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PROTECTING THE NATION'S BLOOD SUPPLY
FROM INFECTIOUS AGENTS: THE NEED
FOR NEW STANDARDS TO MEET NEW
THREATS

TENTH REPORT

BY THE

COMMITTEE ON GOVERNMENT
REFORM AND OVERSIGHT

together with

ADDITIONAL VIEWS



AUGUST 2, 1996.—Committed to the Committee of the Whole House on
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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
Washington, DC, August 2, 1996.

Hon. NEWT GINGRICH,
Speaker of the House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Government Reform and Oversight, I submit herewith the committee's tenth report to the 104th Congress.

WILLIAM F. CLINGER, Jr.,
Chairman.

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104TH CONGRESS }
2nd Session } HOUSE OF REPRESENTATIVES { REPORT
104-746

PROTECTING THE NATION'S BLOOD SUPPLY FROM INFECTIOUS AGENTS: THE NEED FOR NEW STANDARDS TO MEET NEW THREATS

AUGUST 2, 1996.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. CLINGER, from the Committee on Government Reform and Oversight, submitted the following

TENTH REPORT

together with

ADDITIONAL VIEWS

On July 25, 1996, the Committee on Government Reform and Oversight approved and adopted a report entitled "Protecting the Nation's Blood Supply From Infectious Agents: The Need For New Standards To Meet New Threats." The chairman was directed to transmit a copy to the Speaker of the House.

I. EXECUTIVE SUMMARY

In the early 1980's, 10,000 hemophiliacs and 12,000 other patients were infected with the human immunodeficiency virus (HIV) through blood and blood products. Approximately 300,000 people were infected with the Hepatitis C virus (HCV), many of whom have never been told of their exposure to infection.

The lessons of these tragedies compel greater vigilance and higher regulatory standards to protect the Nation's blood supply from emerging infectious agents and blood borne pathogens.

Threats to blood safety are both natural and man-made, as aggressive new infectious agents emerge and blood safety practices evolve. As a result, substantial improvements are needed in coordination between the Public Health Service (PHS) agencies within the Department of Health and Human Services (HHS), particularly

the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH).

At the first of two subcommittee hearings on blood safety issues, HHS Secretary Donna Shalala announced that the Department's focus on blood safety issues will be expanded and elevated, with the Assistant Secretary for Health charged to improve the coordination and effectiveness of blood safety policy.

Current FDA and CDC regulatory systems are not adequate to meet the aggressive nature of emerging threats to blood safety. Product recalls and notification regarding possible exposure to blood borne pathogens are not well communicated to physicians, pharmacists, patients or the public. Regulation of blood collection, testing and the production of blood-derived therapeutics is not well coordinated or consistently managed to minimize known risks.

The public is not well served if patients are permitted to believe there is no risk in blood transfusions or in the use of blood derived therapies. While such risks are extremely small, and the U.S. blood supply is safer than it has ever been, greater efforts should be made to convey known risks to consumers who may wish to minimize even those risks through the use of alternative procedures or therapies.

Findings in brief

1. The blood supply is safer than it has ever been.
2. The blood supply continues to face new infectious disease challenges.
3. In response to the recommendations of the Institute of Medicine (IOM), HHS has begun to implement higher regulatory standards to protect the Nation's blood supply from emerging infectious diseases and blood borne pathogens.
4. The public is provided insufficient information on the risks of blood and blood products.
5. The FDA has not effectively managed regulatory review of blood issues, particularly its advisory committee on blood safety issues, the Blood Products Advisory Committee (BPAC).
6. Despite a BPAC recommendation to the contrary, the FDA took the first step toward closing the "window period" of possible HIV transmission by licensing the p24 antigen test for screening of donated blood.
7. Fifteen years after the AIDS virus emerged as a threat to the blood supply, FDA still has not developed an effective system for communicating blood product recalls to pharmacists, doctors or patients.
8. The size of plasma pools for fractionated products can increase the risk of infectious disease transmission.

Recommendations in brief

1. Congress should establish the Blood Safety Council and the Advisory Committee on Blood Safety and Availability in statute.
2. Congress should consider establishing an indemnification system for individuals who suffer adverse consequences from the use of blood and blood products.

3. HHS should take steps to ensure that the estimated 300,000 living recipients of blood and blood products who were infected with Hepatitis C virus before 1990 are notified of their potential infection so that they might seek diagnosis and treatment.

4. HHS should disseminate more clinically useful information to providers of care and to the public regarding blood safety issues.

5. FDA should immediately develop an effective system of recall notification for blood and plasma products.

6. FDA should immediately cease its practice of providing advance notice of safety and compliance inspections to some plasma fractionators.

7. Plasma fractionators should limit the size of plasma pools, with pool sizes determined as much by public health risk factors as by production economies of scale.

II. BACKGROUND

Each year, approximately 4 million patients in the United States receive transfusions of whole blood and blood components derived from 20 million units of whole blood and blood components.¹ When receiving a transfusion, each of these patients forms a very personal bond of trust with one or more blood donors and with all those responsible for the collection, processing, storage, distribution and administration of these potentially lifesaving therapies.

The advent of the era of antibiotics promoted a complacent view among medical professionals and the Federal Government that new, fatal, untreatable, infectious diseases were afflictions of the past. Tragically, a new retrovirus, Human Immunodeficiency Virus (HIV) which produced Acquired Immune Deficiency Syndrome (AIDS), challenged that view when it infected the U.S. blood supply in the early 1980's.

CDC Director David Satcher testified at the November 2, 1995 subcommittee hearing that:

In the past few decades, many of the best scientific minds in the country expected infectious diseases to be eliminated as a public health problem in the United States. As recent events have shown, these pronouncements were premature. Infectious diseases remain the leading cause of death worldwide and among the most important causes of death in the United States.

In addition, we are faced increasingly with new and re-emerging infectious disease challenges. At home, we have seen the re-emergence of a public health scourge, tuberculosis; recent outbreaks of food and waterborne illnesses, such as those caused by E. Coli 0157.H7 and cryptosporidiosis; and the emergence of a new hanta virus. On a global front, the worldwide HIV/AIDS epidemic is now in its fifteenth year. We recently witnessed an epidemic of plague in India; diphtheria outbreaks in the New Independent States of the former Soviet Union; and the frightening re-emergence of the Ebola virus in Zaire.

¹*HIV and the Blood Supply: An Analysis of Crisis Decisionmaking*, Institute of Medicine, National Academy Press, 1995, p. 1 ("IOM Report").

To meet the challenges posed by infectious diseases and to reduce their potential threat to safety of the blood supply, a strong public health capacity is needed at both the Federal and State levels. At the Federal level, CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) provide our first line of defense in ensuring that the Nation's blood supply and products made from blood are free of infectious agents.

The U.S. blood supply is currently safer than it has ever been but the HIV experience in the early 1980's and the more recent experience with Hepatitis C virus (HCV) transmission from intravenous immunoglobulin illustrate the need for continued vigilance regarding unrecognized, uncharacterized, and new threats to the blood supply.²

Threats to blood safety are first detected in those who regularly rely on blood derived therapies. They serve as a "human shield" or early warning system for the presence of infectious agents in the blood supply. For example, persons with severe hemophilia are exposed to more blood products from more blood donors than any other patient group.³ Hemophiliacs⁴ are dependent on clotting factor concentrates, concentrated amounts of the deficient clotting proteins, made from the pooled plasma of up to 20,000 individuals.⁵ If there is an infectious agent in the blood supply, it will be seen in the hemophiliac population first.

Hemophilia is a lifelong, hereditary blood clotting disorder which primarily, but not exclusively, affects males. In addition, there are an additional 25,200 men and women in the United States who rely heavily on multiple infusions of blood and plasma protein products, according to estimates provided by the NIH Office of Rare Diseases and the National Heart, Lung, and Blood Institute.⁶

In the early 1980's, 10,000 people with hemophilia, fully 50% of all U.S. hemophiliacs at the time, as well as 12,000⁷ other transfusion recipients, were infected with HIV through blood products prior to 1985, when a screening test was implemented that could detect HIV antibodies in donated blood. Many also unknowingly infected their spouses and children before learning of their own infections.

CDC estimates that 290,000 (approximately 7%) of the 3.9 million Americans chronically infected with HCV acquired their infection from transfusion.⁸ Most of these individuals received transfusions prior to the availability of a screening test in 1990.⁹ The Institute of Medicine report described HCV infection as "often silent, is one of the major causes of cirrhosis, hepatocellular car-

²*Protecting the Nation's Blood Supply from Infectious Agents: New Standards to Meet New Threats*, 104th Cong., 1st Sess., p. 105 (1995) ("HRIR hearings") (statement of Dr. David Satcher).

³July 16, 1996 letter from Stephen Bajardi, executive director, National Hemophilia Foundation to HRIR Subcommittee staff (in subcommittee files).

⁴Individuals with a hereditary deficiency of coagulation Factors VIII or IX. Dorland's Medical Dictionary, 28th edition, 1994.

