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Health, Education, and  
Human Services Division

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The Honorable Tom Bliley  
Chairman, Committee on Commerce  
House of Representatives

Subject: Blood Supply: Availability of Blood to Meet the Nation's Requirements

Dear Mr. Chairman:

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 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 donations 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.

In light of these developments, you asked us to provide information on (1) recent trends in blood donation and the demand for blood transfusions, (2) the expected effect of a ban on blood from 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 be distributed.

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, not in the community supply of blood available to anyone in need. Further, the projection relies on data from only 2 years, the most recent of which is now 2 years old. 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 accuracy of these estimates. While the estimates of the potential increase in the blood supply from donations by individuals with hemochromatosis vary widely, most of these increases could not occur until current regulations are changed. Therefore, such donations will not affect the available blood supply for some time.

This correspondence is based on data collected from and discussions with officials from HHS; the American Red Cross and America's Blood Centers, the major blood banking organizations; the American Association of Blood Banks, the professional and accrediting organization for blood facilities and transfusion services; and the American Blood Resources Association, representing the paid plasma collection industry. We carried out our work between June and September 1999 in accordance with generally accepted government auditing standards.

## 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.<sup>1</sup> Whole blood is rarely transfused into patients. Instead, each unit of whole blood is separated into specialized components, consisting of various types of blood cells (for example, red blood cells and platelets) and plasma.

In addition to whole blood, approximately 370 plasma collection centers collect about 11 million liters of plasma from 1.5 million paid donors annually, involving a total of approximately 13 million separate donations each year.<sup>2</sup> Many different components of plasma are used for medical treatment, ranging from treating the trauma of burns and surgery to replacing blood elements that are lacking as a result of disease, such as hemophilia.

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.<sup>3</sup>

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 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, first identified in 1995, is a chronic, progressive neurodegenerative disease that is inevitably fatal. It is believed that nvCJD is caused by infective proteins called prions. As of August 1999, there were 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 (BSE) in

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<sup>1</sup>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.

<sup>2</sup>Plasma is the liquid portion of blood, containing nutrients, electrolytes (dissolved salts), gases, albumin, clotting factors, hormones, and wastes.

<sup>3</sup>Technically, allogeneic donations include all blood collected from one individual for use in another. Thus, blood from directed donations and imported blood is also allogeneic, although those sources are usually discussed separately.

the United Kingdom, probably prior to 1990. Cattle herds in the United Kingdom suffered an epidemic of BSE, which peaked in 1992 and subsequently declined as the result of government actions to change the composition of cattle feed. Although nvCJD's incubation period is unknown, the disease may manifest itself long after the initial exposure—the incubation period for other human prion diseases ranges roughly from 4 to 40 years. 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 and no confirmed cases of BSE in U.S. cattle.<sup>4</sup>

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.<sup>5</sup> However, the proportion of individuals who have mutations associated with hemochromatosis and later develop the disease is unknown, because not all of these individuals become ill.<sup>6</sup> Treatment of hemochromatosis has two phases: (1) iron depletion therapy, in which the patient receives a therapeutic phlebotomy 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. NBDRC, an affiliate of the American Association of Blood Banks, recently projected that the demand for blood will outstrip supply by next year. While the blood supply has tightened, current evidence indicates that the blood supply has declined more slowly than NBDRC assumed. Projecting the future supply of and demand for blood is inherently difficult because of the uncertain ability of the blood industry to respond to potential shortages by increasing supply or reducing demand. Because blood cannot be stored for long periods,<sup>7</sup> blood banks have little incentive to collect more than is needed, and they may be able to increase collections if required. Similarly, physicians and blood transfusion centers may be able to use blood more judiciously, decreasing aggregate demand.

Any conclusions about the trends in the blood supply are hampered because information about the blood supply has not been gathered routinely at short intervals. Until 1995, the National Institutes of Health (NIH) funded surveys of blood banks and transfusion centers. In 1998, NBDRC conducted a privately funded survey that measured the blood supply in 1997. NBDRC is expected to announce the results of a new survey of the blood supply (without information about transfusions) in November 1999, and the National Heart, Lung, and Blood

<sup>4</sup>The Centers for Disease Control and Prevention (CDC) conducts surveillance for nvCJD. The Department of Agriculture monitors cattle herds for BSE.

