to be released, he ended up coding on us. We were sent out of the room and they were brought in, and they brought us over to the ICU, and they had done a blood gas. We thought getting through that was enough, but the doctor came out and said we have another problem. Of course, the first thought was maybe something happened with his heart. They came out and said that not knowing how it was, the virus was attacking his bone marrow and he needed a blood transfusion and he needed it now.

Of course, my first reaction was, well, take my blood, because he and I are both AB positive. Well, he looked at me and said, you don't understand. We do not have enough time for you to give your blood and for it to go through all the testing.

So we are like, okay, we will take that. Then he came back a few moments later and said, "Hold on, let your family know, stay here, we may need you anyway, we can't find blood." Of course, knowing that he needs blood and they can't find it and they are saying we may still need you anyway, even though we don't have the time, it was hard to imagine—I had given blood in the past, taking it for granted when I needed it, or especially if my son or child needed it, it would be there.

Just that moment of wonderment, of wondering if it is going to be there, was going to be there in time enough to make the changes that it needed to with it, it was definitely a moment unforgetting.

Knowing that someone out there gave the little time it took to give blood, that we still have him here today. My husband put it pretty good one time. He asked what we would tell people to go give blood, and my husband said, I just challenge them to look in any child's face or look in my child's eyes and explain to them why they couldn't have taken that 30 minutes, 45 minutes' worth of their time to save his life or save a person's life.

It is very simple to do, and we are just grateful that someone gave that time to do it.

Mr. SPERRY. The only thing I would like to add is many people don't realize, and we didn't realize, when you have the need for blood, most of us take for granted it is there. When it is sometime for a blood transfusion or you go on the operating table, your blood is there. When the doctor comes back to you and says, We can't find the blood, it is not in this hospital, it is not in the other hospital, you start to wonder. Luckily for us, believe it or not, it was the last pint in the city of Amarillo we got, and he was headed out.

So my wife said it, and that is what I have said, it only takes 30 minutes for someone to go give blood. Look in his eyes and that tells you what you get from giving blood. This little boy is alive. If you have watched him before this meeting started, he is healthy. It is a painless procedure, and I advise everybody to give blood. If they don't feel like they can, then you can look in his eyes and explain why.

Mr. UPTON. Boy, that was perfect. I even thought about maybe I should give you an extra 10 minutes since there are three Sperrys.

But I would like to note that by unanimous consent, all members' statements will be made part of the record as well.

Dr. Wilkinson, welcome.

TESTIMONY OF SUSAN L. WILKINSON

Ms. WILKINSON. Thank you very much. My name is Susan Wilkinson and I am pleased to be here today to speak on behalf of the American Association of Blood Banks. I currently serve as the President of the AABB, the professional association representing approximately 2,200 institutions, including community and Red Cross blood centers, as well as hospital transfusion services and 9,000 individuals involved in blood banking and transfusion medicine.

AABB members are responsible for virtually all of the blood collected and over 80 percent of the blood transfused in the United States. The AABB would like to commend the subcommittee for holding this series of hearings addressing the critical public health issues related to blood safety and availability. We would also like to echo a statement made by Chairman Bliley, as well as several other members of the subcommittee and previous witnesses that you have heard, that the Nation's blood supply is safer than it has ever been.

However, as you have heard from a variety of witnesses, safety cannot be considered in a vacuum. Congress and the country must also pay careful attention to assuring the broad and timely availability of safe blood and blood components.

The AABB and professionals in blood banking and transfusion medicine throughout the country have serious concerns about the availability of the blood supply. Already there seem to be daily reports of isolated blood shortages across the country. In Cincinnati, where I serve as Deputy Director of Clinical and Technical Services at the Hoxworth Blood Center and on the faculty of the University of Cincinnati, we have issued an unprecedented four emergency appeals to date in 1999.

In the past, we seldom had to resort to such appeals. Although these shortages are not necessarily nationwide and most often take place during particular times of the year, they raise health concerns for the blood providers and the patients we serve.

As a national blood data resource center reported to the subcommittee last month, the best available data suggests if current trends continue, the demand for blood will surpass the supply as early as the Year 2000. If this forecast proves true, at a minimum, patients will have to delay elective surgeries, a somewhat misleading term in that certain cancer, orthopedic, and cardiac procedures are considered elective.

The NBDRC data indicates that 8.6 percent of more than 2,000 hospitals surveyed postponed elective surgeries due to a lack of blood and that nearly 25 percent experienced at least 1 day in which nonsurgical blood needs could not be met.

If a lack of blood leads to a patient not receiving timely treatment, he or she will certainly consider this a crisis. We strongly believe that the availability of the Nation's blood supply is a major public health issue that Congress, the administration, and the blood banking and transfusion communities cannot afford to ignore.

Several factors contribute to the trend toward a decreased blood supply and increased usage and they include the following: First, with the aging population, more people are requiring transfusions and other blood-related therapies. Advances in many medical areas have led to the development of additional therapies necessitating increased blood usage, including cancer treatment, organ transplants, heart surgeries and other therapies.

New safety measures, including policies requiring additional donor deferrals, have reduced and will almost certainly continue to reduce, the number of eligible donors.

Finally, the challenges of assuring a continuing stream of committed blood donors and educating the public as to why donating blood is vital to our Nation's health have become increasingly difficult.

The AABB strongly urges Congress and the administration to act now to ensure not only a safe, but an available blood supply as we enter the new millennium. We recommend the following steps be taken:

First, in order to be prepared for potential shortages before they strike, the Federal Government should provide additional support for blood supply data collection and analysis.

In 1996, recognizing the significant need for blood supply data, the AABB conceived and founded the National Blood Data Resource Center. In prior years, data had been collected by the Center for Blood Research at Harvard, which received funding from the National Heart, Lung and Blood Institute.

When this Federal funding ceased, the AABB saw the need to fill this void. The AABB is very proud of the fine work the NBDRC has produced and is excited about its ongoing and future data initiatives. Annual support from Congress and NHLBI is needed to collect and analyze on a routine and timely basis information to better forecast and take steps to avoid possible blood supply shortages.

The public and private sectors need to work together to increase retention and recruitment of blood donors. The AABB has been a supporter of many volunteer recruitment efforts, including the upcoming National Blood Donor Month initiative, a public outreach campaign to promote increased blood donations. On January 4, as Chairman Upton stated, Congress will help kick off this month with a "Fight for Life Congressional Blood Drive Challenge." We are pleased to note that Chairman Upton and Representatives Brown and Waxman have agreed to serve on the honorary committee for this event and we hope other members of the subcommittee will also take this important challenge.

Additional research regarding donor behavior and motivation is necessary to enhance donor retention and recruitment. The complexities associated with blood donation today, together with ever-increasing demand on personal time, have made the recruitment process more difficult than ever. The AABB has recommended that the government convene a national meeting to highlight recruiting efforts and to provide appropriate education on what makes recruitment successful and what makes it fail.

Fourth, policymakers should thoroughly consider the implications of new blood safety initiatives on availability of this valuable resource. Efforts to enhance safety, even when the risks involved are theoretical, can have significant effects on the blood supply. For example, it is estimated that FDA's recent proposal to require deferral of donors who have spent at least 6 months in the United Kingdom between 1980 and 1996 will eliminate 2.2 percent of donations. Moreover, it is particularly troubling that many of those deferred due to this policy will be the community's most relied upon repeat donors. Finally, government should help ensure that nonprofit blood centers and transfusion services have adequate resources available to support a safe and available blood supply.

At the same time, costly new blood products and therapies are being introduced and the FDA is mandating new safety measures. Federal reimbursement for blood products and services is being severely limited. Nonprofit blood centers and financially strained hospital transfusion services do not have the capacity to absorb these additional burdens. A timely example is the recent Medicare proposal to establish a prospective payment system for outpatient services, including transfusion services. Under this proposal, blood services would be reimbursed at a level far below what they actually cost; in some instances, only one fourth of a procedure's true cost.

Faced with such severe underpayments and already tight restricted budgets, many hospitals likely will not be able to offer patients these necessary services.

My final comments to the subcommittee will address error and accident reporting. The AABB supports the goal of identifying errors and accidents as a means of ensuring that patients receive

quality care. Since 1958, the AABB has developed standards for voluntary compliance in blood collection and transfusion. The AABB also conducts independent assessments and accredits facilities, including blood collection centers and hospital-based transfusion services that are in compliance with AABB standards and applicable Federal and State regulations.

Since January 1998, the AABB has had in place a quality management system that requires that AABB-accredited facilities have in place a process to capture, assess, investigate and monitor errors and accidents. AABB's accreditation system is well recognized in the medical community, has been granted deemed status by HCFA under the Clinical Laboratory Improvement Act, as amended, and is formally recognized by the Joint Commission on Accreditation of Health Care Organizations. An error and accident reporting system should lead to corrective and preventive measures and be designed to facilitate the ultimate goal of promoting the best possible patient care.

In conclusion, blood represents the unique public health benefit for the patients whose lives depend on this resource. We hope that Congress will work with the blood community in taking the abovementioned steps to ensure a safe and available blood supply. Thank you very much.

[The prepared statement of Susan L. Wilkinson follows:]

PREPARED STATEMENT OF SUSAN L. WILKINSON ON BEHALF OF THE AMERICAN ASSOCIATION OF BLOOD BANKS

My name is Susan Wilkinson and I am pleased to be here today to speak on behalf of the American Association of Blood Banks (AABB). I currently serve as President of the AABB, the professional association representing approximately 2,200 institutions, including community and Red Cross blood centers as well as hospital transfusion services, and over 9,000 individuals involved in all aspects of blood collection, processing, distribution and transfusion. AABB members are responsible for virtually all of the blood collected and over 80 percent of the blood transfused in the United States.

The AABB would like to commend the Subcommittee for holding this series of hearings addressing the critical public health issues relating to blood safety and availability. We would also like to echo a statement made by Chairman Bliley as well as several other Members of the Subcommittee—the nation's blood supply today is safer than it has ever been. However, as you have heard from a variety of witnesses, safety cannot be considered in a vacuum; Congress and the country must also pay careful attention to assuring the broad and timely availability of safe blood and blood components.

Serious Concerns about Blood Availability

The AABB and professionals in blood banking and transfusion medicine throughout the country have serious concerns about the availability of the blood supply. Already, there seem to be daily reports of isolated blood shortages in geographic communities across the country, from San Diego, to Detroit, to Pittsburgh. In Cincinnati, where I serve as Deputy Director of Clinical and Technical Services of the Hoxworth Blood Center and on the faculty of the University of Cincinnati, we have issued an unprecedented four emergency blood appeals this year. In the past, we seldom had to resort to such appeals and would go for a year without any. Although these shortages are not nationwide and most often take place during particular times of the year, they raise real health concerns for blood providers and the patients we serve.

Moreover, as the National Blood Data Resource Center (NBDRC) reported to the Subcommittee last month, the best available data suggest that if current trends continue, the demand for blood will surpass the supply as early as the year 2000. If this forecast proves true, at a minimum, patients will have to delay elective surgeries—a somewhat misleading term in that certain cancer or heart surgeries are considered "elective." The NBDRC data indicate that 8.6 percent of the more than 2,000 hospitals surveyed postponed surgeries due to a lack of blood and that nearly

25 percent experienced at least one day in which non-surgical blood needs were not met. If a lack of blood leads to a patient not receiving timely treatment, he or she will certainly consider this issue a crisis. We strongly believe that the availability of the nation's blood supply is a major public health issue that Congress, the Administration and the blood banking and transfusion medicine communities cannot afford to ignore.

Likely Causes of Increasing Blood Shortages:

Several factors contribute to the trend toward a decreased blood supply and increased usage. They include the following.

• With the *aging of the population,* more people are requiring transfusions and other blood-related therapies. Persons aged 65 or older receive twice as much blood per capita as younger individuals.

• Advances in a wide array of medicine have lead to the development of *additional therapies necessitating increased blood usage,* including cancer treatments, organ transplants, heart surgeries, and other therapies.

