The substantial funds that this operation uncovered flowing from the illicit drug trade underscores just how serious the challenge is from these illicit drug dealers and the corruption they foster in the banking system and in democratic institutions throughout the world.

The magnitude of the disclosure and expanse of the monies and influence from illicit drugs shows our need for a serious and meaningful war on drugs. Our drug czar, Barry McCaffrey, believes that the term ''war on drugs'' is not appropriate to apply to the problems of drugs in our Nation. Many of us disagree. Our Speaker's task force efforts will hopefully turn this around.

Operation ''Casablanca'' makes it clear that what is at stake here deserves a war footing by our Nation and the international community. We need to fight drugs on all fronts, including both the demand and supply side simultaneously, as well as hitting them in the pocketbooks, just as ''Casablanca'' has done.

UNLAWFUL TRANSFER OF MISSILE TECHNOLOGIES WARRANTS IMMEDIATE INVESTIGATION

(Mr. HAYWORTH asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. HAYWORTH. Madam Speaker, I, along with many of my colleagues, had an opportunity to hear the Vice President of the United States speak on foreign policy matters last night; and, Madam Speaker, the Vice President went into great detail of his concern and disdain for the transfer of missile technology from the Russians to the Iranians. But, Madam Speaker, not one word was uttered by our Vice President about concerns of the transfer of our own missile technology to the Chinese government.

There are serious questions that exist, Madam Speaker. Indeed, The Washington Post reports this morning that $632,000 in donations to the Democrat party were given by Loral Missile Defense System CEO Bernard Schwartz, the party's largest single donor in the 1996 election.

Madam Speaker, this transcends the issue of Democrats versus Republicans. As Americans, this Congress needs to investigate the unlawful transfer of missile technologies from this government and from our defense capabilities to the People's Republic of China.

Madam Speaker, this House must investigate. There is no other choice.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to the provisions of clause 5 of rule 1, the Chair announces that she will postpone further proceedings today on each motion to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote is objected to under clause 4 of rule XV.

Such rollcall votes, if postponed, will be taken after debate has concluded on all motions to suspend the rules, but not before 5 p.m. today.

RICKY RAY HEMOPHILIA RELIEF FUND ACT OF 1998

Mr. HYDE. Madam Speaker, I move to suspend the rules and pass the bill (H.R. 1023) to provide for compassionate payments with regard to individuals with blood-clotting disorders, such as hemophilia, who contracted human immunodeficiency virus due to contaminated blood products, and for other purposes, as amended.

The Clerk read as follows:

H.R. 1023

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Ricky Ray Hemophilia Relief Fund Act of 1998''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—HEMOPHILIA RELIEF FUND

Sec. 101. Ricky Ray Hemophilia Relief Fund.
Sec. 102. Compassionate payment relating to individuals with blood-clotting disorders and HIV.
Sec. 103. Determination and payment.
Sec. 104. Limitation on transfer of rights and number of petitions.
Sec. 105. Time limitation.
Sec. 106. Certain claims not affected by payment.
Sec. 107. Limitation on agent and attorney fees.
Sec. 108. Definitions.

TITLE II—TREATMENT OF CERTAIN PRIVATE SETTLEMENT PAYMENTS IN HEMOPHILIA-CLOTTING-FACTOR SUIT UNDER THE MEDICAID AND SSI PROGRAMS

Sec. 201. Treatment of certain private settlement payments in hemophilia-clotting-factor suit under the Medicaid and SSI programs.

TITLE I—HEMOPHILIA RELIEF FUND

SEC. 101. RICKY RAY HEMOPHILIA RELIEF FUND.

(a) ESTABLISHMENT.—There is established in the Treasury of the United States a trust fund to be known as the ''Ricky Ray Hemophilia Relief Fund'', which shall be administered by the Secretary of the Treasury.