<sup>5</sup>Fewer data are available on the prevalence of hemochromatosis in other populations.

<sup>6</sup>There are two genetic mutations, C282Y and H63D, associated with the gene for hemochromatosis. C282Y is considered the major mutation. Individuals who inherit one copy of C282Y or H63D do not develop the disease although some may exhibit symptoms. According to a CDC official, an estimated 60 to 80 percent of individuals who have two copies of C282Y—one inherited from each parent—eventually develop symptoms.

<sup>7</sup>Red blood cells may be preserved as a liquid for up to 42 days. They also may be frozen for up to 10 years, but this is rarely done because it is prohibitively expensive.

Institute of NIH recently arranged for NBDRC to collect data on blood donations on a monthly basis from a sample of blood centers. In the future, NBDRC hopes to expand this survey to collect information on transfusions as well.

Based on the results of its 1998 survey, NBDRC has projected that the demand for blood will outstrip supply by next year.<sup>8</sup> That projection rests on the overall 5.5 percent decrease in the blood supply from 1994 to 1997 (see table 1) and on the observed 3.7 percent increase in the number of units transfused during those years.

**Table 1: Blood Supply Trends**

| Supply source  | 1989              | 1992              | 1994              | 1997                    | Percent change (1994-1997) |
|--|-------------------|-------------------|-------------------|-------------------------|----------------------------|
| Total units  | 14,229,000        | 13,794,000        | 13,340,000        | 12,602,000 <sup>a</sup> | -5.5%                      |
| Allogeneic units collected and imported units <sup>b</sup> | 13,224,000        | 12,241,000        | 11,993,000        | 11,741,000              | -2.1                       |
| Directed units collected                                   | 350,000           | 436,000           | 334,000           | 205,000                 | -38.6                      |
| Autologous units collected                                 | 655,000           | 1,117,000         | 1,013,000         | 643,000                 | -36.5                      |
| Rejected on testing  | 675,000<br>(4.7%) | 625,000<br>(4.5%) | 432,000<br>(3.2%) | 232,000<br>(1.8%)       | -46.3                      |
| <b>Total available supply</b>                              | <b>13,554,000</b> | <b>13,169,000</b> | <b>12,908,000</b> | <b>12,370,000</b>       | <b>-4.2</b>                |

<sup>a</sup>Sum of units does not add exactly to total units in NBDRC data.

<sup>b</sup>Imported units totaled 285,000 in 1989, 206,000 in 1992, and 220,000 in 1994. They were included in the allogeneic total and not reported separately in 1997.

Source: E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1989," *Transfusion*, Vol. 33 (1993), pp. 139-44; E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1992," *Transfusion*, Vol. 35 (1995), pp. 802-12; E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1994," *Transfusion*, Vol. 38 (1998), pp. 625-36; NBDRC; and GAO calculations.

Our analysis of blood supply data found that the blood supply decreased less than the 5.5 percent figure implies. The supply of allogeneic and imported blood decreased only 2.1 percent from 1994 to 1997, and the community supply—the blood available to anyone in need (including crossed-over autologous and directed units)—decreased about 2 percent from 1994 to 1997 (see table 2). The supply designated for particular transfusion patients, both autologous and directed, decreased by 37 percent from 1994 to 1997, accounting for two-thirds of the overall 5.5 percent decline.<sup>9</sup> As the general blood supply has become safer, fewer patients have donated their own blood in advance of a procedure or requested that friends or family members donate blood for them. However, some portion of these losses in autologous and directed donations would have to be replaced by units from the allogeneic supply for patients who previously would have had their blood needs met by autologous or directed units.

<sup>8</sup>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.

<sup>9</sup>In particular, the number of autologous and directed units collected but not transfused dropped 63 percent between 1994 and 1997.