• *New safety measures, including policies requiring additional donor deferrals,* have reduced and will almost certainly continue to reduce the number of eligible donors. We are particularly concerned about the impact policies, such as the deferral of donors who have traveled to the United Kingdom for at least six months between 1980 and 1996, will have on preventing reliable, repeat donors from providing this needed public health resource.

Ways to Ensure a Safe and Adequate Blood Supply:

The AABB strongly urges Congress and the Administration to act now to ensure not only a safe, but an available blood supply as we enter the new millennium. We recommend that the following steps be taken in this effort.

• First, in order to be prepared for potential shortages before they strike, *the federal government should provide additional support for blood supply data collection and analysis.* In 1996, recognizing the significant need for blood supply data, the AABB conceived and founded the National Blood Data Resource Center. In prior years, data had been collected by the Center for Blood Research at Harvard Medical School, which received funding from the National Heart Lung and Blood Institute. However, when this federal funding ceased, there was a clear vacuum in public or private support for national blood data collection, which the AABB saw the need to fill. The AABB is very proud of the fine work the NBDRC has produced and is excited about its ongoing and future data initiatives. We are also very pleased that the NHLBI has agreed in the short-term to purchase data from the NBDRC, which will help enable the Center to gather more timely, monthly data regarding the blood supply. Additional, annual support from Congress and NHLBI is needed to collect and analyze on a routine, timely basis information to even better forecast and take steps to avoid possible blood supply shortages.

• The *public and private sectors need to work together to increase retention and recruitment of blood donors.* The AABB has been a supporter of many donor recruitment efforts, including the upcoming National Volunteer Blood Donor Month initiative. The AABB invites Members of the Subcommittee, their staffs and all of Capitol Hill to participate in this special event in January 2000. This annual event sponsored by a coalition of blood organizations spearheaded by the AABB and including America's Blood Centers and the American Red Cross involves a broad public outreach campaign to increase awareness about the need to donate blood and promote increased blood donations. On January 4, 2000, Congress will help to kick-off the month with the "Fight for Life Congressional Blood Drive Challenge," which pits Republicans and Democrats against each other in a friendly battle to see which side of the aisle can contribute the most blood. We are pleased to note that Chairman Upton and Representatives Brown and Waxman have agreed to serve on the honorary committee for this event and we hope that all of their colleagues on the Subcommittee will participate in this important effort.

• *Additional research regarding donor behavior and motivation is necessary in order to enhance donor retention and recruitment.* The complexities associated with blood donation today together with the ever-increasing demands on personal time have made the recruitment process more difficult than ever. Discussions during a variety of public meetings have revealed a lack of understanding of the full range of difficulties associated with recruiting and retaining donors. In this light, the AABB has recommended to the Advisory Committee on Blood Safety and Availability that the government convene a national meeting to highlight recruiting efforts and to provide appropriate education on what makes recruitment succeed and what makes it fail. The AABB also believes there is a need for research into behavioral sciences to determine what motivates individuals to donate. In 1998, the

AABB's National Blood Foundation (NBF) provided funding for an NBDRC survey regarding donation incentives. In the near future, the NBF will award an additional $175,000 grant to study the blood donation decision process. In addition, we recommend a critical review of donor suitability requirements to provide recommendations on how to streamline the process and delete unnecessary and outdated requests for information. Both federal and private support for research efforts is essential if we are to obtain critical information to increase donations as soon as possible, and before more drastic blood shortages occur.

• *Policymakers should thoroughly consider the implications of new blood safety initiatives on availability of this valuable resource.* Efforts to enhance safety, even when the risks involved are theoretical, can have significant effects on the blood supply. For example, it is estimated that FDA's recent proposal to require deferral of donors who have spent at least six months in the United Kingdom between 1980 and 1996 will eliminate 2.2 percent of donations. This may not seem like a high number, but when combined, each such chipping away at the blood supply can add up to a significant public health dilemma. Moreover, it is particularly troubling that many of those deferred due to this policy will be the community's most relied on repeat donors. In addition, the ensuing donation reductions are likely to be even more severe in certain locales—for instance, East Coast cities. We were pleased to hear that FDA intends to gather and analyze additional data regarding the impact on the blood supply as this deferral policy is implemented and scientific information about the actual threat of new variant Creutzfeldt-Jakob disease (nvCJD) transmission through blood. Blood availability should not be unduly reduced absent a true blood safety risk.

• Finally, the *government should help ensure that nonprofit blood centers and transfusion services have adequate resources* available to support a safe and available blood supply. At the same time costly new blood products and therapies are being introduced and the FDA is mandating new safety measures, federal reimbursement for blood products and services is being severely limited. Nonprofit blood centers and financially strained hospital transfusion services do not have the capacity to absorb these additional financial burdens.

A timely example is the recent Medicare proposal to establish a prospective payment system for outpatient services, including transfusion services. Under this proposal, blood services would be reimbursed at a level far below what they actually cost. For example, Medicare would pay only $325 for therapeutic apheresis, a therapy used to treat individuals with severe medical conditions, including certain life-threatening blood disorders, which in reality costs closer to $1,400 to provide. Faced with such severe underpayments and already tightly restricted budgets, many hospitals likely will not be able to offer patients this necessary care.

Shortfalls in blood-related reimbursement have even a larger impact in the inpatient setting, where the vast majority of blood services are provided. Medicare and private reimbursement payments lag far behind the state of blood-related care and medical technology. FDA and the blood community continue to move forward in requiring notable new blood safety measures. But the Health Care Financing Administration (HCFA) is not providing fair reimbursement to cover these safety measures. The AABB strongly urges Congress to act to ensure that Medicare provides fair payments for blood safety measures as soon as they are approved by the FDA. Just as blood safety is a national priority, assuring fair payments and patient access to quality blood therapies should be a priority as well. Recognizing this fact as well as the underlying reimbursement problem, the federal Advisory Committee on Blood Safety and Availability recently adopted a resolution recommending that the Secretary of the Department of Health and Human Services work with Congress to seek additional resources to support the introduction and maintenance of mandated blood safety measures. We hope that Congress will act immediately to ensure necessary coordination of blood-related policies at FDA and HCFA and other divisions of HHS. By enhancing reimbursement to fair levels, you can help guarantee that patients have access to the safest and best possible blood products and therapies.

Error and Accident Reporting

Congress and other policymakers should also consider these decreases in reimbursement and the increasing budgetary constraints facing blood centers and hospital transfusion services, along with the all-important impact on blood safety and patient care, as you address the issue of error and accident reporting. The AABB supports the goal of identifying errors and accidents as a means of ensuring that patients receive quality care. Since 1958, the AABB has developed standards for voluntary compliance in blood collection, processing and transfusion. The AABB also conducts independent assessments and accredits facilities, including blood collection centers and hospital-based transfusion services, that are in compliance with AABB's

Standards and applicable state and federal regulations. Since January 1998, the AABB has had in place a quality management system that requires AABB-accredited facilities to have in place a process to capture, assess, investigate, and monitor events that deviate from accepted policy or procedure or that fail to meet AABB Standards and other applicable regulations and requirements. AABB's accreditation system is well-recognized in the medical community, has been granted deemed status by HCFA under the Clinical Laboratory Improvement Act, as amended (CLIA), and is formally recognized by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

In establishing an error and accident reporting system, we believe that the most important question is what will be done with the information collected. **An error and accident reporting system should lead to corrective and preventive measures and be designed to facilitate the ultimate goal of promoting the best possible patient care.** Policymakers must be aware that any new regulation which requires additional man-hours of data collection and submission, if gathered to no useful corrective purpose will only serve to further divert strained hospital staffing resources away from patient care. Such an outcome would threaten to worsen, rather than improve the safety of transfusion services.

Conclusion

Blood represents a unique public health benefit for the patients whose lives depend on this resource. As the federal Advisory Committee on Blood Safety and Availability recognized during a recent meeting, blood merits special attention due to several of its unique characteristics—including the fact that it is a donated national resource and is provided, in the vast majority of cases, by nonprofit institutions. We hope that Congress will work with the blood community in taking the above-mentioned steps to ensure a safe and available blood supply.

Mr. UPTON. We do appreciate your work. Thank you.

Ms. Fredrick, welcome.

TESTIMONY OF JACQUELYN FREDRICK

Ms. FREDRICK. Mr. Chairman and members of the subcommittee, I am pleased to be here today to discuss the issues of safety and availability of the Nation's blood supply. My name is Jackie Fredrick, and I am the Chief Operating Officer and responsible head of the American Red Cross Blood Services.

Red Cross Blood Services is the Nation's largest supplier of blood products, serving more than 3,000 hospitals across the country. Today I want to address the vital public health issue of ensuring an adequate blood supply. I am going to highlight for you what the Red Cross has been doing to meet this challenge.

As Chairman Bliley, Chairman Upton, and Surgeon General Satcher have all stated, the Nation's blood supply is safer than ever before. Now we must work together to make the same intellectual and financial investments to ensure the availability of the blood supply.

During the past decade, the Red Cross has made substantial investments in procedures, programs and equipment to continually improve the safety of the blood supply. We have invested more than $300 million over the past 5 years alone in the establishment of eight state-of-the-art laboratories, a single computer system that maintains the world's largest blood donor data base, standard operating procedures in all of our blood centers, and an independent quality assurance program.

Most recently, the Red Cross has been at the forefront in the implementation of nucleic acid testing, or NAT, having invested well over $17 million. I would refer you to my written statement for a thorough description of our surveillance programs for emerging infectious diseases and our error and accident reporting systems. We

are especially pleased to hear the subcommittee highlight the important research of Dr. Harold Kaplan, as the Red Cross has lent significant support to his project on error and accident reporting.

Although blood safety is our top priority, we are strongly committed to increasing the availability of the blood supply. Compared to the more than $300 million that the Red Cross has invested to improve the safety of the blood supply, we have had only a small fraction of that amount available to us to invest in the availability of the blood supply.

The Red Cross collected more than 6 million units of blood last year. Over the past 2 years, as you have heard, we have increased collections by 500,000 units, or 8 percent. During that same time period, however, our distribution of blood to hospitals has increased 11 percent.

It is clearly evident that even in good times, the Nation's blood supply is fragile. While blood donations in some parts of the county are increasing, donations in other areas have been on the decline. From 1994 to 1999, the largest urban areas served by the Red Cross, such as Detroit, Philadelphia, and Baltimore, have experienced a decline in donations of more than 9 percent. For that same time period, there has been an 8 percent rise in donations in the rural midwestern areas of the country and an 11 percent increase in the Sunbelt and western portions of the country served by the Red Cross.

With our nationwide blood system, we are able to move this precious resource wherever and whenever it is needed. Part of availability is making sure the right blood is in the right place at the right time, and the Red Cross last year moved over 650,000 units of blood to areas of need.

To counteract these supply and-demand trends, the Red Cross is engaged in a number of efforts to continuously recruit new donors and retain previous donors. These initiatives include implementing innovative donor recruitment and retention techniques using state-of-the-art technology; identifying best practices to be used throughout the Red Cross system; improving the convenience and comfort of the donation experience; reaching out to minority and youth populations; and investigating the use of technologies such as the Internet to reach current donors.

If we are to cultivate the next generation of blood donors, we need to look to youth and segments of our society who have been underrepresented in the donor pool. Later this year the Red Cross will launch the first program in a 3-year minority recruitment initiative patterned after a highly successful program at North Carolina Central University, resulting in tenfold increase in donations. We currently are working with over 70 historically black universities and colleges on this effort.

If we are to meet the public health challenge of an adequate blood supply, the Federal Government must partner with the Red Cross and our independent blood center colleagues. We must work together to ensure that appropriate resources, both human and monetary, are invested to meet the Nation's future blood need. This includes funding additional research on donor motivation, studies to help us monitor the supply, and especially blood utilization, public education campaigns targeted at making the public generally

aware of the critical importance of donating blood, and making the process more user friendly.

Finally, because blood centers are operating in the same managed care environment as hospitals, we face similar pressure to reduce costs while increasing the quality of our services. We are very concerned about HCFA's proposed rule covering outpatient services, as it would not adequately cover the cost to hospitals for the majority of products and services provided by blood centers. The proposed rule jeopardizes Medicare patient access to the most life-saving therapies.