⁵IOM Report, p. 1.

⁶NIH correspondence with the HRIR Subcommittee, July 16, 1996 (in subcommittee files).

⁷IOM Report, p. 1.

⁸CDC correspondence with HRIR Subcommittee, July 18, 1996 (in subcommittee files).

⁹Testimony of Assistant Secretary Philip Lee, HRIR hearings, p. 29.

cinoma, or both, in the United States, and is a common precipitant of liver failure necessitating liver transplantation.”¹⁰

In 1992, Representative Porter Goss (R-FL), Senator Edward Kennedy (D-MA), and Senator Bob Graham (D-FL) asked HHS Secretary Donna Shalala to investigate the role of the Government in the transmission of HIV to hemophiliacs. HHS in turn commissioned the National Academy of Sciences’ Institute of Medicine (IOM) to review the situation and make prospective recommendations to assure greater safety in the blood supply from emerging and re-emerging infectious agents. The resulting report “HIV and the Blood Supply: An Analysis of Crisis Decisionmaking” was released on July 13, 1995.

The IOM concluded that HHS failed to recognize that the blood supply was not immune to a new infectious agent, HIV, about which there was substantial scientific uncertainty. Furthermore, a lack of leadership on the part of the FDA, CDC, NIH and the blood collection and plasma fractionation industries resulted in a pattern of decisionmaking characterized by adoption of the most limited public health responses. These inadequate responses did not contain the spread of HIV through the blood supply and opportunities to prevent primary and secondary infections were missed, with particularly tragic consequences for the bleeding disorders community.¹¹

Other factors were also at work that resulted in the infection of large numbers of blood and blood product recipients. “Many of our blood banking centers were created over 40 years ago as small community volunteer programs and were ill-equipped to respond to the HIV threat. Industry on the other hand, failed to respond for other reasons, notably a lack of medically knowledgeable management and emphasis on profit with a need to maintain productivity in a competitive market.”¹²

THE ROLE OF THE FOOD AND DRUG ADMINISTRATION (FDA)

The Food and Drug Administration derives its authority to regulate biologic drugs, “any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of diseases or injuries of man . . .” from the 1902 Virus Act. It is the oldest law currently administered by FDA (P.L. No. 57-244, 32 Stat. 328 (1902); 42 U.S.C. 262 (1982)), predating the Federal Food, Drug and Cosmetic Act of 1906.

FDA helps ensure the safety of the Nation’s blood supply by minimizing the risk of infectious disease transmission and other hazards while maintaining an adequate supply. FDA oversees all phases of blood preparation and manufacture from donor screening and selection and testing to product collection, processing, labeling, and storage. FDA’s Center for Biologics Evaluation and Research (CBER) licenses blood establishments that ship blood products in interstate commerce and inspects these establishments and more than 2,500 registered intrastate blood establishments.

¹⁰ IOM Report, p. 86.

¹¹ IOM Report, p. 208-209.

¹² Testimony of Dr. John Penner, p. 48.

THE ROLE OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION
(CDC)

The Centers for Disease Control and Prevention (CDC) is the Federal agency responsible for disease and injury prevention. CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. The agency's name was expanded to include "prevention" through "The Preventative Health Amendments of 1992."¹³ CDC articulates its vision for the 21st century as "Healthy People in a Healthy World Through Prevention."¹⁴

CDC evaluates public health problems by applying a four step scientific analysis: define the problem, identify risk factors, develop and test prevention strategies, and implement nationwide prevention programs. CDC conducts its programs in collaboration with State and local health departments, national and community-based organizations, academia, business, and labor.

The CDC uses its nationwide surveillance system of State public health officers to identify and monitor blood-borne diseases. CDC believes that its epidemiological investigations alerted the Federal Government to the presence of HIV in the blood supply, even though a screening test did not become available until 1985. Dr. Satcher testified that CDC estimates "over 700,000 lives were saved because of the epidemiological investigations that were able to show that there was something being transmitted through the blood supply and other means."¹⁵

The CDC also conducts a Hemophilia Monitoring Project which monitors infectious agents in the hemophilia population. The CDC maintains an internal working group on blood safety, which coordinates blood safety issues and evaluates any new or potential threats to the blood supply through the National Center for Infectious Diseases (NCID). NCID's mission is to "prevent illness, disability, and death caused by infectious diseases in the United States and around the world." It is noteworthy that there is no specific mention of blood in the NCID list of priorities.¹⁶

The CDC's Blood Donor Study,¹⁷ in conjunction with the Red Cross, selected blood banks, and selected local public health departments around the country, has been interviewing HIV-positive donors at 20 regional centers since 1988 to evaluate their risk factors for HIV-1, in order to determine their motivations for donating. This will allow investigators to estimate the length of time between infection and detection of antibodies in individuals who subsequently convert to HIV positive status, as well as the current risk of HIV transmission from blood transfusions.

Each month, CDC publishes the HIV/AIDS Surveillance Report, which contains the cumulative number of AIDS cases reported to

¹³ P.L. 102-531.

¹⁴ *CDC Priorities Paper*, April 1995.

¹⁵ *Protecting the Nation's Blood Supply from Infectious Agents: New Standards to Meet New Threats*, 104th Cong., 1st Sess., testimony of CDC Director David Satcher, HRIR hearings, p. 105; and *For a Healthy Nation: Returns on Investment in Public Health*, Centers for Disease Control and Prevention, p. 29-30.

¹⁶ *Major NCID Prevention Activities*, FY 1995, National Center for Infectious Diseases, Centers for Disease Control and Prevention.

¹⁷ Official title "An evaluation of the behavioral, donation history and laboratory characteristics of US blood donors infected with human immunodeficiency virus (HIV)." CDC communication with HRIR Subcommittee, July 17, 1996 (in subcommittee files).

CDC, as well as new cases. The data are broken down into various exposure categories, including transfusion recipients of HIV-infected blood.

THE ROLE OF THE NATIONAL INSTITUTES OF HEALTH (NIH)

NIH is the primary agency of the Federal Government charged with the conduct and support of biomedical and behavioral research. It also has major roles in research training, health information dissemination, and health services research. The National Heart, Lung, and Blood Institute (NHLBI), one of the NIH Institutes, is the principal Federal funding agency for research on blood.

NHLBI sponsors REDS (Retrovirus Epidemiology Donor Study), an extensive project to determine the current and ongoing prevalence of human retroviruses, as well as Hepatitis C and other emerging viruses and infectious agents in blood donors. REDS also was designed to determine outcomes of specific non-HIV infections in affected donors and recipients.

Because REDS can study repeat blood donors, it can determine the retroviral infection rate. So far, REDS investigators have found a greater incidence of non-HIV retroviral infection in blood donors than they had expected. The researchers are also examining why individuals who know they have risk factors for retroviral infection continue to donate blood.

A major advantage of the study is its large repository of samples collected from blood donors. As new tests for blood-borne infections are developed, it will be possible to screen the stored samples to provide better information on currently known retroviruses and on other uncharacterized infectious agents. However, the Office of AIDS Research recently recommended¹⁸ that AIDS funds should be redirected from supporting research related to the safety of the blood supply after REDS funding expires in August 1998.¹⁹

NIH also conducts ongoing research to improve blood banking operations and blood safety, such as development of methods to destroy infectious agents in blood components and development of physician guidelines for the appropriate use of blood products. In FY 95, NHLBI awarded \$182,892,000 in extramural grants through the Blood Diseases and Resources program on basic and applied research into diseases which require treatment with blood products.

In 1987, the NHLBI launched a broad education effort by establishing the National Blood Resources Education Program (NBREP), which was tasked with dissemination of information about the blood supply to more than 30 national organizations with interests in blood donation, transfusion, and public education. NBREP had two goals: to ensure an adequate supply of safe blood to meet the Nation's needs, and to ensure that blood components are transfused only when therapeutically appropriate. This program was phased out in FY 1994 because NHLBI officials felt that many of

¹⁸ *Report of the NIH AIDS Research Program Evaluation Working Group of the Office of AIDS Research Advisory Council*, March 13, 1996.

¹⁹ April 30, 1996 NHLBI correspondence with subcommittee staff (in subcommittee files); and *Report of the NIH AIDS Research Program Evaluation, Natural History, Epidemiology, and Prevention Research Area Review Panel Findings and Recommendations of the Office of AIDS Research Advisory Council*, June 7, 1996.

the educational materials being developed duplicated materials developed by the blood banking community.²⁰

THE HRIR SUBCOMMITTEE INVESTIGATION

The Committee on Government Reform and Oversight's Subcommittee on Human Resources and Intergovernmental Relations (HRIR) initiated an investigation into the safety of the blood supply in April 1995. The subcommittee sought assurance that the U.S. Department of Health and Human Services' Public Health Service (PHS) agencies, particularly the Food and Drug Administration, are aggressively maintaining safeguards to detect emerging infectious agents and eliminate blood-borne pathogens from the Nation's blood supply.