**Table 2: Trends in the Community Supply of Blood**

| Supply source   | 1989              | 1992              | 1994              | 1997              |
|---|-------------------|-------------------|-------------------|-------------------|
| Allogeneic and imported units                               | 13,224,000        | 12,241,000        | 11,993,000        | 11,741,000        |
| Total autologous and directed units collected               | 1,005,000         | 1,553,000         | 1,347,000         | 848,000           |
| Autologous and directed units transfused                    | 453,000<br>(45%)  | 702,000<br>(45%)  | 587,000<br>(44%)  | 501,000<br>(59%)  |
| Autologous and directed units discarded, other              | 480,000<br>(48%)  | 789,000<br>(51%)  | 678,000<br>(50%)  | 251,000<br>(30%)  |
| Autologous and directed units crossed-over <sup>a</sup>     | 72,000<br>(7%)    | 62,000<br>(4%)    | 82,000<br>(6%)    | 96,000<br>(11%)   |
| <b>Total community supply (allogeneic and crossed-over)</b> | <b>13,296,000</b> | <b>12,303,000</b> | <b>12,075,000</b> | <b>11,837,000</b> |
| Change from previous survey                                 | —                 | -7.5 %            | -1.9 %            | -2.0 %            |

<sup>a</sup>Units crossed-over are added to the general supply.

Source: E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1989"; E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1992"; E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1994"; NBDRC; and GAO calculations.

The number of units rejected on testing has decreased over this period because donors who have diseases for which tests have been introduced have been removed from the donor pool and because succeeding generations of tests have become more accurate, resulting in fewer donors falsely testing positive for a disease. However, if a new test were introduced for some disease, the number of units rejected could increase as donors testing positive for the condition are screened out.

Trends in the number of units transfused support the view that the blood supply is not in crisis (see table 3). Overall, the blood banking system had an adequate supply to meet increasing demand. Total units transfused increased 3.7 percent from 1994 to 1997, and allogeneic transfusions increased 7 percent in the same period. Between 1994 and 1997, the proportion of units lost before transfusion decreased, and more directed donor and autologous units were crossed-over to the community supply. However, the blood supply cushion (percentage of units not transfused) also dropped sharply from 1994 to 1997.

**Table 3: Transfusion Trends**

| Year | Transfusions <sup>a</sup> | Percent of available supply |
|------|---------------------------|-----------------------------|
| 1989 | 12,059,000                | 89.0                        |
| 1992 | 11,307,000                | 85.9                        |
| 1994 | 11,107,000                | 86.0                        |
| 1997 | 11,517,000                | 93.1                        |

<sup>a</sup>Transfusions of whole blood or red blood cells.

Source: E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1989"; E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1992"; E. L. Wallace and others, "Collection and Transfusion of Blood and Blood Components in the United States, 1994": NBDRC; and GAO calculations.

Other evidence seems also to indicate that the blood supply cushion has narrowed, although 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. More 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.<sup>10</sup>

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 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.<sup>11</sup> On the other hand, some evidence indicates that the demand for blood can be reduced. For example, the amount of blood used for the same procedures varies widely among hospitals, and at least one pilot program has shown that the use of blood can be substantially reduced without affecting clinical outcomes. Similarly,

<sup>10</sup>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.

<sup>11</sup>For example, heart surgeries typically require 6 units of blood and 6 units of platelets, and bone marrow transplants generally involve 20 units of blood and 120 units of platelets. Among the procedures requiring the greatest use of blood are the treatment of trauma patients, heart surgeries, orthopedic surgeries, and some cancer treatments.

improved surgical techniques and better understanding of the clinical thresholds that trigger blood transfusions has reduced the demand for blood in some instances.<sup>12</sup>

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, not type-specific, have a longer shelf life, are readily available and in large quantities, and would deliver oxygen therapeutically and quickly to tissues and organs. Some products in development include hemoglobin-based oxygen carriers and perfluorocarbons. However, most products are still in the early stages of research and development. While some of these products have reached clinical trials, their future contribution to the blood supply cannot be predicted. For example, the half-life of one company's product is 12 to 48 hours, which is less than the 60-day half-life of fresh red blood cells. Because it will take at least several years for an artificial blood alternative to reach the market, blood substitutes will not be available to meet blood needs in the short-term.

These data on the blood supply only address supply trends for whole blood. According to the American Blood Resources Association, plasma collections have also decreased—approximately 10 to 15 percent in recent years. Some of the factors affecting blood collection overall, such as changes in the donor pool, have also had an effect on plasma collections. While plasma donors are paid for their donations, the \$25 to \$30 payment may no longer be worth the time and inconvenience of plasma donation. Nevertheless, the American Blood Resources Association does not foresee any crises in the plasma supply in the short-term. Association officials estimate that about 30 percent of the plasma collected in the United States is currently exported, but it is unclear whether some of that plasma could be reallocated to meet shortages in this country, should they occur.