Mr. Chairman, I would like to join your fellow committee members who have thanked you for holding these hearings. They have assisted greatly in raising the awareness and importance of blood safety in our Nation. I also want to thank you personally for your commitment and your blood donation in Great Lakes. Our staff enjoyed your visit and expects you back in exactly 48 days.

This concludes my prepared statement. I would be happy to answer any questions you or members might have.

Mr. UPTON. I thought it was 56 days.

Ms. FREDRICK. You donated last week.

Mr. UPTON. You are already counting. I understand.

[The prepared statement of Jacquelyn Fredrick follows:]

PREPARED STATEMENT OF JACQUELYN FREDRICK, CHIEF OPERATING OFFICER, AMERICAN RED CROSS BIOMEDICAL SERVICES

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today to discuss the issues of safety and availability of the nation's blood supply. My name is Jackie Fredrick, and I am the chief operating officer and responsible head of American Red Cross Blood Services. Red Cross Blood Services is the nation's largest supplier of blood components, serving more than 3,000 hospitals across the country. Last year, we collected more than 6 million units of whole blood through the generous donations of approximately 4.5 million volunteer donors. Each day, 22,000 donors visit one of 400 Red Cross blood donation sites. For more than 50 years, the Red Cross has remained an innovator and a leader in transfusion medicine and research. The Red Cross has provided the nation with safe and reliable blood components and products for generations. Through blood services, the Red Cross is touching more lives than ever before.

Today, I am here to address the vital public health issue of ensuring an adequate blood supply. I am going to highlight for you what the Red Cross has been doing to meet this challenge. We have made substantial investments to improve safety. Indeed, as Chairman Bliley, Chairman Upton and Surgeon General Satcher have all stated, our nation's blood supply is safer than ever before. Now, we must work together to make the same intellectual and financial investments to ensure the availability of the blood supply.

Safety Initiatives Undertaken by the Red Cross

During the past decade, the Red Cross has made substantial investments in procedures, programs and equipment to continually improve the safety of the nation's blood supply. We have invested more than $300 million over the past five years alone in the establishment of eight state-of-the-art testing laboratories; a single, standardized computer system that maintains the largest blood donor database in the world; standardized operating procedures in our 37 Blood Services regions; and an independent quality assurance program with more than 200 experts who monitor every aspect of our operations to ensure compliance with our standard operating procedures and all federal regulations.

The Red Cross has been proactive in its efforts to ensure that new, viral screening tests are implemented as soon as they become available. Most recently, the Red Cross has been at the forefront in the implementation of nucleic acid testing, or NAT, having invested $17 million on this effort. NAT, which the Red Cross is conducting under an Investigational New Drug protocol, has the potential to detect the actual DNA of the virus in a blood donation rather than waiting for the body's response to the virus through the creation of antibodies, as most currently licensed

tests do. As such, NAT may greatly reduce the "window period"—the time between when an individual is infected and the point at which evidence of the virus can be detected in that person's blood. As Surgeon General Satcher stated, NAT will be especially helpful in screening donations from individuals newly infected with the hepatitis C virus (HCV) and the human immunodeficiency virus (HIV).

Red Cross Surveillance Activities

Each year the Red Cross invests more than $20 million in basic and applied research at our Jerome H. Holland Laboratory for the Biomedical Sciences, one of the world's premier blood research facilities. At the Holland Laboratory, more than 270 world-class Red Cross scientists and technicians evaluate and monitor possible threats to the blood supply and develop cutting-edge technologies that bring innovative products and services to patients. We actively monitor and detect the emergence of infectious diseases through ARCNET, the most comprehensive blood collection-related epidemiological database in the world. This includes 16 million records, with each record consisting of donor demographics, screening test results and deferral history.

The Red Cross monitors the blood supply for emerging infectious diseases. For example, Holland Laboratory researchers have conducted a number of studies on Chagas disease and tick-borne diseases such as babesiosis. Red Cross regional staff are also involved in a study to assess the risk of bacterial contamination of blood products—referred to as the BaCon study.

Surveillance within the Red Cross extends beyond research. Through its quality assurance program, the Red Cross has sophisticated surveillance programs in place to monitor and review all elements involved in collecting, manufacturing, testing and distributing blood components. For example, a system of "In-Process Reviews," or IPRs, has been established at each of the Red Cross's eight national testing laboratories. IPRs consist of reviews and documentation of all critical control points in the testing process to ensure that testing technicians have performed each task in the testing process correctly. Another level of review follows the IPR and ensures that documentation for all testing is recorded correctly. Finally, there are quality control and quality assurance steps, which include another round of review of infectious disease test results and general system audits. Together these levels of review enable us to track and trend all unexpected outcomes and helps to ensure our compliance. Next year the Red Cross will implement a new laboratory information system that will automate many functions now performed by employees.

For some time, the FDA has required licensed, registered blood establishments, including the Red Cross, to report errors and accidents as a tool to ensure the safety, potency and purity of blood and blood products. The Red Cross has achieved a high degree of compliance in reporting errors and accidents in a timely manner, as required by the FDA. The Red Cross encourages the application of any measures that may increase the safety of the blood supply including the research that is being conducted by Dr. Harold Kaplan that includes a new method for reporting errors and accidents. We were pleased to hear that Dr. Kaplan's important research was brought to the Subcommittee's attention at its last hearing. The Red Cross has lent significant support to this research because of its potential to enhance the current error and accident reporting system by assessing and correcting errors before they happen.

Ability of the Blood Supply to Meet Anticipated Patient Needs

The Red Cross has not only committed financial resources, but also invested in human talent by bringing together the best in the field to make improvements to the safety of the blood supply. We are equally committed to blood availability. To address future needs in blood availability, however, we will need to make the same financial and intellectual investment as we have with blood safety.

The Red Cross collected more than 6 million units of blood last year. We have seen an increase of 500,000 units in our collections over the past two years, an 8 percent increase. During that same time period, however, our distribution of blood to hospitals increased by 11 percent. The increase in demand is also reflected in the fact that very few components expire before they can be used, and that number continues to decrease.

Recent studies by the National Blood Data Resource Center (NBDRC) and the General Accounting Office (GAO) have highlighted concerns about the availability of blood components. Both NBDRC and the GAO cite trends in collections and demand for blood that point to possible widespread shortages in the near future. The Red Cross shares its data with the NBDRC, and during the time period of the NBDRC study (1994-1997), we had a decline in donations of 2 percent, while the NBDRC report shows a similar nationwide decline of 5 percent. We look forward

to continuing our work with the NBDRC to build upon the progress that has been made in collecting comprehensive data on the supply and utilization of blood.

Although we have seen an increase in donations overall, there are times when individual Red Cross Blood Services regions experience serious shortages of certain blood types. As the GAO pointed out in its study, shortages tend to be in specific blood types such as O and B, with type O in shortest supply because it is the universal blood type. Shortages tend to occur during the summer months and holiday seasons, and in times of bad weather. For example, in September, before Hurricane Floyd, Red Cross Blood Services regions in the Southeastern United States made sure that their hospitals had stocked shelves to meet patient needs. During and after Hurricane Floyd, many previously scheduled blood drives had to be cancelled throughout much of Virginia, North Carolina and South Carolina resulting in the loss of approximately 10,000 units to the Red Cross system. Through our nationwide system, the Red Cross was able to ensure that hospitals in this area of the country had an uninterrupted supply of blood throughout the storm and its aftermath with 18 regions shipping in approximately 8,000 units.

It is clear that, even in good times, the nation's blood supply is fragile. While blood donations in some parts of the country are increasing, donations in other parts have been in decline. For example, from 1994-1999, the largest urban areas served by the Red Cross, such as Detroit, Philadelphia and Baltimore have seen a decline in collections of more than 9 percent. For the same time period, we have seen an 8 percent rise in donations in the rural Midwestern areas of the country. The Sunbelt and Western portions of the country served by the Red Cross have experienced an even more dramatic increase in donations—more than 11 percent during the past five years. The Red Cross nationwide blood services system allows us to move blood to hospitals wherever and whenever it is needed. During the past year, we made available 650,000 units from sections of the country where there was a sufficient supply to those areas where this resource was needed. Market research has indicated that donors are driven by altruistic reasons. Once their local community needs are met, they welcome the opportunity for their life-giving donation to help people in other parts of the country.

The aging of the U.S. population impacts both the supply and demand for blood. As a group, older Americans (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. To meet anticipated future demands upon the blood supply, the Red Cross is working smarter and more efficiently to increase our collection base. We are applying the same proven techniques used by corporate America to understand and attract customers—and in our case to make blood donation more appealing.

We are engaged in a number of efforts to continuously recruit new donors and retain previous donors. These initiatives include:

- implementing innovative donor recruitment and retention techniques using state-of-the-art technology;
- identifying best practices to be used throughout the Red Cross system;
- improving the convenience and comfort of the donation experience;
- reaching out to minority and youth populations; and
- investigating other ways to apply technology, such as the Internet, to reach potential and current blood donors.

The Red Cross is currently piloting new blood drive scheduling software to improve the efficiency of blood drives, enhancing the experience for both the donor and blood drive managers. We are implementing a new nationwide telerecruiting system that allows the Red Cross to contact more donors, more often, and in a more efficient manner. Use of the Internet as a means of scheduling donor appointments also holds tremendous promise.

As the Subcommittee has heard from other witnesses, the Blood Donor Record, or BDR, is a lengthy document that requires donors to answer very personal questions that are required by FDA standards. As part of our effort to use technology to make our system painless and paperless, we are working with leading technology companies to develop hand-held, computerized BDRs that will give blood donors more privacy and speed up the health history process.

The Red Cross is striving to identify the most effective ways of doing business in donor recruitment and collections. Our PRIDE project team (Process Reengineering and Improvements Done by Everyone) is examining the best business practices in our system and ensuring their implementation throughout our 37 regions. The team's work encompasses donor recruitment and collections, production and distribution, sales and marketing, quality assurance, performance management and organizational design.

As the Subcommittee has stressed, it is important not only to attract new donors, but to retain them after their initial experience. Research has indicated that donations from individuals who are repeat donors tend to be safer than those from first-time donors. The Red Cross has performed research on donor motivation and what it takes to bring people back. Through focus group research, we know that it is important for volunteer donors to feel a connection with the patients who benefit from the gift of their donation. We also know that donors find it important to be part of the Red Cross "family." To drive this point home, we are conducting a pilot program in the Southeastern United States called "Hero's Welcome," which shares the story of blood donation and the people it helps. As we approach the holidays and the year 2000 date change, the Red Cross is launching a special blood donation initiative called "Millenium Hero." The program is intended to ensure adequate donations prior to and following January 1, 2000.

Donor comfort is important to ensuring that people have as pleasant an experience as possible when they take time out of their busy schedules to donate. We are investigating the development of ergonomic chairs and looking for ways to measure donors' hemoglobin levels or "hematocrit" without having to perform an ear or finger stick. Our goal is to foster an environment that is friendly and painless, as well as one that encourages repeat donations.

If we are to cultivate the next generation of blood donors, we need to look to youth and segments of our society who have been underrepresented in the blood donor pool. Later this year, we will launch the first program in a three-year minority recruitment initiative. This exciting program, entitled "The Power is in You," encourages blood donation by African Americans and is based on a highly successful effort at North Carolina Central University, spearheaded by Ted Parrish, which has increased blood donation on campus tenfold. The Red Cross currently has relationships with 76 of the 118 historically black colleges and universities. By working with historically black colleges and universities, we hope to increase blood donation on campus and throughout the African-American community.

The Red Cross is launching regional and national youth recruitment initiatives, such as "It's What's Inside That Counts" and "Generation V," which enable high school and college blood drive coordinators and their teams to run frequent and successful blood donation programs. At the elementary school level, we have held blood drives in which children are first educated about the need for blood donation and then recruit their parents and teachers to donate blood. By teaching the importance of blood donation at an early age, we hope it will encourage these youth to become donors when they are old enough to do so.