Hearings were held on October 12, 1995 and November 2, 1995. HHS Secretary Donna E. Shalala announced HHS' response to the IOM report recommendations at the October 12th hearing. The perspectives of consumers, clinicians, and the blood collection and plasma fractionation industries on blood safety were also heard in testimony at these hearings.

In addition, FDA supplied approximately 44,000 pages of documents requested by the subcommittee on the following dates: June 6, 1995; July 5, 1995; July 20, 1995; July 21, 1995; August 30, 1995; September 12, 1995; September 21, 1995; October 5, 1995; October 6, 1995; December 8, 1995; March 25, 1996; April 5, 1996; May 6, 1996; May 24, 1996; June 3, 1996; June 5, 1996; and June 6, 1996.

Interviews and/or conference calls were conducted with FDA personnel on the following dates: August 8, 1995; September 8, 1995; November 7, 1995; November 30, 1995; March 6, 1996; March 26, 1996; April 4, 1996; April 8, 1996; April 9, 1996; April 18, 1996; April 29, 1996 (two meetings); May 10, 1996; May 16, 1996; May 24, 1996; and July 17, 1996 (two conference calls).

NIH supplied requested documents to the subcommittee on the following dates: September 28, 1995; October 3, 1995; October 31, 1995; January 22, 1996; and April 30, 1996.

Interviews and/or conference calls were conducted with NIH personnel on the following dates: October 2, 1995; October 6, 1995; and July 17, 1996.

CDC supplied documents to the subcommittee on December 27, 1995.

Interviews and/or conference calls were conducted with CDC personnel on the following dates: September 20, 1995; October 31, 1995; and February 13, 1996.

HHS Office of the Inspector General (OIG) supplied documents to the subcommittee on April 18, 1996; April 24, 1996; and May 2, 1996. OIG staff briefed the subcommittee on April 30, 1996.

Interviews and/or conference calls were conducted with HHS personnel on the following dates: September 18, 1995; September 26, 1995; and December 8, 1995.

An interview was conducted with Health Resources and Services Administration (HRSA) personnel on October 5, 1995.

²⁰ HRIR Subcommittee staff conference call with Sandra Lindsay, NHLBI Office of Legislative Affairs, July 16, 1996 (notes in subcommittee files).

Interviews and/or conference calls were conducted with American Association of Blood Banks (AABB) personnel on the following dates: June 27, 1995; July 27, 1995; October 30, 1995; and April 25, 1996.

Interviews and/or conference calls were conducted with American Red Cross (ARC) personnel on the following dates: June 28, 1995; October 31, 1995; February 9, 1996; February 14, 1996; March 1, 1996; and April 3, 1996.

Interviews and/or conference calls were conducted with American Blood Resources Association (ABRA) and/or ABRA member companies on the following dates: August 3, 1995; August 24, 1995; September 20, 1995; September 21, 1995; October 3, 1995; October 13, 1995; October 19, 1995; October 24, 1995; October 25, 1995; October 26, 1995 (ABRA); October 26, 1995 (ABRA member company); October 27, 1995; October 30, 1995 (ABRA member company); October 30, 1995 (ABRA member company); October 30, 1995 (ABRA member company); March 20, 1996; April 23, 1996; and May 8, 1996.

An interview was conducted with International Plasma Products Industry Association (IPPIA) personnel on May 6, 1996.

Interviews and/or conference calls were conducted with National Hemophilia Foundation (NHF) personnel on the following dates: September 6, 1995; October 24, 1995; December 13, 1995; and March 20, 1996.

Interviews and/or conference calls were conducted with Council of Community Blood Centers (CCBC) personnel on the following dates: August 8, 1995; September 7, 1995; and October 30, 1995.

The subcommittee staff also participated in the September 22, 1995 Institute of Medicine Forum on Blood Safety and Availability and the ABRA Annual Plasma Forum on June 14, 1996.

The hearing records, documents and interviews of the subcommittee's investigation serve as the basis for the findings and recommendations of this oversight report.

III. FINDINGS

1. The blood supply is safer than it has ever been

The U.S. blood supply is currently safer than it has ever been, due largely to a blood safety system enforced by FDA which consists of five layers: donor screening, blood testing, donor deferral, inventory management to insure that products have been thoroughly tested and that donation records have been verified, and mandatory investigation and reporting by blood establishments to FDA of any accidents and errors relating to these safeguards. Blood establishments are also required to correct any system deficiencies that are found.²¹

Better screening tests for viruses, such as HIV and Hepatitis, and viral inactivation measures have increased the margins of safety for many blood products since the 1980's. However, after infection with HIV, there is a period of time known as a "window" in which infection may be present but antibodies to the virus have not been produced in sufficient quantity for detection. This window can

²¹Testimony of Dr. Kathryn Zoon, HRIR hearings, p. 88.

last up to 6 months in some individuals, but is usually about 20 days. Antigens²² appear and can be detected sooner, reducing the window by 10 days or more. Donated blood from persons infected with HIV, who do not yet exhibit antibodies to the virus, may be able to transmit the disease to others.

FDA believes, "Reducing the window period further reduces the chances that HIV-contaminated blood will enter the blood supply and infect recipients of transfused blood or other blood products."²³

FDA issued guidance to the blood industry on August 8, 1995 recommending testing of blood donors within 3 months after the licensure of the first HIV antigen test kit. FDA approved the first application for licensure of the antigen tests on March 14, 1996.

The use of viral inactivation measures in plasma products, such as the addition of solvent detergents and/or heat treatments,²⁴ appears to have eliminated the risk of HIV and some forms of Hepatitis from antihemophilic factor products.²⁵

2. *The blood supply continues to face new infectious disease challenges*

NIH held a consensus conference on infectious agents in the blood supply in January 1995. Several emerging threats to the blood supply were identified. The report of that conference also discusses the criteria to evaluate, detect and eliminate emerging blood-borne agents.²⁶

Creutzfeldt-Jacob Disease (CJD) is a spongiform encephalopathy²⁷ caused by a prion, a newly identified, infectious protein. It is noteworthy that prions are not bacteria, viruses, or parasitic agents. Prion diseases of humans may incubate for 30 years or more.²⁸ CJD can only be diagnosed with certainty on autopsy of the brain. There is concern that consumption of Bovine Spongiform Encephalopathy (BSE) or "Mad Cow Disease" infected beef could produce a variant form of CJD (vCJD) in humans.²⁹

There is a theoretical risk that CJD can be transmitted via transfusion of blood or blood products.³⁰ CJD has been transmitted through tissue transplants such as dura mater³¹ and corneas, by injections of human growth hormone pituitary extracts and during procedures with contaminated surgical instruments.³²

FDA stated in November 1994, "there has never been a reported case of transmission of CJD by blood or plasma products, and it is not known whether CJD can be transmitted by blood. However

²² Molecules that stimulate the production of antibodies. "IOM Report" definition, p. 305-6.

²³ FDA Talk Paper "FDA Takes Steps To Increase Safety of U.S. Blood Supply," August 10, 1995.

²⁴ IOM Report, p. 92.

²⁵ IOM Report, p. 78.

²⁶ NIH consensus statement *Infectious Disease Testing for Blood Transfusions*, January 9-11, 1995.

²⁷ A rare, untreatable and fatal neurological disease; S.B. Prusiner "The Prion Diseases," *Scientific American*, January 1995, p. 48; and statement of Dr. Ronald Gilcher, HRIR hearings, p. 56.

²⁸ *Ibid*, p. 51.

²⁹ *Ibid*, p. 48.

³⁰ FDA's *Summary of Meeting (via Conference Call) of Transmissible Spongiform Encephalopathies Advisory Committee*, July 2, 1996 (in subcommittee files).

³¹ "The outermost, toughest, and most fibrous of the three membranes (meninges) covering the brain and spinal cord, *Dorland's Medical Dictionary*, 28th edition, 1994.

³² See *supra* note 27, p. 49.

. . . it is prudent to withdraw the (blood of the infected donor and the plasma products made from it) at this time.”³³

FDA requires that if a blood or plasma donor meets any of the following qualifications, all in-date blood components and plasma derivatives should be withdrawn and quarantined and consignees³⁴ notified: a diagnosis of CJD is discovered via post-donation information; a donor has a family member with a diagnosis of CJD; a donor has received human pituitary-derived hormones, including growth hormone; or a donor has received a dura mater transplant.³⁵ If manufacturers determine that a plasma product is in short supply, they may release the quarantined product with appropriate CJD labeling.

In the past 7 years, more than 20 reported cases of CJD have been confirmed in blood donors in the United States, with some level of product recall.³⁶ The American Red Cross has overseen three major withdrawals since November 1994, that together involved more than 200 lots of blood. Each lot has the potential to transfuse or be manufactured into products for 1,000 to 10,000 patients. Bayer, Baxter/Highland, and Sandoz have also withdrawn plasma products and albumin due to CJD affected donors.³⁷

Also in June 1995, NIH, and the American Red Cross began a collaborative study to determine whether CJD could be transmitted by blood and blood products. Results will not be available until after February or March 1997.³⁸

In April 1995, the American Red Cross, in collaboration with the CDC and the New York Blood Center initiated a long-term investigational lookback study to evaluate the transmission of CJD through blood components. The ARC reports that “no cases of CJD have been identified among the recipients of blood from donors who subsequently developed CJD, but long-term surveillance of these recipients continues.”³⁹

Hepatitis C Virus (HCV)—an estimated 300,000 individuals⁴⁰ are still alive who acquired HCV infection through blood and blood products prior to 1990 because a screening test for donated blood was not available. Most of these individuals do not know of their infection. A screening test for HCV became available in 1990.