(b) INVESTMENT OF AMOUNTS IN FUND.—Amounts in the Fund shall be invested in accordance with section 9702 of title 31, United States Code, and any interest on and proceeds from any such investment shall be credited to and become part of the Fund.

(c) AVAILABILITY OF FUND.—Amounts in the Fund shall be available only for disbursement by the Secretary of Health and Human Services under section 103.

(d) TERMINATION.—The Fund shall terminate upon the expiration of the 5-year period beginning on the date of the enactment of this Act. If all of the amounts in the Fund have not been expended by the end of the 5-year period, investments of amounts in the Fund shall be liquidated, the receipts of such liquidation shall be deposited in the Fund, and all funds remaining in the Fund shall be deposited in the miscellaneous receipts account in the Treasury of the United States.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Fund to carry out this title $750,000,000.

SEC. 102. COMPASSIONATE PAYMENT RELATING TO INDIVIDUALS WITH BLOOD-CLOTTING DISORDERS AND HIV.

(a) IN GENERAL.—If the conditions described in subsection (b) are met and if there are sufficient amounts in the Fund to make each payment, the Secretary shall make a single payment of $100,000 from the Fund to any individual who has an HIV infection and who is described in one of the following paragraphs:

(1) The individual has any form of blood-clotting disorder, such as hemophilia, and was treated with antihemophilic factor at any time during the period beginning on July 1, 1982, and ending on December 31, 1987.

(2) The individual —

(A) is the lawful spouse of an individual described in paragraph (1); or

(B) is the former lawful spouse of an individual described in paragraph (1) and was the lawful spouse of the individual at any time after a date, within the period described in such subparagraph, on which the individual was treated as described in such paragraph and through medical documentation can assert reasonable certainty of transmission of HIV from individual described in paragraph (1).

(3) The individual acquired the HIV infection through perinatal transmission from a parent who is an individual described in paragraph (1) or (2).

(b) CONDITIONS.—The conditions described in this subsection are, with respect to an individual, as follows:

(1) SUBMISSION OF MEDICAL DOCUMENTATION OF HIV INFECTION.—The individual submits to the Secretary written medical documentation that the individual has an HIV infection.

(2) PETITION.—A petition for the payment is filed with the Secretary by or on behalf of the individual.

(3) DETERMINATION.—The Secretary determines, in accordance with section 103(b), that the petition meets the requirements of this title.

SEC. 103. DETERMINATION AND PAYMENT.

(a) ESTABLISHMENT OF FILING PROCEDURES.—The Secretary of Health and Human Services shall establish procedures under which individuals may submit petitions for payment under this title. The procedures shall include a requirement that each petition filed under this Act include written medical documentation that the relevant individual described in section 102(a)(1) has (or had) a blood-clotting disorder, such as hemophilia, and was treated as described in such section.

(b) DETERMINATION.—For each petition filed under this title, the Secretary shall determine whether the petition meets the requirements of this title.

(c) PAYMENT.—

(1) IN GENERAL.—To the extent there are sufficient amounts in the Fund to cover each payment, the Secretary shall pay, from the Fund, each petition that the Secretary determines meets the requirements of this title in the order received.

(2) PAYMENTS IN CASE OF DECEASED INDIVIDUALS.—

(A) IN GENERAL.—In the case of an individual referred to in section 102(a) who is deceased at the time that payment is made under this section on a petition filed by or on behalf of the individual, the payment shall be made as follows:

(i) If the individual is survived by a spouse who is living at the time of payment, the payment shall be made to such surviving spouse.

(ii) If the individual is not survived by a spouse described in clause (i), the payment shall be made in equal shares to all children of the individual who are living at the time of the payment.

(iii) If the individual is not survived by a person described in clause (i) or (ii), the payment shall be made in equal shares to the parents of the individual who are living at the time of payment.

(iv) If the individual is not survived by a person described in clause (i), (ii), or (iii), the payment shall revert back to the Fund.