Dedication of Red Cross Resources

The possibilities to increase blood donation are numerous, and to us, exciting. As a not-for-profit organization, however, the Red Cross must be a careful and responsible steward of its funds, and scarce resources must be prioritized. Accordingly, our highest priority has been to increase the safety of the blood supply. As I said earlier, since 1994, the Red Cross has invested more than $300 million in technologies and systems to improve the safety of the blood supply. In comparison, during the same five-year period, we have had only a small fraction of that amount available to invest in the availability of the blood supply.

Need for Federal Support

The federal government must partner with the Red Cross and our independent blood center colleagues to meet the public health challenge of an adequate blood supply. We must work together to ensure that the appropriate resources, both human and monetary, are invested to meet the nation's future blood needs. This includes funding additional research on donor motivation, studies to help us monitor the supply and utilization of blood, and public education campaigns targeted at making the general public aware of the critical importance of donating blood. In addition, the screening process for blood donors must be made more user-friendly. For example, the FDA should consider allowing blood centers to simplify the BDR, especially for repeat donors.

We are committed to bringing the best science to the donor screening process. We view with concern, therefore, the recent recommendation from FDA requiring that anyone who has spent more than 6 months in the United Kingdom between 1980 and 1996 be indefinitely deferred from donating blood. There is very little science supporting this deferral policy, yet it has been estimated that the nation could lose at least 2.2% of donations, almost 300,000 units per year, at a time when the blood supply is marginal. We encourage FDA to review this policy frequently, and we will assist them by providing whatever data is available and appropriate.

Finally, because blood centers are operating in the same managed care environment as hospitals, we face similar pressures to reduce our costs, while improving the quality of our services. Reimbursement programs, such as those administered by HCFA and other third-party providers, must fully reimburse hospitals and blood centers to ensure that patients receive the newest and most innovative blood services. We are very concerned about HCFA's proposed rule covering out-patient services. As proposed, the rule would not adequately cover the costs to hospitals for the majority of products and services provided by the Red Cross. The proposed rule jeopardizes Medicare patient access to the most up-to-date lifesaving therapies. As the nation's largest provider of blood components, we will continue to work with Congress and HHS to ensure the formulation of a fair and reasonable reimbursement system.

Mr. Chairman, I would like to join your fellow Committee members who have thanked you for holding these series of hearings. They have assisted greatly in raising the awareness of the importance of blood safety and availability. I also want to thank you for your personal commitment to ensuring that vital blood components are available for those in need, as evidenced by your recent donation at our Great Lakes Region. Our staff enjoyed the time that they spent with you last week and welcome your return 48 days from now.

This concludes my prepared statement. I would be happy to answer any questions you or Members of the Subcommittee may have.

Mr. UPTON. Dr. Bianco.

TESTIMONY OF CELSO BIANCO

Mr. BIANCO. Mr. Chairman, thank you for your blood donation.

Mr. Chairman and honorable members of the Commerce Committee, I am Dr. Celso Bianco, Vice President for Medical Affairs for the New York Blood Center. Today I am honored to represent America's Blood Centers as their President. ABC is the federation of independent community blood centers that provide about half of this Nation's volunteer blood donor supply.

On behalf of ABC, I would like to applaud the committee, Chairman Upton and Chairman Bliley and Surgeon General David Satcher, for their efforts to enhance the safety of the blood supply through improved error and accident reporting. We address this topic in separate written comments to the committee. Today my comments will focus on five very important issues.

First, we ask Congress to encourage the Department of Health and Human Services, HHS, to do what it can to ensure that a dependable supply of volunteer donor blood is available. Our written testimony contains copies of letters that outline specific actions that we believe HHS can contribute.

Over the past 10 years, the need for blood has increased, as data from the national Blood Data Resource Center clearly demonstrates. At the same time, the number of Americans willing and able to voluntarily give blood has decreased.

The number of those willing to donate has decreased because they are too busy and because there has been a decline in support from corporate America for voluntary blood donations by their employees. The number of those able to donate has decreased because the Food and Drug Administration continues to add new donor criteria.

We agree with criteria that ensures a safer blood supply. However, we are deferring more and more perfectly healthy Americans because of speculation.

Community blood centers are working hard to make sure that this potential crisis does not threaten the health of patients needing blood. It is very important to understand that often the need

for blood is urgent, meaning the blood needs to be already on the shelf when the emergency occurs. We just heard from Mr. and Mrs. Sperry about that. But ultimately, the blood needs to be there or lives will be lost. That is why we are so concerned when stocks of blood are low.

Think of the Oklahoma City bombing, the shootings at Columbine, the school bus hit by the train. Most of the blood used to save those lives was given within the first few hours of the tragedy.

We live on the edge. For instance, in New York today, we have a 3-day blood supply of the O-positive blood and 1½ days supply of the O-negative type blood. We have also asked HHS to eliminate unscientific barriers to donation, and to encourage eligible Americans to give blood. We believe that the national leadership must foster a culture of blood donation.

The congressional challenge that you just talked about is an example of this type of leadership.

Second, we recognize that FDA has made great contributions to blood safety in the past. However, we are now spending more and more resources chasing theoretical or minuscule risks, such as those from mad cow disease and malaria, instead of focusing on well-recognized problems. For example, we defer 50,000 healthy people a year from donating blood because they visited Mexican resorts in areas defined as malarial zones. Not one of the 10 U.S. cases of transfusion-related malaria in the last decade was transmitted by someone that visited Mexico. They were all transmitted by people who emigrated to the U.S. from West Africa.

Similarly, we will defer over 250,000 healthy donors who have traveled to the United Kingdom because of the theoretical risk of transmitting variant CJD. Instead, Congress should encourage FDA to focus on the over 200 Americans reported to FDA who have died because they got the wrong unit of blood, or because of bacterial contamination. In a 1997 report, the General Accounting Office recommended that FDA focus on these clerical errors and on preventable transfusion reactions.

Third, we ask that Congress encourage FDA to use science as the basis for its decisionmaking and that FDA apply consensus development processes, like negotiated rulemaking, when considering controversial policies. At ABC's annual meeting this past February, FDA Commissioner Jane Henney called blood safety one of her highest priorities. She also pledged that FDA would again become a science-based organization. We are ready to contribute to joint efforts in this area. We are ready to accept decisions based on science.

Fourth, we ask that Congress ensure proper representation of the blood service community on bodies that advise FDA. In a 1996 study of the tragedy of AIDS in the blood supply in the early 1980's, the Institute of Medicine of the National Academy of Sciences recommended that FDA strike a proper balance in committee membership, but today there are no representatives of the blood community on FDA's most important Blood Products Advisory Committee.

Fifth, we ask that Congress ensure the Health Care Financing Administration pays for blood safety mandates from FDA. Last April, Surgeon General Satcher said that, "We as a society need to

assure unequivocally that the blood supply is safe." Dr. Satcher went on to state that we must be ready to pay for safe blood as a disease prevention, rather than spending money on treatments. We support Surgeon General Satcher. We understand that HCFA is looking at the best options to assure that the FDA blood safety mandates result in a timely change in HCFA's reimbursement to hospitals.

In essence, we ask Congress to support volunteer blood donations, to focus FDA on demonstrated safety risks, to encourage science-based decisions, to ensure adequate representation of the volunteer blood center community in the Blood Products Advisory Committee, and to assure adequate HCFA reimbursement.

I thank Congress for this opportunity. Please know that America's Blood Centers, the community blood centers, will do everything possible to assure the safest and most dependable blood supply possible. Congress must also do what it can to help us meet our goals.

Thank you. I am open to questions.

[The prepared statement of Celso Bianco follows:]

PREPARED STATEMENT OF CELSO BIANCO, PRESIDENT, AMERICA'S BLOOD CENTERS

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First, we ask Congress to encourage the Department of Health and Human Services (HHS) to do what it can to ensure that a dependable supply of volunteer donor blood is available. Our written testimony contains copies of letters that outline specific actions that we believe HHS can contribute. Over the past ten years, the need for blood has increased—as data from the National Blood Data Resource Center clearly demonstrate. At the same time, the number of Americans willing and able to voluntarily give blood has decreased. The number of those *willing* to donate has decreased because they are too busy and because there has been a decline in corporate America's support for voluntary blood donations by their employees. The number of those *able* to donate has decreased because the Food and Drug Administration (FDA) continues to add new donor deferral criteria.

We agree with criteria that ensure a safer blood supply. However, we are deferring more and more perfectly healthy Americans because of speculation.

Community blood centers are working hard to make sure that this potential crisis does not threaten the health of patients needing blood. It's very important to understand that often the need for blood is urgent, meaning the blood needs to be already on the shelf when the emergency occurs. We can tinker with the system through sharing of blood between blood centers and go out on emergency appeal. But ultimately, the blood needs to be there or lives will be lost. That's why we are so concerned when stocks of blood are low. Think of the Oklahoma City bombing, the shootings at Columbine, the school bus hit by the train. Most of the blood used to save those lives was given within the first few hours of the tragedy.

We have also asked HHS to eliminate unscientific barriers to donation, and to encourage eligible Americans to give blood. We believe that the National leadership must foster a culture of volunteer blood donation.

Second, we recognize that FDA has made great contributions to blood safety in the past. However, we are now spending more and more resources chasing theoretical or minuscule risks, such as those from mad cow disease and malaria, instead of focusing on well-recognized problems. For example, we defer 50,000 healthy people a year from donating blood because they visited Mexican resorts in areas defined as malarial zones. Not one of the 10 U.S. cases of transfusion-related malaria in the

last decade was transmitted by someone who visited Mexico! They were all transmitted by people who *emigrated* to the US from West Africa. Similarly, we will defer over 250,000 healthy donors who have traveled to the U.K. because of the theoretical risk of transmitting variant CJD. Instead, Congress should encourage FDA to focus on the over 200 Americans reported to FDA who have died because they got the wrong unit of blood, or because of bacterial contamination. In a 1997 report, the General Accounting Office recommended that FDA focus on these clerical errors and on preventable transfusion reactions.

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In essence, this Committee and Congress can support the safety and availability of the volunteer blood supply by:

1. Supporting volunteer blood donations and encouraging HHS to make this issue a National priority;
2. Focusing FDA on demonstrated safety risks;
3. Encouraging science-based decisions;
4. Ensuring adequate representation of the volunteer blood center community in the Blood Products Advisory Committee; and
5. Assuring adequate HCFA reimbursement for measures that increase the safety and availability of the volunteer blood supply.

I thank Congress for this opportunity. Please know that America's Blood Centers, the community blood centers, will do everything possible to assure the safest and most dependable blood supply possible. Congress must also do what it can to help meet our common goals.

Thank you.

Mr. UPTON. Thank you all very much.

Again, we got a unanimous consent request earlier that all members' statements be made part of the record. At this point the members will be asking some questions. We will try to stick to this 5-minute time clock as well, as we rotate with questions here certainly before the votes.

I have a question that I asked, I guess 2 weeks ago, at our hearing. I asked the audience, though not under oath: How many folks here have donated blood at least once in their lifetime, raise your hand?

I am so glad. We want to make sure our blood competition drive is open to the press as well. Some of us feel like we give blood every day and they take it.

How many people here have given blood in the last year raise your hand?

Again, okay. Again I want to make the point you can do that every 56 days.

The Sperrys, we appreciated your story, and even more for those in the audience. I don't know if they put these books out on the table, but there is a book that is a weekly calendar put out. We can make sure that anyone in the audience that would like one, we will make these available "Pints for Half Pints." There is a story on a number of really remarkable kids, most of whom survived. But your son is there for the first full week in March. It is really a remarkable story, very touching for him and all of these wonderful children that were highlighted in this, and again it reminds us about the need for blood.

It sort of reminded me as you told your story and as I read it in advance as well, in not only giving blood, that everyone that can ought to do so, but also the story of one of our colleagues, Bill Young, who has been a leader in the bone marrow tests. I was among many that participated in a drive here on Capitol Hill to have my blood marrow tested, stored in a bank, and I can hardly wait for the day when someone comes and calls and says, We need you, and I will be there. It is that type of volunteer effort that really does save lives. We witness your son, who has certainly been a little active this morning. We appreciate that.