Treatment of HCV is usually with interferon⁴¹ and approximately 12–15% of individuals will clear the infection with the first treatment.⁴² There is some evidence that individuals with HCV who do not respond to the first treatment may be able to clear the infection with a second round of treatment, or with higher dosages of interferon or combinations of drugs. Many infected persons do

³³ FDA Talk Paper, “Voluntary Market Withdrawal of Blood Products,” Nov. 17, 1994.

³⁴ Consignees are hospitals, pharmacies, etc., which may have received the affected products, not the patient recipient.

³⁵ FDA *Summary of Meeting (via conference call) of Transmissible Spongiform Encephalopathies Advisory Committee*, July 2, 1996 (in subcommittee files).

³⁶ *Ibid*; and July 17, 1996 conference call with Dr. Joseph Fratantoni, FDA, and HRIR Subcommittee staff (notes in subcommittee files).

³⁷ American Red Cross Press Release “American Red Cross Announces Precautionary Voluntary Withdrawal of Plasma Derivative Products,” June 6, 1996.

³⁸ Conference call with Dr. Paul McCurdy, NHLBI, July 17, 1996 (notes in subcommittee files).

³⁹ See *supra* note 37.

⁴⁰ Testimony of Assistant Secretary Philip Lee, HRIR hearings, p. 29.

⁴¹ The only FDA approved drug to treat HCV.

⁴² HRIR Subcommittee conference call with Teresa L. Wright, M.D., Associate Professor of Medicine, University of California, San Francisco, July 17, 1996 (notes in subcommittee files).

not develop symptoms. Others, however, will develop severe cirrhosis of the liver, which will require a liver transplant or be fatal.

The February 1994 transmission of Hepatitis C virus to patients who received immune globulin intravenous (IGIV) products illustrates the need for continued vigilance regarding unrecognized, uncharacterized and new threats to the blood supply. These were the first reported cases of Hepatitis C infection from licensed IGIV products and prompted withdrawal of the products from the world market.⁴³

Hepatitis G Virus (HGV)—accounts for 0.3% of all acute viral hepatitis in the United States.⁴⁴ The virus is transmissible via blood transfusion and is present in the U.S. volunteer blood donor population.⁴⁵ “The association of the virus with chronic liver disease and its presence in patients with dual infections due to HBV or HCV is irrefutable,” reported Howard C. Thomas, M.D., of St. Mary’s Hospital in London.⁴⁶

Parvovirus B19—is a common virus that has been implicated in a wide variety of clinical conditions.⁴⁷ Immunosuppressed individuals cannot destroy the virus, which limits blood cell production leading to chronic anemia.

Parvovirus B19 “is being increasingly recognized as an important human pathogen, and has been established as the cause of ‘aplastic crisis’ in patients with sickle cell disease.”⁴⁸ Because many hemophiliacs are infected with HIV and therefore immunosuppressed, first-time exposure to Parvovirus via factor concentrate may present an additional health risk.

Chagas’ Disease—(also called American trypanosomiasis) is an infection caused by the parasite *Trypanosoma cruzi* and transmitted to humans primarily by the reduviid bug. It is a major cause of illness and death among poor people in developing countries and is endemic in almost all Latin American countries. In most cases, Chagas’ disease is a mild illness. In immunocompromised individuals, however, the disease can be severe or fatal.

If detected early enough, drug treatment can shorten the acute phase and decrease mortality, but it is only partially effective in curing the disease. Without treatment, infected individuals remain chronically infected for their lifetime.

Chagas’ has been transmitted through blood and blood products.⁴⁹ Since this disease is not endemic to the United States, affected individuals would be unlikely to receive an accurate and prompt diagnosis. There is growing concern that with increasing immigration to the United States from Latin American countries, transfusion could become the primary means of transmission in

⁴³Testimony of Dr. Satcher, HRIR hearings, p. 105; and FDA February 25, 1994 Talk Paper, *Immune Globulin Intravenous Removed From World Market*.

⁴⁴Testimony of Dr. Satcher, HRIR hearings, p. 106.

⁴⁵J. Linnen, et al. “Molecular Cloning and Disease Association of Hepatitis G Virus: A Transfusion-Transmissible Agent,” *Science*, 271, p. 505, 1996.

⁴⁶American Association of Blood Banks Newsletter, Nov. 1994.

⁴⁷A genus of viruses that infect mammals and birds. Human parvoviruses cause aplastic crisis in patients with hemolytic anemia or sickle cell disease, spontaneous abortion and fetal death. Persistent infection in immunocompromised patients can lead to chronic bone marrow failure. *Dorland’s Medical Dictionary*, 28th edition, 1994.

⁴⁸E.A. Lowenthal, A. Wills, P.D. Emanuel, R. Player and J.T. Prachal, Sickle Cell Acute Chest Syndrome Associated with Parvovirus B19 Infection: Case Series and Review, *American Journal of Hematology* 51, 207, 1996.

⁴⁹Testimony of Dr. Ronald Gilcher, HRIR hearings, p. 58.

this country. This concern is heightened by the fact that many infected individuals are asymptomatic, chronic carriers.

American Red Cross studies prove Chagas' disease is present in the Los Angeles/Orange Counties blood donor population. The ongoing study, which began in April 1994, has found that 1 in 10,000 donations overall in this region is confirmed positive for *Trypanosoma cruzi*,⁵⁰ although the rate of transmission is believed to be quite low.

Bacterial contamination—bacterial contamination of transfused blood products is a well-recognized source of sepsis, often due to improper preparation of the venipuncture site at the time of blood collection as well as improper screening of ill donors.

About 10%-15% of blood product recipients experience an adverse reaction and 1% experience a serious side effect. Approximately 30 people die each year in the United States as a direct result of blood product transfusion. This estimate may be conservative because transfusion reactions can mimic common post-surgical or intensive care problems. The delayed effects associated with the infectious process may be another reason for under-reporting of blood product transfusion reactions. One example is the transmission of *Yersinia Enterocolitica*, a gastrointestinal microbe from a blood donor which multiplies in stored blood.

According to testimony, Babesiosis,⁵¹ Cytomegalovirus⁵² and Epstein Barr virus⁵³ are also occasionally transmitted through transfusion.⁵⁴

Unfortunately, many infectious agents are transmitted by blood and may not be discovered until weeks, months or years after the transfusion.

The CDC's most significant concerns are with the challenges of new infectious agents of which we are now unaware, so that uncharacterized threats to the blood supply are detected as soon as possible.⁵⁵ The American Association of Blood Banks (AABB) is also convinced that it is critical to be vigilant with respect to unknown infectious agents in the blood supply.⁵⁶

Other infectious agents such as HIV-1 and II, and Hepatitis B and C, still continue to be transmitted through blood product transfusions, although at a very low rate. Hepatitis A virus outbreaks have recently been reported in clotting factor concentrates for the first time in the United States.⁵⁷ The presence of HIV O variant has been documented recently in the United States, and current screening tests for donated blood must be modified to detect it.⁵⁸

Assistant Secretary for Health Philip Lee testified that "the level of scientific uncertainty in the early and mid-1980's was very great.

⁵⁰Evaluation of Blood Donor Screening Strategies for *Trypanosoma Cruzi* in Los Angeles. E.J. Read, D.A. Leiby, A.A. Pan, R.J. Stumpf, R.Y. Dodd, paper presented at the November 9-15, 1995 AABB Convention, San Diego, CA.

⁵¹A tick born parasite, statement of Dr. Ronald Gilcher, HRIR hearings, p. 56.

⁵²A herpes virus, Dorland's Medical Dictionary, 28th edition, 1994.

⁵³"A virus of the genus *Lymphocryptovirus* that causes infectious mononucleosis. Also called human *herpesvirus 4*." Dorland's Medical Dictionary, 28th edition, 1994.

⁵⁴Statement of Dr. Ronald Gilcher, HRIR hearings, p. 56.

⁵⁵Testimony of Dr. David Satcher, HRIR hearings, p. 104.

⁵⁶Testimony of Karen Lipton, AABB, HRIR hearings, p. 150.

⁵⁷Morbidity and Mortality Weekly Report, Centers for Disease Control, January 19, 1996, Vol. 45, No. 2.

⁵⁸FDA Talk Paper, "First Group O HIV Infection Reported in the United States," July 5, 1996.