HHS recently organized an interagency committee to develop strategies for increasing the blood supply. The group recommended that (1) the blood supply be monitored on an ongoing basis, (2) steps be taken to encourage more donations by current blood donors, (3) donor relations be improved to facilitate the recruitment and retention of donors, (4) restrictions be removed to safe donations from individuals currently disqualified from donating, and (5) economic issues facing the blood industry be addressed. HHS has already agreed to fund, through NIH, monthly surveys of the blood supply to be conducted by NBDRC, and the Department reported that specific initiatives in each of the other areas are under way. For example, NIH is conducting research to find ways to increase the number of donations by regular blood donors.

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

FDA has issued guidance recommending that collections be prohibited from donors who had resided or traveled in the United Kingdom for a total of 6 months or more between 1980 and 1996 because of the theoretical risk of nvCJD being transmitted through blood transfusions.

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<sup>12</sup>Paul C. Hebert and others, "A Multicenter, Randomized Controlled Clinical Trial of Transfusion Requirements in Critical Care," *New England Journal of Medicine*, Vol. 340, No. 6 (1999), pp. 409-17. In addition, the use of drugs that stimulate blood-cell production and techniques such as intraoperative blood salvage and preoperative and intraoperative hemodilution can reduce the need for transfusions.

FDA will review this policy at 6-month intervals to consider any new scientific information and the policy's impact on the blood supply.

It has not been shown that nvCJD is transmissible by blood transfusion. However, 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. Yet 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. Blood is still collected and transfused in the United Kingdom. However, because it is possible that infectious agents are concentrated in white blood cells, leukofiltration to remove white blood cells is being introduced for all whole blood collections.

In June 1999, FDA's Transmissible Spongiform Encephalopathy Advisory Committee recommended that the agency prohibit blood donations by persons who had resided or traveled in the United Kingdom. The committee members were polled for their recommendations on the duration of residence that should trigger the ban. The median recommendation was for 6 months, with another cluster of votes at 1 year. One week later, the HHS Blood Safety Committee, chaired by the Assistant Secretary for Health and Surgeon General, unanimously endorsed this recommendation and selected 6 months as the trigger for the exclusion. In August 1999, FDA issued industry guidance for implementing this recommendation.<sup>13</sup>

In making its recommendation, the FDA advisory committee tried to balance the twin goals of minimizing losses to the blood supply and eliminating as much risk as possible. A survey of blood donors done for the committee by the American Red Cross found that 23 percent of donors had traveled to the United Kingdom between 1980 and 1996. A previous survey of U.S. blood donors found that 1.7 percent of them traveled to the United Kingdom each year, a figure that is close to the results of a Department of Commerce survey that estimated that 1.4 percent of Americans traveled to the United Kingdom in 1997. 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.

Estimates of the degree of risk reduction achieved by this exclusion are problematic for several reasons. 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; therefore, any change in this assumed relationship would lead to a significantly different risk reduction estimate. Indeed, HHS told us that it 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 in each of the British cases (41 of the 43 known cases), the individual was born in the United Kingdom and resided there for at least 10 years between

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<sup>13</sup>Canada implemented this donor exclusion policy at the same time.



1980 and 1996; thus, HHS reasoned that any exclusion threshold of 1 year or less would reduce the presumed risk by tenfold or more.

Blood banks have expressed concern that this exclusion will eliminate more than 2.2 percent of the blood supply.<sup>14</sup> First, there is the possibility that some potential donors will fail to attend to the details of the exclusion policy and decide not to donate blood even though they are eligible to do so. For example, eligible individuals who visited the United Kingdom for less than 6 months between 1980 and 1996 might not consider donating blood because they had heard that visitors to the United Kingdom should not give blood. One possible, although unlikely, illustration of the potential impact of this exclusion is an analysis of data from the American Red Cross survey that found 15 percent of the blood supply would be lost if all travelers to the United Kingdom for at least 1 week between 1980 and 1996 did not donate. There is also concern that potential donors who have not traveled to the United Kingdom 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. Finally, there is concern 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. In addition, not all new donors become regular donors. 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.