You know, I was on C-SPAN this morning, I did calls with my colleague, Mr. Strickland, who is a member of this subcommittee as well, and one of the calls that I received was, I believe, a gentleman from Kentucky, who on trips to Ohio had noticed a lot of people on crack. And his question to me, which I wasn't able to give him an answer, but I said I would ask this this morning, was whether or not these tests in the blood he donated last week—I know it is NAT-tested later on—my suspicion is that that NAT test, nucleic acid test, given the acronym NAT, does in fact weed out anyone that might have some illegal substance in their blood. Is that true, Ms. Fredrick? Do you want to answer that?

Ms. FREDRICK. That unfortunately is not true. The testing we do for viruses such as hepatitis and the HIV virus, those viruses happen to be present to a greater extent in people who use illegal drugs, but we have multiple layers of safety in the blood supply.

The first layer is the health history and the questions we ask. Though we believe they are rather cumbersome, the purpose of those is to solicit truthful answers about risk activities that might put the donor——

Mr. UPTON. That is right. I did note to the gentleman that called that there was a lengthy questionnaire that took about 10 or 15 minutes to fill out, because they wanted—I mean, the person that walked through with me, he made sure that everything was answered. I had one question on an anticholesterol drug that I take, and I told him about that, and he said that shouldn't warrant any trouble. But in fact that was a question.

I noted, in fact, that there were some folks, I think there is a question on tatoos on that, whether you have had a tatoo. I remember that question, because I don't have any tatoos. I just checked no.

But go a little bit more on the drugs. I am sorry to interrupt.

Ms. FREDRICK. As you know, we ask extensive questions about lifestyle. Those questions we do ask about illegal use of drugs for

injection, because mostly we are concerned about the transmission, obviously, of viruses such as hepatitis and HIV.

The blood then goes on and is tested for those viruses, but in fact we cannot do testing for actual presence of any illegal drugs like crack cocaine.

Mr. UPTON. Okay. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. Again, thank you for calling this hearing. This is our third hearing. I was proud for a number of years to give blood, but I guess coming from Houston and my sinus problems, I have been rejected now for the last 4 or 5 years because of the medication.

That is one of the questions I would ask. I understand, you know, and I have gone through the questionnaire, because frankly the church my wife and I attend, we have a blood drive as often as we can, the Shriners. There is an effort at the Texas Medical Center in Houston. But I think the outreach more is to nontraditional groups. I do know, for example, churches in my community that do it, so—because of the fear of the amount of blood supply and the shortness we have had, particularly over holiday periods of time.

I know the tatoo issue and things like that. But that is one of the frustrations that I have tried to do, and I guess there is a fear because of whatever sinus medication or something you are taking. Doctor, could you answer that?

Mr. BIANCO. In general, we will not defer a donor because of a sinus medication. We will defer if they were recently taking an antibiotic because of the fear that there could be some bacteria in the blood that we take. As it is stored for several days, there is opportunity for those bacteria to grow. But just a sinus medication, just decongestants, should not be a call for deferral.

But I think you hit a very important problem, Mr. Green. It is that because of concerns of safety, we have been overzealous, overcautious. Today, as I tried to say in this statement, we are deferring incredible amounts of healthy Americans because of the fear of that minuscule risk that is there, as if we could eliminate all the risk.

What we are creating is the shortage on the other side. We discourage a lot of people. You had a reaction that is not the common reaction. Your reaction was to say, I can't give, I will get my church and groups to give. Most of the people that get deferred get very depressed, very upset, feel rejected, feel they are not healthy, and they have trouble dealing with that rejection. That is a network. They don't encourage other people to donate.

We have to find ways to change that behavior. We have to find ways we are donating for the whole community. If we don't give, we help give.

Mr. GREEN. I understand the reason. Maybe the pendulum swung so much because of the problems we had a decade ago with the quality of the blood supply because of the AIDS virus and some of the tragedies that we have seen. I don't know if I want to actually weaken it, but I also know maybe we need to—the questionnaire is involved, and I would hope that there would be other ways you could check the blood.

Mr. BIANCO. The quality of tests also has changed substantially, Mr. Green, particularly with the addition of the NAT testing that we just mentioned. It is our ability to detect those infections and to shorten what we call the "window period" to days. It is incredible in terms of reducing the risk of transmission of those viruses.

So the history, medical history, becomes in a certain way as one of the layers a little bit less important than it was in the past.

Mr. GREEN. Ms. Wilkinson, you make a point in your testimony that there are daily reports of isolated blood shortages. Again, my district in Houston, I know we have experienced that in geographic communities all across the country, from San Diego to Detroit to Pittsburgh. Can you put it in better context for us and explain why these sporadic shortages are occurring and why this is something we should be concerned about?

Ms. WILKINSON. I think again it is really twofold. We see less people who are willing to donate. People have articulated people's busy lifestyles. I think support from corporate America has declined over the years. Again, bringing a mobile operation into an organization obviously takes time away from the job. So there has been less interest from corporate America in supporting the community blood program. I know in our community, this is an area we are trying to focus on very significantly, again in order to increase getting the donors in the door.

Again, the other end of the spectrum is increased usage. We have seen at least in our community, a tremendous increase in blood products. Again, it goes back to procedures like more aggressive therapy for cancer treatment, transplants, traumas. They are able to get patients to hospitals much more quickly now because of air care support. Again, the likelihood of saving that person's life increases. But along with that comes the usage of blood and blood components. So I think all of those factors contribute to the shortages we are seeing.

Mr. GREEN. Thank you, Mr. Chairman. I would just like to ask Ms. Fredrick, and Dr. Bianco also, if they would just address that sometime in other questions.

Ms. FREDRICK. I would say to you, for instance in Houston, like many of our urban centers, the medical intensity of the procedures that go on in our urban areas, this is where people come to have bone marrow transplants, open heart surgery. So you have a great need in the large urban areas of this country in the use of blood, and the population not able to meet all of those needs. So in many large areas, Houston to be one, not only does the local community support the blood supply, but actually communities throughout the country also support the blood supply.

The other issue around that is our urban centers tend to be very diverse. We need to spend more time, more effort, in reaching out to all the different populations we have in our communities, the Hispanic population, the African American population, youth. That is a job we need to think more about, reaching different groups to encourage blood donation, because we are becoming a more diverse community, not less so.

Mr. BIANCO. Just to add a number to what Jackie just mentioned, Gulf Coast Regional Blood Center in Houston had an increase of 15 percent in demand for blood last year.

Mr. GREEN. Thank you, Mr. Chairman. I can also share the doctor's concern because of the economy in Texas and people do spend a great deal of time, maybe a long weekend in Mexico, the west coast of Mexico, and that fear, I can understand that may be something we need to look at. Thank you, Mr. Chairman.

Mr. UPTON. Thank you. I do want to make sure that the record is correct, too, when I talked about tatoos. It is only if you have received a tatoo in the last year. Again, I don't have any.

You have heard these buzzers. We have a vote on the House floor. So we are going to temporarily adjourn for about 15 minutes and then come back. It will be about a quarter of.

[Brief recess.]

Mr. UPTON. I think we are okay for a little while. We don't have votes for another hour.

At this point, I yield to a member of the subcommittee, Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. Let me begin by asking Dr. Wilkinson, as a lay person, a reformed lawyer, I don't know a lot about medicine, but I think there is a perception out there among the public that when you give blood, a lot of people don't want to give it unless there is an emergency, and then you can just run down there and give it. As was pointed out in the speakers' testimony, that is not always the case.

Can you quickly, because I want to ask other panelists a couple of questions, tell us the timeframe involved and sort of walk us through? If you go and give blood, are you tested first to see if you are acceptable, and then do they have to test the blood? How quickly can that be done?

Ms. WILKINSON. We don't pretest the blood. But let's say you decide you want to give blood; you come to the neighborhood blood center, and you will be asked to give some demographic information and then you will be given a health history form. This is the questionnaire that Mr. Upton referred to, that I guess can appear somewhat long to someone who may not have gone through the process before.

Typically, a lot of blood centers will have a part of the form that is self-administered and ask general health questions about you as a donor. It will ask for medications you have been on. It will ask about any systemic diseases that you might possibly have that would disqualify you as a donor.

I want to emphasize that all of this obviously is intended to protect the recipient; but there are some reasons that the questions are being asked, in fact, to protect the donor. So we don't draw blood when it is inappropriate for you as the donor.

Mr. BRYANT. I guess the real point of my question: How long would it take if you had that emergency and if you are relying on that, then I can run in and give blood—how long would it take to get that blood if it were acceptable to the recipient?

Ms. WILKINSON. So it is available for distribution, it takes approximately 2 days.

Mr. BRYANT. That is a point I wanted to make. We have an audience that may be watching on television, and the fact is, it is not just a matter of walking down, taking your blood out of the body and giving it to someone else.

Ms. WILKINSON. That is exactly right. From the day of donation, your unit goes through a number of test procedures with NAT. The turnaround time, most typically, blood centers are releasing products on the second day.

Mr. BRYANT. Dr. Bianco, you make some excellent points I think in terms of how we think of things in Washington, too. I think this panel has been really good on the practical side, kind of what I describe as where the rubber meets the road. This is where it happens. But you make some good recommendations. I wanted to quickly read those and see particularly if Ms. Fredrick or Dr. Wilkinson, anybody from the professional standpoint—certainly the Sperrys have an experience personally—but from a professional standpoint, if you have any disagreement.

I think the five points you make that we ought to consider in Washington are having HHS take a stronger position on voluntary blood donation and encouragement. Number 2, focusing the FDA on demonstrated safety risk. Number 3, using science-based decisions in making the determinations on whether to have these restrictions in place or not. I think that is very good, using sound science. Number 4, ensuring adequate representation of the volunteer blood community and their products advisory committee, which I think again is a very strong and ought to be an acceptable recommendation on your part. I think someone ought to have a presence on that panel and have input. And the fifth, assuring adequate HCFA reimbursement for measures that increase safety and availability of the overall blood supply.

The trends are down in this country for all these reasons we have talked about, and it is time the government, the Federal Government, took notice of this. I think, again, those five recommendations are very strong, and I just wondered if Ms. Fredrick or Dr. Wilkinson—I know, Dr. Bianco, you feel that way or you wouldn't have made it. Do you all have any comments?

Ms. FREDRICK. Yes, I think we very much support what Celso said. We would also encourage the need to increase the funding and the intellectual capital we spend on this issue.

If you look at the great progress we have made in safety in this country, it has come at a financial investment and an investment of experts, intellectual investments. We would like to see that same sort of investment now made in availability to draw on the partnership between the private sector and the public sector, government and blood centers, to really solve the issue of availability.

Ms. WILKINSON. I would certainly concur with Celso's five recommendations. Again, I think it is very important that we emphasize some issues about educating the public on the need for blood donation and how in fact those products are used; the real patients, in fact, whose lives are changed by receiving that product from an altruistic donor.

Mr. BRYANT. If I may make one comment to follow up on my first comment to Dr. Wilson, there is a perception in the public if an emergency comes up, a shooting or the bridge collapses, that we can all run down there and give blood, but in fact there is a delay of up to 2 days before that blood can actually be used, and you have to have that blood in the bank, so to speak.

Ms. WILKINSON. That is correct.

Mr. BRYANT. Literally and figuratively.

Mr. BIANCO. The word "bank" is what gives a false impression. It is a feeling people have that we open the door and it is all there, sitting on the shelf. It is not a bank, really. It is a pipeline. It is coming in every day, it is going out every day, and it doesn't last too long. A platelet donation we can use within 5 days. The maximum life for a unit of red cells is 42 days. So they are very short-lived products.

Mr. BRYANT. Thank you.

Mr. UPTON. Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman, and I apologize for being late and not hearing your testimony, although I did have an opportunity to read some of it. But the area that I just wanted to focus on briefly, you had talked about in your testimony, I guess it was Dr. Bianco, about the consensus development processes at FDA, and I had the impression that your view is that they are not operating with consensus development as it relates to blood.

Would you elaborate on that just a little bit?