There was disagreement among the scientists and the physicians on a number of these issues. And that same problem we face today. I mean, the scientific uncertainty.”⁵⁹

3. *In response to the recommendations of the Institute of Medicine (IOM), HHS has begun to implement higher regulatory standards to protect the Nation’s blood supply from emerging infectious diseases and blood borne pathogens*

The IOM presented its report to HHS on July 13, 1995. HHS Secretary Donna E. Shalala created a task force of Public Health Service agencies to evaluate the recommendations and develop an implementation plan.

At the subcommittee’s October 12, 1995 hearing, Secretary Shalala announced that HHS accepted all of the recommendations put forth by IOM,⁶⁰ except the recommendation to create a prospective compensation program for individuals harmed by blood and blood products,⁶¹ similar to the National Vaccine Injury Compensation Program.

HHS will create a Blood Safety Committee consisting of the CDC Director, NIH Director and the FDA Commissioner. The committee will be chaired by the Assistant Secretary for Health. The committee will be advised by the Advisory Council on Blood Safety and Availability, which will include representatives of industry, consumers, scientific experts, and ethicists.

The Secretary views the Advisory Council as “a forum in which to examine broad public health and societal implications of blood safety issues. These include availability, informed consent, social choice, the allocation of research resources, and the impact of economic factors on availability.”⁶²

According to HHS, the Blood Safety Committee will provide a high level forum for decisionmaking, priority setting, and inter-agency coordination on an ongoing basis, as well as facilitating rapid and effective responses to new developments. It will be convened to bring broad-based input from the consumer sector, medical care providers, legal and ethical experts, and blood products service organizations and related industries to consider broader societal concerns around blood safety that cannot be resolved through the evaluation of scientific data alone.⁶³

The FDA’s Blood Products Advisory Committee (BPAC) will provide expert scientific advice to the FDA on regulatory matters relating to the blood supply and human tissues for transplantation, which are areas under FDA’s regulatory authority.⁶⁴ BPAC input will be sought when there is controversy over the applicable scientific standard, interpretation of clinical trial data, or when outside expertise is needed on manufacturing and supply issues in

⁵⁹ Testimony of Dr. Philip Lee, HRIR hearings, p. 23.

⁶⁰ IOM Report, p. 13.; and statement of Secretary Shalala, HRIR hearings, p. 17–18.

⁶¹ Representative Porter Goss (R–FL) introduced a retrospective compensation bill in the 104th Congress, H.R. 1023 “The Ricky Ray Hemophilia Relief Fund Act” to compensate hemophiliacs who acquired AIDS through blood and blood products prior to 1987. The bill would authorize a \$1 billion trust fund to provide payments of \$125,000 to HIV-infected hemophiliacs, their survivors, and infected family members.

⁶² Testimony of Secretary Shalala, HRIR hearings, p. 10.

⁶³ Minutes of the Blood Safety Committee, January 17, 1996, U.S. Department of Health and Human Services, p. 3.

⁶⁴ *Ibid.*

order to support FDA regulatory decisions. The BPAC also provides FDA with public input on regulatory policy development in these areas.⁶⁵

Following the Secretary's October 12, 1995 announcement of the creation of the Blood Safety Committee at the hearing, the committee met on December 11, 1995, January 17, 1996, April 24, 1996 and June 11, 1996. Agenda issues have not been released and no appointments have yet been announced to the Advisory Council on Blood Safety and Availability.

From the documents provided by HHS to the HRIR Subcommittee, the PHS agencies appear to use the committee for exchange of information on blood safety issues on a bimonthly basis. The meeting is chaired by Assistant Secretary for Health Dr. Philip Lee and is attended by agency heads and their deputies as voting members. Additional PHS staff are included as required.⁶⁶

The Advisory Council is scheduled to meet two times each year and have 18 voting members, as well as non-voting ex officio representatives of the PHS agencies.⁶⁷

4. The public is provided insufficient information on the risks of blood and blood products

Federal, State and local public health officials, as well as physicians and other health care providers, must evaluate the inevitable risks in the use of blood and blood-derived therapies. Those risks, however small, must then be communicated to patients in time, and in a form, to be useful in their consideration of alternative, less risky, treatment options.

Dr. John A. Penner, a professor of medicine and pathology at Michigan State University, testified that the "public has long enjoyed the sense that blood provided through the best of intentions by volunteers, their neighbors in the communities, is not only life-saving but essentially risk-free. . . . Although the public and health care workers have been disillusioned by events over the past 15 years, they still unrealistically expect and demand complete, safe, and risk-free blood and blood products."⁶⁸

He believes that physicians have also left the burden of knowledgeable use of blood products to others and have avoided careful evaluation of these products.⁶⁹ Dr. Penner feels that transfusion education is critically needed by most physicians. He conducted a study, funded by NIH, which attempted to alter physician practices in relation to the use of blood products. While physicians decreased the number of blood products transfused, they failed to improve "the appropriateness of their ordering practices and often administered concentrates unnecessarily when platelet levels were decreased, but not to a degree that would require support" with blood products.⁷⁰ He concluded that "a strong educational program with

⁶⁵ Minutes of the Blood Safety Committee meeting, U.S. Department of Health and Human Services, January 17, 1996.

⁶⁶ Ibid.

⁶⁷ Ibid.

⁶⁸ Testimony of Dr. John Penner, HRIR hearings, p. 48.

⁶⁹ Ibid.

⁷⁰ J.A. Penner, R.G. Brigham, Intervention/Education to Improve Hemostatic Product Use, Final Progress Report for National Heart, Lung & Blood Institute, Grant #HL33922-05, submitted 2/92.

frequent reinforcement will be needed before any significant reduction in inappropriate use can be obtained.”⁷¹

According to testimony, the degree to which a patient is informed of the risks associated with blood products also varies from geographic location and from physician to physician.⁷² For three decades, the risk of contracting Hepatitis was considered a medically acceptable risk with regard to use of blood and blood products.⁷³ If Hepatitis had not been tolerated as a medically acceptable risk, available technologies to kill Hepatitis virus could have also killed the unknown HIV present in the blood supply, greatly reducing the exposure of blood product users to HIV.⁷⁴

Patients have a number of autologous (self-donation) options to reduce use of donated and pooled blood products. These options include: preoperative donation of blood products, intraoperative salvage of red blood cells, postoperative salvage of blood from surgical wound drainage.⁷⁵ It appears that, little, if any information, is routinely provided to patients regarding these options.

5. The FDA has not effectively managed regulatory review of blood issues, particularly its advisory committee on blood safety issues, the Blood Products Advisory Committee (BPAC)

A test for HCV became available for screening blood donors in 1990. At that time, an estimated 300,000 persons were still alive who had been infected through blood products and were unaware of their infection. Treatment options were available. The FDA's BPAC considered whether patients who received the HCV infected units should be notified of their exposure on all of the following dates: Oct. 31, 1989; Jan. 17–18, 1991; Sept. 26–27, 1991; March 12–13, 1992; March 25–26, 1993; Dec. 2–3, 1993; and Dec. 15–16, 1994.⁷⁶ However, the BPAC has not taken action on this issue.

Nevertheless, Subcommittee Chairman Shays received a commitment from Secretary Shalala and Assistant Secretary for Health Philip Lee at the October 12th hearing that HCV notification would be the first issue considered by the new Advisory Council on Blood Safety and Availability.⁷⁷

In another area, the BPAC again failed to reach a final decision on an important public health issue. In March 1994, the National Hemophilia Foundation (NHF) recommended to BPAC that manufacturers of plasma products update their product package inserts to include the risks of Parvovirus B19 and Hepatitis A attendant to use of these products. The issue was again considered in March 1996 but no decision was ever made. The National Hemophilia Foundation believes that specific warnings of possible infectious disease transmission via clotting factor concentrates, although needed to ensure informed treatment decisions, are not on the package insert because the BPAC has been unable to make a decision on the matter.⁷⁸

⁷¹Testimony of John Penner, M.D., HRIR hearings, p. 52.

⁷²Patricia De Filippi, HRIR hearings, p. 65.

⁷³Statement of Corey Dubin, HRIR hearings, p. 40.

⁷⁴Ibid, p. 44; and IOM Report, p. 93–94.

⁷⁵Statement of Ronald Gilcher, M.D., HRIR hearings, p. 59.

⁷⁶BPAC minutes (in subcommittee files).

⁷⁷Testimony of Dr. Lee, HRIR hearings, p. 29–30.

⁷⁸National Hemophilia Foundation's June 6, 1996 correspondence with HRIR Subcommittee (in subcommittee files).

According to testimony, FDA is also not working effectively with manufacturers to expedite the development of new screening tests and viral inactivation techniques for blood product sterilization.⁷⁹ One manufacturer submitted a 510(k)⁸⁰ application for a Chagas' disease screening test as a medical device to FDA's Center for Devices and Radiological Health (CDRH), at the suggestion of FDA in November 1995. The company had already received approval of a 510(k) for diagnostic testing in 1994. In November 1995, FDA informed the company that the screening indication required filing a Product Licensing Application (PLA) with the Center for Biologics Evaluation and Research (CBER). As a result of this confused regulatory system, to date there is still no approved Chagas disease screening test for donated blood and plasma.