(B) FILING OF PETITION BY SURVIVOR.—If an individual eligible for payment under section 102(a) dies before filing a petition under this title, a survivor of the individual may file a petition for payment under this title on behalf of the individual if the survivor may receive payment under subparagraph (A).

(C) DEFINITIONS.—For purposes of this paragraph:

(i) The term ''spouse'' means an individual who was lawfully married to the relevant individual at the time of death.

(ii) The term ''child'' includes a recognized natural child, a stepchild who lived with the relevant individual in a regular parent-child relationship, and an adopted child.

(iii) The term ''parent'' includes fathers and mothers through adoption.

(3) TIMING OF PAYMENT.—The Secretary may not make a payment on a petition under this title before the expiration of the 120-day period beginning on the date of the enactment of this Act or after the expiration of the 5-year period beginning on the date of the enactment of this Act.

(d) ACTION ON PETITIONS.—The Secretary shall complete the determination required by subsection (b) regarding a petition not later than 120 days after the date the petition is filed under this title.

(e) HUMANITARIAN NATURE OF PAYMENT.—This Act does not create or admit any claim of or on behalf of the individual against the United States or against any officer, employee, or agent thereof acting within the scope of employment or agency that relate to an HIV infection arising from treatment with antihemophilic factor, at any time during the period beginning on July 1, 1982, and ending on December 31, 1987. A payment under this Act shall, however, when accepted by or on behalf of the individual, be in full satisfaction of all such claims by or on behalf of that individual.

(f) ADMINISTRATIVE COSTS NOT PAID FROM FUND.—No costs incurred by the Secretary in carrying out this title may be paid from the Fund or set off against, or otherwise deducted from, any payment made under subsection (c)(1).

(g) TERMINATION OF DUTIES OF SECRETARY.—The duties of the Secretary under this section shall cease when the Fund terminates.

(h) TREATMENT OF PAYMENTS UNDER OTHER LAWS.—A payment under subsection (c)(1) to an individual—

(1) shall be treated for purposes of the Internal Revenue Code of 1986 as damages described in section 104(a)(2) of such Code;

(2) shall not be included as income or resources for purposes of determining the eligibility of the individual to receive benefits described in section 3803(c)(2)(C) of title 31, United States Code, or the amount of such benefits, and such benefits shall not be secondary to, conditioned upon reimbursement from, or subject to any reduction because of receipt of, any such payment; and

(3) shall not be treated as a third party payment or payment in relation to a legal liability with respect to such benefits and shall not be subject (whether by subrogation or otherwise) to recovery, recoupment, reimbursement, or collection with respect to such benefits (including the Federal or State governments or any entity that provides such benefits under a contract).

(i) REGULATORY AUTHORITY.—The Secretary may issue regulations necessary to carry out this title.

(j) TIME OF ISSUANCE OF PROCEDURES.—The Secretary shall, through the promulgation of appropriate regulations, guidelines, or otherwise, first establish the procedures to carry out this title not later than 120 days after the date of the enactment of this Act.

SEC. 104. LIMITATION ON TRANSFER OF RIGHTS AND NUMBER OF PETITIONS.

(a) RIGHTS NOT ASSIGNABLE OR TRANSFERABLE.—Any right under this title shall not be assignable or transferable.

(b) 1 PETITION WITH RESPECT TO EACH VICTIM.—With respect to each individual described in paragraph (1), (2), or (3) of section 102(a), the Secretary may not make payment with respect to more than 1 petition filed in respect to an individual.

SEC. 105. TIME LIMITATION.

The Secretary may not make any payment with respect to any petition filed under this title unless the petition is filed within 3 years after the date of the enactment of this Act.

SEC. 106. CERTAIN CLAIMS NOT AFFECTED BY PAYMENT.

A payment made under section 103(c)(1) shall not be considered as any form of compensation, or reimbursement for a loss, for purposes of imposing liability on the individual receiving the payment, on the basis of such receipt, to repay any insurance carrier for insurance payments or to repay any person on account of worker's compensation payments. A payment under this title shall not affect any claim against an insurance carrier with respect to insurance or against any person with respect to worker's compensation.