Mr. BIANCO. Yes. The relationship of blood centers—and I can understand historically why it happened, it all relates to the AIDS crisis—was during many years an adversarial relationship. On the other hand, I think that we have sufficient expertise within the blood transfusion community in which we can sit down around the table and make some very reasonable decisions.

I think there are many examples that come from other agencies of the Federal Government, for instance the Energy Department, and the decisions about pollution standards and all that, that were achieved in terms that were much better for the American population, because everybody sat around the table, saw what is possible to do, and instead of just rules that were issued continuously, trying to control the process and sometimes a little bit out of focus.

They were in focus a few years ago, but now the issues are different. So I think that if there was more interaction we would be more successful in reaching that.

Mr. WHITFIELD. Is there anyone else who would like to comment on that general area?

This Blood Products Advisory Committee, that is a committee at FDA; is that correct?

Ms. WILKINSON. Yes.

Mr. WHITFIELD. Are blood centers represented on that?

Mr. BIANCO. Currently there are no blood center members sitting on the committee. It used to be the tradition that one or two representatives of blood centers sat in the committee. Currently there are physicians, there are scientists, but there are no blood center persons.

Mr. WHITFIELD. Who appoints those members to that committee?

Mr. BIANCO. FDA. The center for Biologic Evaluation and Research.

Mr. WHITFIELD. Why would there not be a representative of the blood centers on there?

Mr. BIANCO. Again, I believe this is a concern that comes from the AIDS tragedy. It was a concern at one point in the early days in which there was a feeling that FDA was too close to the blood banking community and may not—by being too close, may not have

been as vigilant as they should be. So the pendulum, as somebody said, swung the other way, and so there has been a very big separation.

So the committee was reconstituted in 1995 and the previous committee was dissolved, reconstituted, and from that point on, there were several representatives from advocacy groups like hemophilia groups, but there were no representatives of the blood banking community.

Mr. WHITFIELD. So you feel like it has gone too far the other way now?

Mr. BIANCO. That is what I said in my testimony, it is just a reasonable balance.

Mr. WHITFIELD. There was an example that someone gave about this malaria in Mexico.

Mr. BIANCO. That is the example that I also gave. The example is that we are concerned, obviously. We do not have a test that is practical for malaria screening of blood donors, and there have been for the last 20 or 30 years 1, 2, sometimes 3 cases a year, sometimes no cases a year, among the 12 million units that are transfused. Malaria in general is benign, but it can be fatal on occasion.

So we ask donors, in order to avoid people that could be at risk of transmitting malaria, we ask donors if they have been in a malarial zone. And we are too strict about that in the ways we do it, in my medical opinion; because we, for instance, had asked the FDA to consider a change that if people were just in a resort where there are no mosquitos, where everything is clean, they didn't leave at night to go walk by the forests or by the ruins near some Mexican resort, that those donors would be eligible to donate.

But there have been very strict interpretations of those rules, and we cannot collect for a year a unit of blood from somebody that went to a resort in Mexico, some resorts in Mexico, that are in malarial zones. There are resorts not in malarial zones.

Mr. WHITFIELD. Thank you.

Mr. UPTON. Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman.

I am sorry I wasn't here for your presentation. I had a meeting with the Speaker. So I may ask some questions that have been asked before, but I think it is useful to go through some of this.

I want to talk first about safety. I guess I would leave this for anyone on the panel to answer. But because there is a window for sero conversion for a number of diseases, what is the chance that a unit of blood could have the AIDS virus in it, but the test be negative?

Mr. BIANCO. The window period with the test, the officially sanctioned test that we have today for HIV, is a window of 16 days between the date the average person is infected and the date when the virus appears in the circulation, we can detect it by the test.

With the introduction of the NAT test, that window will be reduced to 11 days.

Now, in the first 10, 11 days of the infection, the virus is not in the circulation, it is not in the blood. It is usually in the lymph nodes, starting to replicate. So the NAT testing will bring us the closest we can to closing that window.

The risk before the NAT testing, derived from some very serious national studies, is 1 in 676,000. After the NAT testing, we don't have numbers measured, and the NAT testing is done under a research protocol, so we don't have a final figure, but we assume that will be way below 1 in a million.

Mr. GANSKE. How about hepatitis?

Mr. BIANCO. For hepatitis C, the window period is very long with the antibody test that we have. It is about 70 days between the date of the infection and the day on which the person develops the antibodies that we can detect. Again, NAT testing here is very useful because the viral load, the number of viral particles in the circulation, increases very rapidly, so the NAT testing in the format we are doing now in the research mode can reduce that window to about 2 weeks.

Mr. GANSKE. But that is in the experimental stage. That is not routinely being done?

Mr. BIANCO. It is being routinely done under our experimental protocol, an IND protocol approved by FDA. But the test is not yet licensed by FDA, but it is being done by the vast majority of the blood centers in the country.

Mr. GANSKE. What percentage of units of blood are tested that way before they go to a patient?

Mr. BIANCO. I would say way over 90 percent.

Mr. GANSKE. So we have a chance in 1 in 676,000 for HIV or for hepatitis?

Mr. BIANCO. We had a chance of 1 in 103,000. Now we believe it is again close to 1 in 600,000 to 1 in 1,000,000 after the NAT test.

Mr. GANSKE. Have there been documented cases in England or anywhere for the transmission of so-called mad cow disease through blood transfusion?

Mr. BIANCO. No.

Ms. WILKINSON. No.

Mr. GANSKE. So do you agree with the ban on utilizing units of blood from people who spent a certain period of time in England?

Mr. BIANCO. No, I do not. I do not believe there is evidence, scientific evidence, that indicates that there is risk.

Mr. GANSKE. Does anyone else on the panel want to comment on that?

Ms. WILKINSON. I agree with what Dr. Bianco just said. It is a theoretical risk only.

Mr. GANSKE. Does anyone pay for blood today? Do any of the blood collecting organizations pay somebody to donate blood?

Mr. BIANCO. Not in the whole blood sector. All donors in the AABB, American Red Cross, America's Blood Centers, are volunteer blood donors from the community, and that is why it is tough. The carrot is what we can do to their hearts and not the dollar bill.

Mr. GANSKE. How long has that policy been in effect?

Mr. BIANCO. The policy started effectively in the country in the late sixties and spread all over, so I would say by the mid-to-late 1970s, early 1980s, 100 percent of the whole blood collection.

Mr. GANSKE. How about plasma?

Mr. BIANCO. Plasma for the manufacturer of plasma products is collected from paid donors. But the plasma industry has a number

of safety measures, and some that we cannot use, like viral inactivation of the product, that guarantees safety.

Mr. GANSKE. Okay. And then my final question would be, and this would be for the entire panel, what is the single thing that government could do that would help increase blood donations? If we could start with Ms. Fredrick?

Ms. FREDRICK. I think the single thing government could do is increase the funding available to look at donor motivation studies, to understand the data and information on the blood supply, blood utilization in particular. We can probably get a lot of the data on blood collection because we are collectors, but in terms of how the blood is being used, projections into the future on how that is going to change is critical. Then I think to serve as a partner with us, bringing in private industry and the private sector to really address this issue with the same expertise that we have in corporate America to address other issues with regards to public.

Mr. BIANCO. I believe that Congress and the Federal Government can help us with leadership and resources. The moment that you, Mr. Upton, go and donate blood, you are sending a message. The moment government officials talk about blood donation, they are sending a message. They are making blood a new priority.

The second thing is resources. Because of all the change in the health care system, we have limited resources at the present time and we have to focus our resources on the safety issues. The piece of the pie that we always dedicated to the recruitment of blood donors is shrinking. Very often we know what to do. We have people that for 30 years in my organization are experts at blood collection, going to places, convincing people, raising their spirits toward donation and events, but we don't have the resources.

Mr. GANSKE. Mr. or Mrs. Sperry, do you have a suggestion?

Mrs. SPERRY. I would like to comment. I appreciated Mr. Upton's remark in putting together a race or competition between them, and that puts a message that even though as every person has a busy life, Congressmen as well too, but they are taking their time to make that effort and go and give blood and to save a life. So to me that is the most important thing, is that if they can show yourselves doing that, that maybe the ordinary American person can look at themselves and say that I can make that same time as well. So I appreciate that effort.

Mr. GANSKE. So Congressmen who are experts at public relations can contribute.

Dr. Wilkinson?

Ms. WILKINSON. Well, I really support everything that everyone at the table has previously said. Again, I think it is a matter of making the public aware of the need, having the public understand what is involved in the donation process, and the recipients at the end of that process.

I can't stress enough the resources issue. This has really become very critical to all of us, not only the blood suppliers, but the hospital transfusion services that are involved in issuing these products to the patient. The reimbursement and resource issue is a large one.

Mr. GANSKE. Thank you.

Mr. UPTON. Thank you, Dr. Ganske. I just want to note for the record that as we think about this competition in January, that two schools in Michigan actually do this routinely. Western Michigan University, which is in Kalamazoo, my district, and Central Michigan University, two terrific teaching universities in terms of educating teachers and putting them into the field, collected more than 1,000 units; in fact, I think it was 1,500 units were collected in the blood drive competition between those two schools. So we have a big challenge ahead of us on Capitol Hill in January.

Ms. Fredrick, you indicated in response to Dr. Ganske's question about the money that NIH is going to be spending to increase donors, and at an earlier hearing, I don't remember if it was the first or second one we talked about, NIH being given $1.8 million, almost $2 million to look into increasing the number of donors. So we look forward to hearing from NIH at some time in the future with regard to what exactly they propose and whether those reforms or procedures are implemented, and in fact how that will be impacted. Particularly with the testimony that we heard at an earlier panel, an earlier day, from the NBDRC—is that right—yes, great acronym—but particularly as they get into monthly reports that they are going to be making available to this committee as well as to private sector folks and you all too, we will really have a fairly good handle, I think, in terms of the need and the donor base and exactly where we are, which we don't have today.

The question that I have—actually a number of questions. We will see when this timer runs out before we move along. I have the blood shortages and related articles, excerpts from Regulatory Daily Report for the period 10-13-99, to October 13 through 5-12—it must be 10-13-98, I will bet, through 5-12-99. Virtually every region of the country they talk about a shortage. It is alphabetical. So it is Alabama to California, Connecticut, Wyoming and South Carolina; specifically the regions. Michigan is included here as well, sadly; Detroit is earmarked and a number of things, southeastern Michigan.

How is this report compiled? I am interested in how is this report put together, and when this happens. And I know Richard Burr, the vice chairman of this subcommittee, represents North Carolina, and one of the tragedies with Hurricane Floyd, not only did they have a large part of North Carolina maybe still under water, a real hardship for thousands of Americans, but one of the side lights that Mr. Burr related to me was that, in fact, a number of blood drives were cancelled because of the flooding, and therefore you could imagine, a number of the surgeries were cancelled as well, whether they be—certainly elective, but maybe even emergency.

How do your organizations—I will be interested really from all three of you here—react? How does this system work? How do you identify before it is too late, and how is it that you actually take blood from one region that has a surplus and measure that and make sure that it gets to the region that does not? Ms. Fredrick? Walk us through this a little bit.

Ms. FREDRICK. Thank you. The way it works in the Red Cross, and I suspect we are a little bit different than the other organizations because we are in fact a self-contained organization, we have something called the National Inventory Management System,

NIMS, or the hub. The hub is in St. Louis, and it is actually a physical location where we can store excess blood from around the country. It is also a virtual inventory. Daily, our regions can report in their inventory levels. So on a weekly basis, I actually get a report, by region, that will show what the blood supply is in every region by blood type.

What we do on a daily basis essentially is look at where the blood is needed and literally say, "St. Paul, we need you to send blood to Detroit; this much at this time."

In the case of Hurricane Floyd, to give you an example of the fragility of the blood supply, we lost 10,000 donations in a 48-hour period, essentially from Daytona Beach up through, in fact, Baltimore.

To give you an example, 10,000 units is what a whole large hospital might use in a year's worth of time. What we did is we essentially activated our national inventory system; 8,500 units went from all of our blood regions that had blood into the five blood regions. We did it ahead of time because we have an early warning system for disasters.

So literally we moved blood by telephone and computers, knowing where the excesses are and where the needs are. We also have a system called production planning that will actually take that down to the daily blood draw at a region and what will be made.