Questions have also been raised by consumer groups about the agency's selection of agenda items for BPAC meetings, drafting of questions which must be voted upon after BPAC deliberation, the comprehensiveness and impartiality of the background information FDA sends to committee members, and the criteria used to select BPAC members.⁸¹

According to NHF, the FDA's policies and procedures for BPAC structure, organization, and the methods used for making decisions regarding its membership are tightly controlled by agency officials.⁸² After the reorganization of the BPAC in the Fall of 1995, the HRIR Subcommittee discovered that only one of the current BPAC members was nominated by individuals or organizations outside FDA. In fact, FDA officials chose at least one individual now serving on the BPAC who was not nominated to represent an organization over other equally qualified individuals who had been nominated by that very organization.⁸³

There are a number of critical sectors, such as consumers who are heavy users of blood products and their treating physicians, which believe they have not had and still do not have input into blood policy decisions at the Federal level.⁸⁴ The National Hemophilia Foundation feels that FDA has not been open to consumer participation in blood safety policy areas.⁸⁵ One hemophiliac consumer, who is also a physician, was added to the BPAC in 1994. A second consumer was added to the committee in 1995. In 1996, there are only two voting consumers and one non-voting consumer on the BPAC, which has 17 members.

⁷⁹ Statement of Patricia De Filippi, National Hemophilia Foundation, p. 40.

⁸⁰ Section 510 of the Federal Food, Drug, and Cosmetic Act requires the filing of a premarket notification by a manufacturer prior to initial marketing of a device or prior to marketing a device with a new intended use, or a modified device (42 Fed. Reg. 42,520, 42,528 (1977); 21 C.F.R. 807.81).

⁸¹ Response of the National Hemophilia Foundation to the Task Force on Blood Safety Report, HRIR hearings, p. 80; and July 2, 1996 letter of complaint about BPAC from Keith Waterbrook, director of Health Services, Jeffrey Goodman Special Care Clinic, Los Angeles, CA to Subcommittee Chairman Christopher Shays (in subcommittee files).

⁸² Response of the National Hemophilia Foundation to the Task Force on Blood Safety Report, HRIR hearings, p. 80.

⁸³ BPAC nomination documents delivered to HRIR Subcommittee on Feb. 20, 1996 in response to Feb. 1, 1996 HRIR Subcommittee document request (in subcommittee files).

⁸⁴ Statement of Dr. John Penner, HRIR hearings, p. 52.; statement of Patricia De Filippi, HRIR hearings, p. 40; statement of Corey Dubin, HRIR hearings, p. 46; and statement of Dr. Ronald Gilcher, HRIR hearings, p. 58.

⁸⁵ Response for the record of the National Hemophilia Foundation to the Task Force on Blood Safety Report, HRIR hearings, p. 77.

Representative Porter Goss (R-FL) has introduced a bill H.R. 1021, "The Blood Products Advisory Committee Act of 1995" to require at least one-third of BPAC voting members to be consumers. He believes this bill will "rearrange what was clearly a conflict of interest, a too-close-for-comfort situation, between people who were making the decisions about protecting the blood supply and the people who were producing the products that were being used."⁸⁶

In addition, testimony indicates that the failure by FDA to appoint treating physicians to the BPAC results in the absence of a critical perspective of medical professionals treating heavy consumers of blood products. As a result, treating physicians have not been able to educate their patients and the public about the risks and benefits of blood products.⁸⁷

On three occasions recently, FDA acknowledged problems in the operation of the BPAC.

The FDA went around the BPAC and sought regulatory advice from an ad hoc committee on CJD in 1995.

FDA's BPAC first met to discuss the potential risk of CJD transmission through blood in December 1994, voting 14 to 1 in favor of withdrawing blood components collected from donors who subsequently developed CJD. But calling the CJD risk theoretical and expressing concern about possibly creating shortages of plasma products, the committee voted against the recall of plasma derivatives despite impassioned pleas from hemophiliac representatives. BPAC voted 9 to 4 in favor of indefinite lookback⁸⁸ and informing recipients of blood components from blood donors who subsequently developed CJD. However, the committee voted 10 to 4 against such notification of plasma derivative recipients.

On June 22, 1995 FDA convened the ad hoc Special Advisory Panel on CJD. The panel endorsed the recommendations made at BPAC's December 1994 meeting to recall blood components made from blood donors who developed CJD and to notify recipients. However, the panel also recommended withdrawal of plasma derivatives from plasma donors who subsequently developed CJD and notification of recipients of these products.

In August 1995 FDA Commissioner Kessler asked 11 of the 13 members of the BPAC to resign due to perceived potential conflicts of interest involving their employment in regulated establishments such as hospital blood banks and regional blood centers. The Commissioner's action followed much criticized BPAC decisions on CJD and p24 antigen testing.⁸⁹

In addition, the subcommittee has learned that the FDA does not manage its inspection responsibilities for the blood industry in the same manner as the agency approaches other regulated industries. The agency requests production schedules from some plasma fractionation companies prior to scheduling annual or biennial domestic biologic establishment inspections. The request for production schedules would serve to notify a firm of an impending inspection.

⁸⁶Testimony of Representative Porter Goss, HRIR hearings, p. 31.

⁸⁷Statement of John Penner, M.D., HRIR hearings, p. 52.

⁸⁸Locating the recipients of infected blood after they have been transfused.

⁸⁹See recommendation 6.

Except in exceptional circumstances, FDA operates on a system of unannounced inspections of all other regulated industries.⁹⁰

In FY 95, FDA's CBER personnel performed 47 inspections. Production schedules were requested from one manufacturer for a period of less than 3 months; from nine manufacturers for a period of 3 to 6 months; from two manufacturers for a period of 1 year and four manufacturers were asked for production schedules of unknown duration. In FY 95, CBER performed a total of six annual/biennial inspections of domestic plasma derivative manufacturers and requested production schedules for 3 to 6 months for two inspections.⁹¹ Furthermore, FDA does not maintain records of these requests for production schedules and was unable to provide a complete assessment of this practice to the subcommittee staff.

6. *Despite a BPAC recommendation to the contrary, the FDA took the first step toward closing the "window period" of possible HIV transmission by licensing the p24 antigen test for screening of donated blood*

After infection with HIV, there is a period of time known as a "window" in which infection may be present but antibodies to the virus have not yet been produced in sufficient quantity to be detected by blood screening tests. This window can last up to 6 months in some individuals, but is usually about 20 days. Antigens appear and can be detected sooner than antibodies, reducing the window by 10 days or more.

Reduction of the window period by 10 days is estimated to result in detection of up to 20 infected (antigen positive/antibody negative) donation cases per year which would be missed using only the antibody tests. Since each donation collected undergoes separation into at least two units, antigen testing could prevent up to 40 individuals from exposure to HIV-tainted blood products each year. That in turn could prevent transmission via sexual contact or other high-risk behavior to an additional estimated 1.7 individuals per infected recipient. As a result, at least 68 individuals per year could be protected from HIV infection through licensing of antigen tests as a screening tool.

On June 23, 1995, the FDA's Blood Products Advisory Committee (BPAC) recommended against routine HIV-1 antigen screening of blood donor units. At the October 12th hearing, Corey Dubin, a voting member of BPAC at the time, described the BPAC deliberation process on antigen testing as a "discussion centered on whether this was the best expenditure of the shrinking monies for AIDS. The BPAC, dominated by blood bankers, was clearly in violation of its mandate regarding the safety of the blood supply. I do not believe that it is the job of the FDA and its BPAC to be considering how AIDS dollars are spent and then basing what should be a purely safety driven decision on that economic analysis."⁹²

On July 12, 1995 Subcommittee Chairman Shays wrote to FDA Commissioner David A. Kessler urging him not to accept the

⁹⁰ FDA briefing with HRIR Subcommittee staff, May 24, 1996 (notes in subcommittee files). See also FDA Field Management Directive, 3/4/88.

⁹¹ June 3, 1996 FDA document delivery to HRIR Subcommittee (in subcommittee files).

⁹² Statement of Corey Dubin, HRIR hearings, p. 45.

BPAC's decision but to approve the immediate licensing of HIV-1 antigen tests for the screening of the Nation's blood supply.

Shays pointed out that antigen testing would further close the window of potential infection in recipients of blood and blood products, a goal which was consistent with remarks made by Commissioner Kessler at a September 26, 1994 NIH conference. Dr. Kessler said he believed that as a public health agency the FDA has "an obligation to foster the development of new technologies, especially if these technologies hold the promise of a blood supply that is even safer. This is especially true for detecting HIV—the AIDS virus. We need to close the window."⁹³

Subcommittee Chairman Shays was also concerned that failure to license antigen testing for donor screening would make it unlikely that any company would pursue RNA technology which could close the window completely within 5 years. On August 8, 1995 Dr. Kessler announced FDA guidance to industry recommending use of the new p24 antigen screening kits within 90 days of the first kit's licensure by FDA.⁹⁴

Also in August 1995, FDA requested the resignations of most of the BPAC members who were affiliated with regulated entities such as hospital blood banks. FDA did not however, increase the voting role of consumers most affected by blood safety decisions.