SEC. 107. LIMITATION ON AGENT AND ATTORNEY FEES.

Notwithstanding any contract, the representative of an individual may not receive, for services rendered in connection with the petition of an individual under this title, more than 5 percent of a payment made under this title on the petition. Any such representative who violates this section shall be fined not more than $50,000.

SEC. 108. DEFINITIONS.

For purposes of this title:

(1) The term ''AIDS'' means acquired immune deficiency syndrome.

(2) The term ''Fund'' means the Ricky Ray Hemophilia Relief Fund.

(3) The term ''HIV'' means human immunodeficiency virus.

(4) Unless otherwise provided, the term ''Secretary'' means Secretary of Health and Human Services.

TITLE II—TREATMENT OF CERTAIN PAYMENTS IN HEMOPHILIA-CLOTTING-FACTOR SUIT UNDER THE SSI PROGRAM

SEC. 201. TREATMENT OF CERTAIN PAYMENTS IN HEMOPHILIA-CLOTTING-FACTOR SUIT UNDER THE MEDICAID AND SSI PROGRAMS.

(a) PRIVATE PAYMENTS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the payments described in paragraph (2) shall not be considered income or resources in determining eligibility for, or the amount of—

(A) medical assistance under title XIX of the Social Security Act, or

(B) supplemental security income benefits under title XVI of the Social Security Act .

(2) PRIVATE PAYMENTS DESCRIBED.—The payments described in this subsection are—

(A) payments made from any fund established pursuant to a class settlement in the case of Susan Walker v. Bayer Corporation, et al., 96–C–5024 (N.D. Ill.); and

(B) payments made pursuant to a release of all claims in a case—

(i) that is entered into in lieu of the class settlement referred to in subparagraph (A); and

(ii) that is signed by all affected parties in such case on or before the later of—

(I) December 31, 1997, or

(II) the date that is 270 days after the date on which such release is first sent to the persons (or the legal representative of such persons) to whom the payment is to be made.

(b) GOVERNMENT PAYMENTS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the payments described in paragraph (2) shall not be considered income or resources in determining eligibility for, or the amount of supplemental security income benefits under title XVI of the Social Security Act.

(2) GOVERNMENT PAYMENTS DESCRIBED.—The payments described in this subsection are payments made from the fund established pursuant to section 101 of this Act.

Amend the title so as to read: ''A bill to provide for compassionate payments with regard to individuals with blood-clotting disorders, such as hemophilia, who contracted human immunodeficiency virus due to contaminated antihemophilic factor, and for other purposes.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Illinois (Mr. HYDE) and the gentleman from Virginia (Mr. SCOTT) each will control 20 minutes.

The Chair recognizes the gentleman from Illinois (Mr. HYDE).

GENERAL LEAVE

Mr. HYDE. Madam Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on the bill presently under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Illinois?

There was no objection.

Mr. HYDE. Madam Speaker, I yield myself such time as I may consume.

Madam Speaker, I rise in support of H.R. 1023, the Ricky Ray Hemophilia Relief Fund Act of 1998. This legislation has 270 cosponsors in the House, including our distinguished Speaker; and I am informed the Minority Leader also supports this legislation.

When communities in our great Nation are devastated by a natural disaster such as floods or tornadoes, we rush to their aid, as well we should. The hemophilia community has been devastated by another type of natural disaster, the HIV contamination of the blood-clotting products which they need to treat their hemophilia. This legislation provides the disaster relief necessary to assist this community through a very difficult time.

In the late 1970s and early 1980s, half of all people with blood-clotting disorders in the United States were infected with HIV due to their use of blood-clotting products which were on the market at that time. During this period, people with blood-clotting disorders needed to use these products to live a relatively normal life; and because each dose came from a pool of

thousands of blood donors, it was almost certain that they would become HIV infected.