So that is how we move it.

Mr. UPTON. You move it by Postal Service, by UPS, by Federal Express?

Ms. FREDRICK. Federal Express and UPS. Generally it is a 24 hour—we need overnight service. So where we have to fly it, it is overnight. Now, we are lucky in that a lot of times we can drive it, like from Lansing to Detroit, for example. But, yes, we rely essentially on commercial carriers.

Now, last January, as you and I were in Michigan, the problem was when the airport was closed, the airplanes couldn't land.

Mr. UPTON. Even people at the airport had trouble.

Ms. FREDRICK. So in that case, you go by land in whatever way you can. Most of the natural disasters we can anticipate. So you move blood ahead of time.

Mr. UPTON. Dr. Bianco, would you like to comment?

Mr. BIANCO. Yes. Our system, we are 73 independent blood centers, but we have a very cohesive group, and through ABC we do a lot of what we call resource sharing. We are actually launching in 2 weeks an Internet-based resource sharing, so the access and the needs are posted on the Internet and the exchanges—currently the system is done by fax.

But essentially, yes, as our members in Florida are having troubles because of the lack of collections and all that, members in other areas will try to supply their needs and help them by shipping blood, but sometimes not really excess. Sometimes we all see the need is desperate in some places and we will cut down on a little bit of our supply to be able to help provide assistance.

Mr. UPTON. Do you assess that every week, or more often?

Mr. BIANCO. The system is not assessed. It is a voluntary system, and it is not assessed. So here what happens is that people will voluntarily part with a portion of their blood supply, and certainly

they will guarantee the needs of their community before they will ship some out. So not always, that resource sharing compensates for deficiencies in other areas.

Mr. UPTON. Dr. Wilkinson?

Ms. WILKINSON. The AABB has a similar system, the National Blood Exchange. Again, people who have excess inventory will post that inventory through the exchange and people that have a need will query the exchange to see if blood is available.

I would like to make a point to the subcommittee that people in blood centers typically do this on an informal basis as well. They typically know colleagues in other blood centers and they contact them on an individual basis to see if excess blood might be available for purchase.

One of the things that at least I have noticed over time, and maybe Jackie also might want to comment on this also, is finding blood to purchase has become increasingly difficult. Typically in the country there were centers that you could rely on almost 100 percent to have some excess blood that would be available for sale and purchase in times of need. Those resources have gotten to be much less. And again, trying to find blood and resource share, this very valuable resource has become increasingly difficult.

Mr. UPTON. I ask for unanimous consent that Mr. Ganske can ask a quick question before we go to Mr. Bryant.

Mr. GANSKE. Thank you, Mr. Chairman. I'm assuming that nobody has asked a question about hemochromatosis patients, so I would like to get your testimony on this. First of all, why don't we go with Dr. Bianco. Can you describe what hemochromatosis is and how patients with that require frequent blood removal and whether then, in fact, this could be a blood supply source, and is there scientific data as to whether that would be a safe source?

Mr. BIANCO. Hemochromatosis is probably the most common genetic trait or disease in the population, the American population. The numbers vary but it affects basically from 5 to 7 percent of the population. And it's a gene that is modified and that makes you absorb more iron than you should. And iron is the fundamental molecule of the hemoglobin that is in our red cells and help carry oxygen. The body doesn't have good mechanisms of getting rid of iron. An even so the person over the years goes accumulating iron; that iron deposits in the lung, in the kidneys, in the liver, and in the heart, and gradually will produce heart disease and diabetes and a number of complications.

This is for the more serious cases, for the people that are homozygotes that receive the same gene from mom and dad. But there is information today, just published a few weeks ago in the medical scientific literature, that the heterozygotes that only have 1 of the 2 chromosomes, 1 of the 2 genes also accumulate more iron than they should.

We only see today hemochromatosis people that already have the complications. But this is a very common gene in the population and these people benefit from donating blood. The rules that apply currently from FDA, even some of the standards that we have in our organization, is that we cannot use for transfusion a blood that is labeled what we call therapeutic phlebotomy; that is, a drawing

that was made with the only purpose of eliminating red cells from the individual.

We have discussed a lot and this was discussed actually at a Blood Products Advisory Committee and the HHS Committee, that those individuals are perfectly normal. The only thing they have is a lot of iron. And they do not have diseases that are different than other people. They often come to blood centers to donate or they go to physicians' offices and they are charged a fee for that process.

So actually what is in discussion is that if we remove the fee, so that would be an encouragement for people not to be totally truthful in their medical history and all of that, part of that blood, those that would be suitable, that would pass the medical history, that would pass all the tests that we use for transfusion. And we are all preparing submissions to FDA to attempt to do that. Now——

Mr. GANSKE. But there's no evidence that if you gave blood from a person with hemochromatosis that that could ever be transmitted to the recipient.

Mr. BIANCO. Oh, it's impossible. Because being a disease that is determined in your genes, it is determined from the moment that you are born, from the genes that you inherited from your parents.

Mr. GANSKE. Do you have an estimate for how many units you might have available if you were able to use?

Mr. BIANCO. The current estimates vary tremendously and they are all theoretical. There are estimates that we could add maybe 20,000, 30,000 units a year to 50,000 units a year in the country and there are estimates that are much higher if these larger populations were to donate. But I can tell you this will help but is not the solution to the supply.

Mr. GANSKE. Dr. Wilkinson, do you have any comments on that?

Ms. WILKINSON. I want to echo Dr. Bianco's last comment. My perception of some of the things that I've read has been that hemochromatosis will make up for the shortfall that we have experienced with the deferral, the 6-month deferral with people who have been to the United Kingdom. Again there is no scientific evidence that says in fact it will make up the shortfall. And I'm concerned that people have looked at this too much as the answer for that shortfall.

Mr. GANSKE. Thank you. And I yield back, Mr. Chairman.

Mr. UPTON. The gentleman's time. All right. The gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. Ms. Fredrick when you talk about the Red Cross I think moving maybe last year 650,000 units, how much is a unit?

Ms. FREDRICK. How much——

Mr. BRYANT. Is that a pint?

Ms. FREDRICK. Yes, it's about a pint, 500 cc's.

Mr. BRYANT. That's what a typical donor would give. They would donate a unit of blood, a pint of blood, when they go in to donate one time.

Ms. FREDRICK. Correct. And that unit of blood is called the whole blood and it is manufactured into multiple components. So you can make a red blood cell which is used to treat anemia, platelets which are used in bleeding disorders, cancer treatment, bone marrow transplantation, and then plasma which is also used in bleed-

ing disorders. So when we move about 650,000 products, those primarily are the red blood cell portion of that whole blood donation.

Mr. BRYANT. For donors, is there an age-wise, an upper end or bottom end, is there a range that you cannot give blood; too young, too old?

Ms. FREDRICK. There is a bottom range, and it's 17 and older can donate. I think every State in this country has passed State laws that allow the 17-year-olds to give. And there really is no upper limit per se as long as you are healthy. I know of a donor who started donating after he was 80 years old. So as long as you meet all of our health requirements, you can continue to donate blood.

Mr. BRYANT. I think what I get from all of your testimony is that again, as the people who are out there, not here in Washington but out there dealing with this problem on a daily basis, at a time when we seem to be excluding more people from donating blood; and the general trend for whatever reason out there, post-World War II people were more inclined to donate blood than we are today, being the selfish society that we've become. All those factors together at a time that that is happening, and blood donations—I think somebody said 1 percent a year—dropping 1 percent a year, that the need for this blood is becoming more as our society ages and as we get into more surgeries that are necessary, more elective surgeries and these kind of things.

Do any of you have any—I know we've sort of talked around this a lot, but do you have any comments on general trends or any encouragement you can give us or anything else that you would like to not only tell this panel but to the people that might be watching this?

Ms. FREDRICK. I think you know half the people, I believe, in this country have experienced blood donation. So it's not that we don't have a pool of wonderful, willing people who donate blood. Our challenge is how we reach those individuals. And I think we have to draw on all the expertise in this country to understand how you reach individuals. Once you do, they are more than willing to donate blood. So our challenge is to determine how to do that: to use technology to our advantage, be it the new telemarketing systems; how you reach donors with direct mail; how you tell donors about people like the Sperrys.

We know that people donate blood because they have a connection with the patient. And so how do we reach the donors and make the patient relevant? I believe there are enough people willing to donate in this community and in this country. It's our job to bring them in and invite them in to donate.

Mr. BIANCO. I think you made a very good point in the decline and the increase. An increase comes a lot from new medical technologies, too. There are the transplants. Bone marrow transplants today save thousands of kids with leukemia. The rate of cure of leukemia goes to about 73 percent today with a bone marrow transplant. It's incredible from what it was 20 years ago. But they require a lot of blood to maintain those kids until the bone marrow takes and grows.

And that's the example, for instance, in Mississippi Valley Regional Blood Center, they increased their collections. But I was looking at my notes here. They had an increase in 10.8 percent dis-

tribution because of changes in their oncology programs and all of that. In the Midwest area, that was always extremely successful in collecting blood.

The other good point you made, people during the war had made that commitment and that generation is not donating as often. They can't. They have aged. We have to bring the new generations into the process. And the only way we'll do that is through leadership again. There are the techniques, we need the technology, but they need examples, they need people that they believe in so that they can commit themselves, competing with these millions of other things that we see every day from TV shows and all that, that are for them sometimes more important.

Mr. BRYANT. Thank you. Dr. Wilkinson do you have a brief comment?

Ms. WILKINSON. Just finally, we live in the country that has the best medical care in the whole world. And again the reason for that good medical care is, as Dr. Bianco stated, our medical technology. Again, we're able to cure diseases that, you know, 15 years ago we couldn't necessarily cure. Blood is both a drug and a biologic. And currently the only way to get this drug and biologic is from another human being. And that's the message that we need to get out to others in this Nation so that they understand the need that we have to provide this as a lifesaving drug.

Mr. UPTON. Mr. Whitfield.

Mr. WHITFIELD. Dr. Wilkinson, you had testified that the Federal Government should support blood supply data collection and analysis. Are you primarily talking about additional funds there, or were you referring to something else?

Ms. WILKINSON. Well, I think I'm—I think we're seeking a mechanism for funding. Currently the National Blood Data Resource Center took over some activities that had been performed at Harvard previously. And one of the things that we became aware of was that currently there is no funding mechanism through, say, National Heart, Lung and Blood Institute to fund such an organization. And we're hoping that we can identify those mechanisms so that we can have an ongoing stream of funding to again collect current and accurate data.

Mr. WHITFIELD. We've had a lot of hearings in this committee regarding organ donation and people signing cards on death that their organs will be given to other patients. Is there a program like that relating to blood or not?

Mr. BIANCO. No, but I think that you hit the nail on the head in that a similar program probably could make a tremendous contribution. We are aware that the Federal Government has made an investment. There's a beautiful Internet site actually explaining to people the organ donation programs. Many States have their own programs that encourage organ donations through driver's licenses, through other things. But again a question of awareness. It's a question of overcoming an initial resistance and maybe a little bit of anxiety about going to a blood center to donate a pint of blood. But at the moment they overcome, just at the end of that donation, you feel so elated that you did something great. But that is—that similarity between the two programs is remarkable.

Mr. WHITFIELD. But there is no organized blood donation program.

Mr. BIANCO. Of this type, no, not yet.

Mr. WHITFIELD. How many blood types are there, by the way?

Mr. BIANCO. There are many blood types but the fundamental blood types are the four types, A, B, AB, and O. And then among those, there is the RH type. Each one of them can be positive or negative. The most frequent blood type is the type O. But that's the universal type that is the blood that can be administered to every other person. The rarest actually is the type AB, this—a certain type that Sperry, that Kirkland had. But Kirkland could have—he is the universal recipient—he could have received any unit of blood available of a matched RH type.

Mr. WHITFIELD. I yield back.

Mr. UPTON. They say round three. The United States writes the books on regulation and safety of blood supply. Would you not agree that our testing and our distribution system is second to none, and other countries would carefully watch what we do in terms of what we do? Would any of you disagree with that statement?