#### POTENTIAL FOR BLOOD DONATIONS FROM INDIVIDUALS WITH HEMOCHROMATOSIS

One measure being considered to alleviate potential shortages in the blood supply is a change in policy to allow blood collected from hemochromatosis patients to be distributed for transfusion.<sup>15</sup> Individuals with hemochromatosis have their blood drawn in a procedure called therapeutic phlebotomy<sup>16</sup> to alleviate excess iron in their blood. Making hemochromatosis patients eligible to donate would essentially provide an increased number of donors because they have to periodically have blood drawn to treat their condition. However, FDA is concerned that these individuals would not truthfully answer donation screening questions about risk factors that would disqualify them, since they could avoid the

<sup>14</sup>American Blood Resources Association officials estimate that the exclusion of donors who have traveled to the United Kingdom between 1980 and 1996 will result in a loss of approximately 1 percent of current plasma donors.

<sup>15</sup>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.

<sup>16</sup>Therapeutic phlebotomy is the removal of a full unit of blood from an individual, about 500 mls, for the purpose of treating a disease.

cost of paying for the therapeutic phlebotomy procedure by donating blood. In April 1999, the Public Health Service's Advisory Committee on Blood Safety and Availability recommended that HHS change its policies and remove any barriers to the use of this blood since there is no evidence that blood from hemochromatosis patients carries an increased risk to recipients. At the same time, the committee recommended that HHS take steps to eliminate any financial incentive for hemochromatosis patients to donate blood.

According to a survey of 2,362 individuals with hemochromatosis, most individuals are insured or partially insured for therapeutic phlebotomies; however, 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.<sup>17</sup> Even though therapeutic phlebotomies are necessary medical treatment for some individuals with hemochromatosis, insurance does not always cover the costs. 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.<sup>18</sup>

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. 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,<sup>19</sup> hospitals and physicians hesitate to use this blood. Some experts in favor of using blood from individuals with hemochromatosis argue that Sweden and Canada have been transfusing such blood for years without any problems. Still, a series of tests or studies may be needed before the blood can be added to the blood supply. For example, in Ontario, Canada, patients are first referred to physicians for exhaustive studies before the physicians refer them back to blood centers to donate blood. Some in the U.S. blood industry consider hemochromatosis donors to be the same as paid donors, implying a decreased level of safety.<sup>20</sup> FDA is similarly concerned that hemochromatosis patients who donate blood rather than pay for a therapeutic phlebotomy will not respond to screening questions truthfully in the absence of any change in the reimbursement policies for their treatment. In 1996, the American Association of Blood Banks issued standards discouraging transfusion of blood from donors who had therapeutic phlebotomy. Because many blood centers conform to these standards, this policy effectively excludes most individuals with hemochromatosis from blood donation; in the United States, the blood obtained by therapeutic phlebotomy from hemochromatosis patients is, at present, discarded.

While HHS is considering options for removing barriers to the use of this blood for transfusion, it is unclear how much a change in policies on blood from hemochromatosis patients would impact the blood supply. Most centers unknowingly use hemochromatosis blood because they do not know at the time it is donated that it came from an individual with hemochromatosis. In most of these cases, even the individuals donating the blood are not

<sup>17</sup>S. M. McDonnell and others, "A Survey of Phlebotomy Among Persons With Hemochromatosis," *Transfusion*, Vol. 39 (1999), pp. 651-6.

<sup>18</sup>S. M. McDonnell and others, "A Survey of Phlebotomy Among Persons With Hemochromatosis."

<sup>19</sup>The processing of whole blood units into packed red cells removes most of the iron-enriched serum.

<sup>20</sup>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.

aware that they have hemochromatosis, but some individuals do donate even after diagnosis. 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 hemochromatosis, and blood banks cannot easily detect hemochromatosis blood because they test hemoglobin, not iron status of the donor. Therefore, the potential gain to be achieved by encouraging donations from individuals with hemochromatosis will be limited by the extent to which such individuals are already donating blood.