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However, at that time HIV had not been identified and no tests were available to detect its presence. Most people with blood clotting disorders are already financially strapped by the medical costs they incur to treat their disorder. With earlier medical costs of over $150,000 and the added tragedies of an HIV infection, these families have been emotionally and financially devastated.

In cases involving other types of blood and blood products, such as transfusion cases, where a primary provider or a small child was infected, settlements usually were for hundreds of thousands of dollars. Many of the HIV infected people with hemophilia were young fathers and children.

After many years of litigation, the manufacturers of these blood clotting products containing HIV have set up a fund which provides $100,000 to individuals and their families. However, when considering the incredible financial burden placed on these families due to medical costs and, in many cases, loss of the primary provider of the family, this amount will not sufficiently lift this community out of the financial crisis that has developed.

While no amount will completely alleviate the losses felt, H.R. 1023 provides a payment equal to that of the industry. The amount available to these families would then be comparable to that potentially realized by other HIV-infected blood victims through settlement.

There is a manager's amendment to this legislation. The bill as reported by the committee included a provision of no more than 2 percent of these payments that may be used for attorneys' fees. Concern was raised during committee consideration that should there be a complication in the processing of an individual's application, 2 percent would be insufficient to address that concern, and the 2 percent limitation on attorneys' fees has been increased to 5 percent.

I know my budget-conscious colleagues may balk at this expenditure, but when an extreme crisis hits an American community, we should as a Nation respond to that community's need. That is what this bill does. To aid this community in crisis, I urge a favorable vote on H.R. 1023.

Madam Speaker, I reserve the balance of my time.

Mr. SCOTT. Madam Speaker, I yield myself such time as I may consume.

Madam Speaker, I rise in support of H.R. 1023, the Ricky Ray Hemophilia Relief Fund Act of 1998. The purpose of the bill is to establish a fund to provide compassionate payments of $100,000 to individuals with hemophilia who contracted HIV, the AIDS virus, from contaminated blood-clotting products.

Hemophilia is a blood-clotting disorder genetically passed to sons by their mothers. In the late 1970s and early 1980s approximately 7,200 boys and men were infected with HIV through the use of blood-clotting products. That is nearly half of all people with hemophilia in the United States.

Because these blood-clotting products were derived from pools made up of literally thousands of donors, including prisoners, it has been nearly impossible to conclude causation and liability to any one manufacturer for selling contaminated blood products. Although, as the chairman mentioned, many cases have been settled, of the dozen or so cases that eventually went to trial, the manufacturers were only held liable in two cases, one of which was reversed and the other is still on appeal. To make matters worse, many of the States have passed so-called blood shield laws to protect blood banks from liability when blood-based diseases are passed on to users.

Notwithstanding the industry's courtroom success and new blood shield laws, the industry recently established a fund to provide $100,000 to individuals who contracted HIV through contaminated blood-clotting products in exchange for signing waivers releasing the industry from any future liability. Many hemophiliacs and their families have accepted this offer. Unfortunately, the $100,000 industry payment is insufficient to cover the enormous costs of blood-clotting drugs which people with hemophilia must continue to have in order to live a relatively normal life, and the enormous costs of drugs to combat the AIDS virus. Accordingly, this legislation is necessary to provide additional financial assistance.

The administration supports this proposal. We want to thank the chairman for the manager's amendment to increase the attorneys' fee provision from 2 to 5 percent, because we support this amendment, because we believe that it will allow claimants greater access to legal counsel in processing their applications under the bill.

Madam Speaker, I reserve the balance of my time.

Mr. HYDE. Madam Speaker, I am pleased to yield 8 minutes to the distinguished gentleman from Florida (Mr. GOSS), one of the driving forces behind this excellent legislation.

(Mr. GOSS asked and was given permission to revise and extend his remarks and include extraneous material.)