The Product Licensing Applications (PLAs) for the short duration p24 HIV-1 antigen tests were filed in 1990 but not approved until 1996.

7. Fifteen years after the AIDS virus emerged as a threat to the blood supply, FDA still has not developed an effective system for communicating blood product recalls or viral outbreaks to pharmacists, doctors or patients

FDA has the authority to request a manufacturer to recall a product if it poses a risk to public health.⁹⁵ Failure by a manufacturer to voluntarily recall a product when requested to do so by FDA can result in the seizure of the violative product and or suspension of the manufacturer's license. That in turn could shut down the manufacturer's operations and destroy public confidence in the product, damaging the market for the product.

FDA regulations require that manufacturers of recalled products notify each of the firm's "directed accounts" about the recall. The regulation doesn't define "accounts" and states that "where appropriate . . . the direct account should in turn notify its customers who received the product about the recall."⁹⁶

Even when the provider of the recalled product notifies a patient of the recall, the notification of the patient by the manufacturers and treating hospitals varies a great deal. Patricia De Filippi, the parent of a hemophiliac, testified that the medical center providing a recalled product did not inform her for 6 months of the recall,

⁹³September 26, 1994 *NIH Conference on the Feasibility of Genetic Technology to Close the HIV Window in Donor Screening*.

⁹⁴August 8, 1995 CBER memo to all registered blood and plasma establishments.

⁹⁵21 C.F.R. 7.11.

⁹⁶21 C.F.R. 7.49; presentation of Glenn Pierce, M.D., National Hemophilia Foundation, to BPAC, March 15, 1996 (in subcommittee files); and HRIR Subcommittee conference call with FDA CBER personnel, July 17, 1996 (notes in subcommittee files).

during which time her son consumed a 6 month supply of the recalled product in home therapy.⁹⁷

In addition to notification of consumers and providers of contaminated products, there are also disputes about nomenclature used for market withdrawal and recall notification. The term “field exchange” has been used by plasma concentrate manufacturers to describe actions referred to as recalls by the FDA in its enforcement report.⁹⁸ Terms such as field exchange have no basis in statute or in FDA regulations, yet the agency has apparently permitted manufacturers of biologic products to utilize these terms in a practice for biological products that is not permitted for drugs, devices or foods.

8. The size of plasma pools for fractionated products can increase the risk of infectious disease transmission

In the United States, there are over 400 FDA-licensed plasma collection facilities and 5 principal pharmaceutical firms engaged in plasma fractionation.⁹⁹ U.S. plasma collection facilities conduct approximately 13 million plasmapheresis collection procedures annually and provide 60 percent of the world’s need for plasma.¹⁰⁰ Plasmapheresis, a method of collecting plasma from the donor instead of whole blood, increases the plasma yield from each donor and can reduce the number of donors in each pool of plasma from which products are manufactured.¹⁰¹

Source plasma is the non cellular fluid portion of blood that is used as a raw material in the production of plasma-based therapies. These products are used in the treatment and diagnosis of conditions such as cardiac surgery, immune disorders, hemophilia, burns, trauma, and to provide protection against Hepatitis B, Rh disease and tetanus.

These products are made with the pooled plasma of up to 60,000¹⁰² people for some products. Some potential donors have HIV, Hepatitis and other infectious diseases. Therefore, manufacturers attempt to reduce the viral load of the initial plasma prior to manufacturing, creating a greater safety margin.¹⁰³

But some virus gets through the donor screening process, and viral inactivation procedures such as heat treatments, pasteurization and solvent detergents are used in an effort to kill the remaining viruses in the pool.

Therefore, donor pool size is equivalent to risk. Reduction in pool size reduces the number of donors to which a recipient of

⁹⁷Statement of Patricia De Filippi, p. 38.

⁹⁸FDA January 16, 1996 Talk Paper “Factor VIII and Factor IX Products Associated with Hepatitis A Transmission,” and NHF March 11, 1996 press release “Alpha Therapeutic Corporation Conducts ‘Field Exchange’ of Lots of Alphanine SD . . . Due to Possible Transmission of Hepatitis A Virus.”

⁹⁹Plasma fractionation is the separation of plasma into its major proteins. Since the production of antihemophilic factor (a.k.a. clotting factor concentrates) requires donations from thousands of donors, these donations are pooled into a large batch for further processing. IOM Report, p. 311.

¹⁰⁰Testimony of James Reilly, American Blood Resources Association, HRIR hearings, p. 181–182.

¹⁰¹Testimony of Dr. Bruce Evatt, CDC, HRIR hearings, p. 117.

¹⁰²HRIR conference call with FDA CBER personnel, July 17, 1996 (notes in subcommittee files).

¹⁰³Testimony of Dr. Thomas Waytes, Immuno-U.S., HRIR hearings, p. 226.

fractionated products is exposed. The fewer the donors to which a recipient is exposed, the less the risk.¹⁰⁴

First time donors present the greatest risk to the plasma and blood supply. Ninety-five percent of plasma donations which test positive for HIV or Hepatitis B or C come from first time donors who do not return to make a second donation within 3 months.¹⁰⁵

Some companies have used this information to develop manufacturing approaches to enhance the safety of pooled plasma products. In 1994, Immuno-U.S. (“Immuno”), a producer of plasma products, established a first-time donor applicant rejection system. Under this policy, the company destroys all plasma from first time donors who do not return to make a second donation within 3 months and undergo a second round of viral testing. This eliminates the chance that a donor in the window period of hepatitis or HIV infection is donating only for the screening test results.

Immuno has also instituted an inventory hold for 3 months in which units of plasma from first time donors which have been screened and found suitable for production are placed on hold for 90 days. If the donor is found to be reactive to screening tests on a subsequent donation or if the donor does not return to donate again with the 90 day period, the previous plasma is destroyed. This is to eliminate the possibility of a window case of Hepatitis or HIV, where the donor may have donated only to get tested for an infectious agent. Ninety-seven percent of plasma units collected by Immuno are followed by at least one additional donation by the same donor and thus have the benefit of this inventory hold follow-up.¹⁰⁶

Immuno reports that as a result of the 3-month inventory hold, the company removed and destroyed 8 times more potentially risky plasma than would have been removed without the benefit of this program. The inventory hold program results in removal and destruction of almost 1% of the plasma collected by Immuno which otherwise would be acceptable for use by FDA standards. However, this has resulted in greater costs of production.¹⁰⁷

The fewer donations from individual donors that go into a plasma pool,¹⁰⁸ the safer that pool will be.¹⁰⁹ In addition, viral load has been reduced by companies¹¹⁰ which locate centers in pleasant and supportive environments, with child care. These provisions in turn encourage frequent, regular donation by desirable, low-risk donors in communities with low incidence of infectious disease.

¹⁰⁴ Testimony of Dr. Bruce Evatt, CDC, HRIR hearings, p. 119.

¹⁰⁵ Testimony of Mark Phillip, Immuno, HRIR hearings, p. 216.

¹⁰⁶ Testimony of Dr. Mark Philip, Immuno-U.S., HRIR hearings, p. 219.

¹⁰⁷ Testimony of Dr. Mark Philip, Immuno-U.S., HRIR hearings, p. 217.

¹⁰⁸ Through utilization of repeat donors, where the donors are clearly identified and monitored very closely.

¹⁰⁹ Testimony of Dr. Bruce Evatt, CDC, HRIR hearings, p. 117.

¹¹⁰ Immuno testified that the company has seen an 88% decrease the last 5 years in viral marker rates for HIV among the donor population, with similar rate reductions for Hepatitis B and C. Testimony of Dr. Mark Philip, Immuno-U.S., HRIR hearings, p. 215.

IV. RECOMMENDATIONS

1. *Congress should establish the Blood Safety Committee and the Advisory Committee on Blood Safety and Availability in statute*

The IOM Report states that the Blood Safety Director should be at the level of a deputy assistant secretary or higher, and should not be a representative of any single PHS agency in order to be effective in coordinating the various agencies of the PHS. The Clinton administration's appointment of the Assistant Secretary for Health as the Blood Safety Director would not obligate this or any future administration to maintain this structure or continue to implement the IOM recommendations.

The roles and responsibilities of the Blood Safety Council, National Advisory Committee and the BPAC should be defined clearly to ensure greater coordination and to ensure that the BPAC confines its decisions to scientific matters under the jurisdiction of FDA.

2. *Congress should consider establishing an indemnification system for individuals who suffer adverse consequences from the use of blood and blood products*¹¹¹

Potential injury from blood, blood products, and blood derivatives continues to be a reality for all people who must use these products in the course of medical treatment. Since 1985, clotting factor products have been treated with viral inactivation measures which have virtually eliminated the threat of HIV.