The American Red Cross estimates that some 4,000 phlebotomies were conducted for patients with hemochromatosis in the Red Cross system in 1998, and 5,000 such phlebotomies were conducted in 1999. America's Blood Centers does not have aggregate data across its member centers, but one of its centers performs about 600 therapeutic phlebotomies per year for individuals with hemochromatosis. However, America's Blood Centers does not know if all these individuals would be eligible to donate blood. Data from the American Red Cross and America's Blood Centers represent only a minority of therapeutic phlebotomies performed each year. One study showed that about two-thirds of the individuals diagnosed with hemochromatosis are phlebotomized in a hospital or in a physician's office; the remaining one-third are phlebotomized at a blood center.<sup>21</sup>

There have been attempts to estimate the number of units of blood that would be available if hemochromatosis blood were used for transfusion, but the range is wide—300,000 units to 3 million units. The upper value, 3 million units, is an overestimation. It is based on the estimated prevalence of individuals in the United States with the major mutation associated with hemochromatosis, and an estimate of the number of therapeutic phlebotomies these individuals may require annually (six units per patient per year), with the assumption that half of these patients would require phlebotomies. However, not all such persons will be eligible to donate and not all units will be suitable for transfusion. Some experts believe 300,000 units is more accurate, although this may be a conservative estimate, since the number includes only blood drawn during the maintenance phase of treatment. Additional blood from eligible individuals undergoing iron depletion therapy and from other hemochromatosis patients who require therapeutic phlebotomy may increase somewhat the potential supply of blood available for transfusion.<sup>22</sup>

In April 1999, members of the Advisory Committee on Blood Safety and Availability concluded that while blood products from individuals with hemochromatosis carry no known increased risk to recipients, financial incentives for blood donation must be removed before blood from these individuals can be added to the blood supply. Initially, HHS considered options for the Health Care Financing Administration (HCFA) to provide reimbursement for all therapeutic phlebotomies. However, HCFA determined that it did not have statutory authority to provide universal coverage. HCFA finances care for the Medicare population, has limited authority over Medicaid, and no regulation of the uninsured. Because most blood donors are under 65, they would not fall under Medicare. Thus, it seems unlikely that the issue of financial incentives for blood donation will be quickly addressed. The blood collection centers would have to cover the costs of therapeutic phlebotomies for all individuals with hemochromatosis if they want FDA to revise current regulations that affect the use of blood from these individuals. While blood centers may be able to recover these costs by selling blood from individuals with hemochromatosis, a question remains whether

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<sup>21</sup>S. M. McDonnell and others, "A Survey of Phlebotomy Among Persons With Hemochromatosis."

<sup>22</sup>Other hemochromatosis patients would include carriers.

they would cover all therapeutic phlebotomies regardless of the suitability of the blood for transfusion.

FDA has agreed to make the necessary regulatory changes to remove the barriers to donation once the financial incentives for hemochromatosis patients to avoid paying for therapeutic phlebotomies are removed.<sup>23</sup> 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 currently 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 the blood collection facilities to concurrently provide safety data, including viral marker rates, incidence of transmissible infections based on seroconversion rates, frequency of post-donation 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 exclusion of donors who have resided or traveled in the United Kingdom for a total of 6 months or more between 1980 and 1996. However, changes to current regulations affecting blood from hemochromatosis patients will occur considerably later than FDA's recent guidance to exclude donors, which has already gone into effect. The issue of coverage for therapeutic phlebotomies has yet to be resolved. HCFA has limited authority beyond Medicare, and anything less than full reimbursement may be considered undue donor incentive. Therefore, unless the blood establishments are willing to absorb the costs of providing phlebotomies to persons with hemochromatosis, it is unlikely that changes in regulations will occur.

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<sup>23</sup>The American Association of Blood Banks has also indicated that if FDA makes changes, 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.

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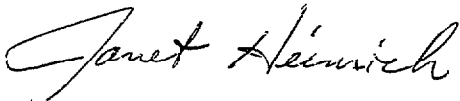
AGENCY COMMENTS

We received comments from HHS on a draft of this report. HHS generally concurred with our description of the issues and provided technical comments, which we have incorporated where appropriate. HHS also said that it would not be possible to fully describe the basis for its decision to recommend excluding blood donors who had resided in the United Kingdom in a report with this limited scope. We believe that the report fairly characterizes the major reasons for that decision.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Honorable Donna E. Shalala, Secretary of HHS, and other interested parties. We will make copies available to others upon request.

Major contributors to this report were Marcia Crosse, Martin T. Gahart, and Angela Choy. Please contact me at (202) 512-7119 if you have any questions.

Sincerely yours,



Janet Heinrich  
Associate Director, Health Financing  
and Public Health Issues

(101864)



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