Dr. Bianco.

Mr. BIANCO. I will not entirely disagree, but I think that in recent years we have been so concerned about the safety of everything, that for instance Europe has introduced task modifications, equipment, much before we did.

Mr. UPTON. Did they have the NAT test before we did in place?

Mr. BIANCO. NAT was—not before we did. It was more or less simultaneous. But for instance, the latest generation of the hepatitis C virus antibody test was in their blood centers about at least 2 years before it was in our blood centers. And certainly they do not have the rigorous demands that FDA makes of the manufacturers. But sometimes these processes could have been speeded up a little bit.

Mr. UPTON. Now, as I understand it, we have about 3 dozen deaths a year in this country because of errors that are made in the system. Is that about right? That's about the average?

Mr. BIANCO. The average because of errors that are fatalities is about 18 a year.

Mr. UPTON. Eighteen a year. And how would you describe those instances of fatalities? Would you say they're all clerical, that they might——

Mr. BIANCO. Those that I'm referring to——

Mr. UPTON. Mislabeled blood, from AB to O or whatever it might be, is that virtually the entire system would be mislabeling.

Mr. BIANCO. For those it's most—it was mislabeling, as you said, or the sample is collected from the wrong patient or the unit is hung on the wrong patient. That is a failure of identification.

Mr. UPTON. So they would list the wrong donor, then it would be——

Mr. BIANCO. Mistype; it would be the wrong type. There was a study that was performed in New York State in 1991 by the State Department of Health, using their reporting system, in which 1 in 12,000 units in the State in that year had been transfused to an unintended recipient.

Mr. UPTON. Really; 1 in 12,000.

Mr. BIANCO. Without fatalities in most of them because of the universal types, but the error occurred.

Mr. UPTON. Right. Now, your facilities that each of you represent, are they—they're all licensed; is that correct?

Ms. WILKINSON. Yes.

Mr. UPTON. They're routinely inspected; right?

Mr. BIANCO. Right.

Mr. UPTON. And for errors, they're promptly reported, and I would imagine that those errors, when and if they occur, would be because they were mislabeled. Is that right or not? What type of errors would you see and notice that would be moved up the line?

Ms. WILKINSON. You could really have a variety of errors. I mean, labeling could be one of the errors; but you might have some errors that were related to testing, errors that might have been related to the manufacturing process. I mean, there's a whole gamut of things that might be considered an error and reportable to the FDA.

Mr. BIANCO. Actually the major number from what I recall the statistics—and FDA has those statistics available—is what we call post-transfusion—post-donation communications, when we ask the donor to call us back if they feel something or if there is something wrong. And I would say that about half of the reports that we made is because somebody says, "Oh, I went home and I realized that I went to a malarial area," and we'll pull those units and an error is defined or accident is defined by FDA as a unit that left our facility and that was not suitable for transfusion.

Most of the errors that are reported are errors that involve violation of some small rule, and they don't really represent a risk to the recipient. But some of them are because they were mislabled, there was some error in the identification or somebody. But that's the nature of the error reporting. But the error reporting forces us to study what was the cause of the error, forces us to go review. And actually we have to submit to FDA, together with the error report and general information about how we investigated the error, and what we did to prevent it from occurring in the future.

Mr. UPTON. I don't know, Ms. Fredrick, if you wanted to add anything to that or not.

Ms. FREDRICK. No, I think Celso accurately described it. I think embedded underneath the accident and error reporting system that's really a requirement by FDA, I'm sure most of us have other surveillance systems that are designed to detect what we call event aberrations much earlier than the error and accident reporting system. So I think in this country, we've been very vigilant about building those systems in place, accumulating that data, even as Celso said, using it to actually improve the system.

Mr. UPTON. Let me ask one question, then I will yield to Mr. Bryant. When I gave blood last week and there was a comprehensive checklist that I circled yes or no based on what the question was, and the attendant there went through it all, and a couple questions I left unanswered or I had a question, it was very carefully gone through as to whether I was eligible or not.

Dr. Wilkinson, Dr. Bianco, when folks—since I did it at my local Red Cross facility, is your check list identical? Is it virtually the

same? Are there some big differences? I mean, how is it that the——

Mr. BIANCO. It's virtually the same. There may be changes in words, there may be changes in——

Mr. UPTON. But you make the same sweeping test, then.

Mr. BIANCO. All are defined both by industry standards that actually are helped by AABB and by FDA guidances. And so all will ask about the similar subjects in a similar way in order to obtain the same information.

Mr. UPTON. Dr. Wilkinson.

Ms. WILKINSON. That is correct. And any changes in a given institution's health history questionnaire must be approved by the FDA before implementation.

Mr. UPTON. Mr. Bryant.

Mr. BRYANT. I want to simply conclude my part of this hearing. I certainly thank you for doing this hearing and I want to conclude by thanking each one of you members of the panel for being here today, obviously very competent and qualified to be here and talk to us about this important issue.

And I will just simply tell you that what you told us, at least I know in my case, was very insightful and most helpful to me in understanding this situation. Certainly I hope that we all as Members of Congress and this panel, that those that may be watching this via television have learned a lot about how simple and how safe the process is and how much, given again today's climate in this country of aging of people together with the medical technology that's increased the need for the use of blood, the medical technology that saves lives. I know in my district, in Memphis especially, and in Nashville, we have two really tremendous medical communities thriving, and hospitals and in other towns that I represent—I don't want to leave anybody out—but at this time when we need more people having that spirit of volunteerism coming out, and certainly coming from the volunteer State of Tennessee itself, I hope that we can certainly get our act together down there in terms of making sure that there's adequate blood donations made from our State and across the country.

But again, thank you very much for your information and especially the comments on how we can work as a Congress to better help your effort. Thank you.

Ms. WILKINSON. Thank you.

Mr. UPTON. Thank you, Mr. Bryant. I do have a couple more questions that I would like to ask before we adjourn, assuming no other members return.

Has HHS been in touch with any of your organizations trying to help on public service announcements, whether it be on hepatitis C or increasing the number of donors in a variety of different regions in the country? That's one of the tasks that I think we charged them with. I wondered if they've actually begun to make any comment—make any contacts using your fine organizations.

Mr. BIANCO. There have been two things. There was a presentation at the latest meeting of the Blood Products Advisory Committee in which HHS presented a series of points in which what they felt from their internal committees could be helpful actions in

terms of increasing the blood supply. And I believe that Dr. Satcher mentioned that here at the first hearing.

The second thing is that we were in contact with the National Institutes of Health, the blood—National Heart, Lung and Blood Institute. They are trying to convene a meeting in January to discuss the issues and to see how they could help. So that contact has happened. However, I hope that through—not however—but really I hope that through these mechanisms we will be able to obtain the resources that will allow us to go to these types of means of public health announcements and all that. But what we want is not just a public health announcement, we want you and leaders to be in those public health announcements. That's how you are going to help us.

Mr. UPTON. Well, I am looking forward myself to someday getting the gallon pin. And since I donated, they sent me a whole batch of material from my local Red Cross unit and they had all those listed, and there was even a 10-gallon pin that was awarded in our region.

I asked the question when Dr. Satcher was here—did a fine job—but I asked the audience that they too, like I did today—how many people had donated, how many again then had donated in the last year? And Dr. Satcher indicates that, Mr. Chairman, Fred—you notice I didn't raise my hand on the second question, and that's because I've been to a number of regions in the world that in fact once you visit, you're not allowed to donate blood, particularly from some parts of Africa and other places. I think he mentioned Togo—malaria-infested areas.

Other than saying I wish I could find a place that doesn't have mosquitos and they would stay away from me—but as we look at malaria and as we look at what happened in New York the last couple weeks with—I think it's the West Nile mosquito-passed virus, we look at perhaps a new hepatitis strain which has been identified this past summer. We look at disease particularly I think in Central America, called Chagas. Don't have that in Michigan yet.

But as you think about other bacterial contaminations, and as we see what happened in the U.K. with mad cow disease, and the new question now that is part of the form that all of us fill out when we donate blood, do you see movements similar to what we saw with mad cow disease that are going to restrict the donors or take potential donors out of play because of these West Nile, Chagas, those varieties of different events? Where do you see us headed toward that?

Mr. BIANCO. We are all concerned about the emergent infections and watching it very carefully. Centers for Disease Control has done a very nice job of surveillance and linking with all of us, including blood centers, to do that. It's possible that some mysterious agent 1 day comes, but fortunately all the agents that we have seen so far have not—since AIDS—have not been threatening to the blood supply. Chagas has been in Latin America for many hundreds of years, maybe thousands of years. It is a serious problem in Latin American countries. And it is transmittable by transfusion. There are tests for Chagas. So if we ever saw, because of immigration or some issue, an increase in the prevalence of Chagas

disease in the country and there are several studies that from time to time are done, we would have the tests, we would have the means to control it.

West Nile fever is the person is so sick that they can't think about donating blood. So the temperature that they took of you as you donated blood would have prevented such donation. But always we have to have our eyes and ears open to a potentially emerging threat. We are ready I think for it.

Mr. UPTON. I don't know if you wanted to comment.

Last question I have is, as you indicated a little bit earlier, all of your facilities are regulated and routinely inspected—the works. Is there any reason to think that there is any blood donor facility in this country that shouldn't be under the same inspection guidelines that you face? I know they're all licensed but in some cases they're not inspected more than every year or 2. And obviously there are, I think, the guidelines across the State lines. If blood crosses State lines, then it's under the full review of the FDA. But it's my understanding that only about 90 percent of the facilities in fact are. And I just wonder about that remaining 10 percent, and I don't know of the 18 deaths that occur routinely, dozen and half, maybe a little bit more from time to time, I don't know how many of those actually come from facilities that may not be in the same ballpark as you all in terms of fully regulated and inspected.

Ms. WILKINSON. One of the things about, say, the fatalities, regardless of whether a facility would be licensed by the Food and Drug Administration, they would still be required to report that to the FDA. And there would be an investigation of that accident through their district FDA office.

Mr. UPTON. But it's not as prompt though, right? It really is a question of being——

Ms. WILKINSON. I really don't know about that. I can't speak to that because, again, I come from a licensed facility. But again, transfusion services typically are not licensed and many are not registered. There is currently a memorandum of understanding between the Food and Drug Administration and HCFA again to assess those facilities. I don't know to what extent those assessments are actually carried out. Again, the vast majority of organizations that are collecting blood certainly fall under the aegis of the FDA and are evaluated on a regular basis. I believe it's the transfusion services that you're speaking about that may fall through that process.

Mr. UPTON. And it's my understanding that transfusion deaths, when a transfusion death occurs, it has to be reported within 72 hours.

Ms. WILKINSON. Well 24 hours telephonically and 72 hours written; yes.

Mr. UPTON. But errors not leading to deaths are.

Ms. WILKINSON. Right. Right. And those are the—that was the genesis for the first guidance document or the first draft that we're still waiting for a final document on from the FDA.

Mr. UPTON. That's one of the things this subcommittee is trying to pursue, those regulations being put out earlier, we're hoping they would come into place well before the year 2001, which seems to be about the time line that the FDA is currently embarking on.

Ms. WILKINSON. Right.

Ms. FREDRICK. I think I want to echo what Susan said. The 18 deaths you speak of are in the transfusion service and are not donor center deaths in the course of developing blood. But I think it would be our feeling that anybody who provides a blood product ought to fall under the same stringent set of guidelines. I think we have all invested, as we said, many, many, many millions of dollars to make sure our systems are prepared for the future and robust enough, and we would hope that the whole blood supply fell into those same regulations.

Mr. BIANCO. I want to support that very emphatically and say that every patient deserves the same quality of blood no matter where, no matter what in our country.

Mr. UPTON. Well, I don't think you can say it better than that. We appreciate your time this morning. I can assure you that this subcommittee will continue to move forward in the future on hearings to make sure that we have not only adequate levels but it continues to be safe. We appreciate your leadership and your testimony. And I guess I can say that without any of my Democrats present, that we look forward to beating them on January 4. And this hearing is now adjourned.

[Whereupon, at 11:55 a.m., the subcommittee was adjourned.]