Blood components from individual donors, however, are not virally inactivated and may transmit infectious diseases. Since it is impossible to make the blood 100 percent safe, society needs to examine effective avenues for compensating those parties who will be injured as result of the inherent imperfections in the blood supply, however small, including alternative dispute mechanisms and no-fault compensation programs as a means to achieve better and more efficient resolutions of claims resulting from transfusion-related injuries.

The solution may be the enactment of a blood and blood products compensation trust fund that would give consumers needed recourse in most legal settings.¹¹² Since blood borne pathogens take years to manifest harm, not only do individuals have to overcome State blood shield laws,¹¹³ but statutes of limitations as well.

Experience to date suggests that development of such a program involves resolution of many complex issues, including development of sufficient funding mechanisms and obtaining the cooperation of both Government and private insurers to support an alternative to the traditional tort system, such as the National Vaccine Compensation Program.¹¹⁴

¹¹¹ Statement of Secretary Shalala, HRIR hearings, p. 17.

¹¹² IOM Report, p. 13.

¹¹³ The blood shield laws were enacted by 47 States in the 1950's and 1960's to exempt blood and blood products from "strict liability or implied warranty claims on the basis that blood and blood products provide a service, not a sale." IOM Report, p. 49.

¹¹⁴ Statement of Karen Shoos Lipton, HRIR hearings, p. 131; statement of Dr. Toby Simon, HRIR hearings, p. 140.

3. *HHS should take steps to ensure that the estimated 300,000 living recipients of blood and blood products who were infected with Hepatitis C virus before 1990 are notified of their potential infection so that they might seek diagnosis and treatment*

Dr. Lee and Secretary Shalala agreed at the October 12 hearing to place the HCV notification issue first on the agenda of the Blood Safety Committee.¹¹⁵ The Blood Safety Committee has met bi-monthly since December 1995 but no public statements have been made on this issue.

HHS has informed the subcommittee staff that the Blood Safety Committee has approved but not yet implemented an outreach plan to medical providers that will identify patients at risk and provide testing, treatment and counseling recommendations. The committee will also identify a model for outreach to affected consumers who would not be in regular contact with a medical provider.¹¹⁶

4. *HHS should disseminate more clinically useful information to providers of care and to the public regarding blood safety issues*

Recommendation 13 of the IOM report states that, “The Department of Health and Human Services should convene an expert panel to inform the providers of care and the public about the risks associated with blood and blood products, about alternatives to using them, and about treatments that have the support of the scientific record.”¹¹⁷

The HHS’ Secretary’s Task Force agreed: “that this type of clinically useful information should be communicated as it becomes available. As issues of importance arise, the PHS Blood Safety Committee and the Advisory Council on Blood Safety and Availability will evaluate the government’s communications efforts, including the activities of the Agency for Health Care Policy and Research and its clinical guidelines program, to determine what additional efforts are needed.”¹¹⁸

HHS should develop a standardized informed consent document to be given to patients prior to transfusion, outlining the risks and benefits of blood and blood product transfusion.¹¹⁹ Patients should be made aware of all options to reduce use of donated and pooled blood products, as well as other non-blood based products such as recombinant products which would reduce the risk of transmitting blood borne pathogens.

In addition, FDA should promptly require plasma fractionators to provide adequate and appropriately updated warning labels for plasma products to ensure that patients are informed of the risks to which they may be exposed through use of these products, whether or not the BPAC is able to reach consensus on this matter.

FDA should also work with plasma fractionators to develop appropriate labeling to include von Willebrand¹²⁰ disease indications

¹¹⁵ Testimony of Dr. Philip Lee and Secretary Shalala, HRIR hearings, p. 29–30.

¹¹⁶ HRIR Subcommittee staff meeting with Marc Smolonsky, Office of the HHS Assistant Secretary for Legislation, June 4, 1996 and conference call of June 5, 1996 (notes in subcommittee files).

¹¹⁷ IOM Report, p. 232.

¹¹⁸ Report to the Secretary—Task Force on Blood Safety, HRIR hearings, p. 21.

¹¹⁹ Statement of Patricia De Filippi, p. 40; testimony of Dr. John Penner, p. 48–49.

¹²⁰ An inherited bleeding disorder affecting 500,000 persons in the United States (half of whom are women) caused by absent or insufficient levels of glycoprotein in the blood. March

for intermediate purity hemophilia products developed for hemophilia treatment. These hemophilia products are currently used off-label for treatment of severe von Willebrand disease.

Dr. John Penner testified that “most of the patients with severe von Willebrand disease are receiving these products as their only means of controlling hemorrhagic episodes. In my practice, I allow surgery to be performed on such patients, despite the fact that I am unsure of the quality and the content of the product that I have ordered. The potential for serious complications exists under these conditions and surely requires a solution that must be addressed by the FDA.”¹²¹

5. FDA should immediately develop an effective system of recall notification for blood and plasma products

A system should be developed and enforced by FDA for notifying consumers and health care providers about potential threats to blood products from infectious diseases, not only manufacturers’ directed accounts. An effective recall system would require manufacturers undertaking voluntary withdrawals and recalls to utilize consistent language for these procedures, so that the impact on directed accounts and consumers is fully realized.

An effective recall communication system would ensure that consumers, as well as manufacturers directed accounts, are promptly advised of identified hazardous products in order that they may discontinue use and reduce their risks of exposure.

6. FDA should immediately cease its practice of providing advance notice of safety and compliance inspections to some plasma fractionators

This practice is inconsistent with FDA’s inspection practices for other industries regulated by FDA.¹²² It is used only by the CBER officials on a joint inspection with FDA Office of Regulatory Affairs¹²³ personnel (ORA), only in some cases, and is not documented when used. This practice may appear to companies as favoritism for competing firms and could affect consumer and industry confidence in the agency’s enforcement practices.

7. Plasma fractionators should limit the size of plasma pools, with pool sizes determined as much by public health risk factors as by production economies of scale

The IOM report stated that “reducing risks by smaller pools would not eliminate risk. Indeed, a substantial pool is necessary to assure the efficacy of some plasma derivatives and reduce certain risks in others. But maintaining these levels could be accomplished while reducing pool sizes by a factor of 20. The critical point to this example is that because FDA promoted no changes in pooling prac-

5, 1996 letter from National Hemophilia Foundation President Stephen Bajardi to Subcommittee Chairman Shays (in subcommittee files).

¹²¹Statement of Dr. John Penner, HRIR hearings, p. 53; and March 5, 1996 letter from National Hemophilia Foundation President Stephen Bajardi to Subcommittee Chairman Shays (in subcommittee files).

¹²²HRIR Subcommittee interview with FDA, May 24, 1996 (notes in subcommittee files).

¹²³FDA field inspection personnel.

tices, it faces in 1995 the same dilemma concerning Creutzfeldt-Jakob disease that it faced in 1983–84 concerning AIDS.”¹²⁴

A reduction in plasma pool size could make product recalls easier and also minimize the potentially disruptive effect of product withdrawal and recalls on supply of plasma products.¹²⁵

¹²⁴IOM Report, p. 165 and p. 222.

¹²⁵Testimony of Dr. Thomas Waytes, Immuno-U.S., HRIR hearings, p. 224.

ADDITIONAL VIEWS OF HON. CAROLYN B. MALONEY

I applaud the Subcommittee on Human Resources and Intergovernmental Relations for its in-depth report entitled "Protecting the Nation's Blood Supply from Infectious Agents: The Need for New Standards to Meet New Threats." Chairman Shays and ranking Democrat Ed Towns have done an outstanding job on the series of hearings held in the Fall of 1995 and in the preparation of the report.

The report raises important and complex scientific, public health and safety issues. It is heartening, indeed, that the committee has found that the Nation's blood supply is safer than it has ever been. This is due in no small measure to the cooperation of government regulators and the Nation's blood suppliers and blood derivative manufacturers. At the same time we all agree that safety is an important concern and continued vigilance is necessary. With more HIV-infected people than any other state—20% of the Nation's total AIDS cases—the safety of our Nation's blood supply is of critical importance to my constituents in New York.

The report urges the Congress to consider establishing an indemnification system for individuals who suffer adverse consequences from the use of blood and blood derivatives. While I agree that Congress should continue to review the underlying causes that produce such a recommendation, it does not appear that the hearing records support the suggestion that the National Vaccine Compensation Program (NVCP) be used as a model for such a system. It does not appear that the true costs of such a "prospective" system have been calculated and weighed. The additional costs imposed on vaccine products for the NVCP are spread over millions of users for products that are themselves modest in cost. Coverage of blood and blood derivatives with such a system, considering the vastly smaller user population, could result in substantial additional costs being passed through to users. This could result in fewer hemophiliacs and other chronic disease sufferers being able to afford these life-giving and lifesaving products and therapies. The alternative would seem to be the use of a taxpayer funded initiative which would give us all some pause. This issue should be given further consideration before Congress takes any legislative action.

Again, I applaud the subcommittee for its work in this area. I agree that we must remain vigilant in our efforts to insure the safety of our Nation's blood supply and look forward to working with the subcommittee in the years ahead to pursue this shared goal.

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