Mr. GOSS. Madam Speaker, I thank the distinguished gentleman from Illinois (Mr. HENRY HYDE), chairman of the Committee on the Judiciary, with my great respect for him, and I thank him personally from my heart for getting this legislation this far.

Madam Speaker, I rise today in support of H.R. 1023, the Ricky Ray Hemophilia Relief Fund Act, which is designed to respond to the tragedies of hemophilia-associated AIDS.

I first became involved in this issue some nine years ago when I met the Ray family. Ricky Ray, like his two brothers, contracted HIV through the use of contaminated blood products. Ricky, the eldest of the three boys, died of AIDS in 1992 at the age of 15. Before his death Ricky and his family courageously spoke out and became national symbols of the terrible situation we are facing. He inspired many of his peers to tell their stories and begin seeking answers from the Federal Government and the blood product manufacturing industry.

I am saddened that he did not live to see the day when legislation named in his honor would win the approval of this body. But we know his brothers and sisters, his parents, and the extended family of friends he established around the country recognize the enormous contribution that he made in his very short life. It is appropriate that the legislation before us bears his name, and I am pleased that Ricky's mother Louise is here with us today.

Madam Speaker, hemophilia is an inherited blood-clotting disorder causing serious internal bleeding episodes that, if left untreated, can lead to disfigurement and death. People with hemophilia rely on blood products, commonly called factor, which are manufactured and sold by pharmaceutical companies.

Because these products are made from the pooled blood of thousands of people, the potential for infection with a blood-borne disease among those who use them is obviously very high, something that has been known for decades. In fact, hemophilia sufferers have long been described as the canaries in the coal mine, because when something goes wrong with the blood supply it shows up in the hemophilia community first.

Soon after the introduction of clotting factor in the 1970s, the hepatitis virus swept through the hemophilia community. Largely as a result of the hemophilia community's experience with the hepatitis virus, the Federal Government adopted the national blood policy, which charged the Public Health Service, including the Centers for Disease Control, Food and Drug, and the National Institutes of Health with ensuring the safety and adequacy of the Nation's blood supply. It is worth noting that the Federal responsibility for blood and blood products is indeed unique. No other product has a national policy.

In the early 1980s a much more deadly disease struck as approximately one-half of the Nation's hemophiliacs, some 7,200 people at a minimum, became infected with HIV through the use of contaminated blood products. How did this happen? Why did the system that was established to safeguard the supply of blood and blood products fail to heed the early warning signs and prove so slow to respond to a dangerous threat?

In 1993 I joined with Senators GRAHAM of Florida and KENNEDY of Massachusetts in asking the Department of Health and Human Services to

conduct a review of the events surrounding this medical disaster. The results of that intensive and objective review are contained in a report prepared by the Institute of Medicine, an arm of the National Academy of Sciences.

The IOM found ''a failure of leadership and inadequate institutional decision-making processes'' in the system responsible for ensuring blood safety, concluding that ''a failure of leadership led to less than effective donor screening, weak regulatory actions, and insufficient communication to patients about the risk of AIDS.''

While the IOM report is important, it does not begin to quantify the human dimension. For me, that is the most compelling part of this tragedy. We cannot talk to these victims without being moved by what they have gone through. It is important to keep in mind that the people with hemophilia already have to manage a sometimes debilitating disease. The average person with hemophilia spends approximately $100,000 per year on clotting factor alone. Many people with hemophilia have had a difficult time obtaining both health and life insurance, understandably.

In addition to the difficulties associated with hemophilia itself, the added complication of HIV AIDS has hit the hemophilia community particularly hard. Each treatment costs somewhere in the range of $10,000 to $50,000 per year, varying on the stage of the disease and the course of the treatment.

As a result of these extraordinary costs and the disproportionate impact of this tragedy on men, who most typically suffer from hemophilia and who tended to be the head of many of these households, many of these folks have been financially devastated. In some cases entire generations have been wiped out: fathers, sons, uncles. Most tragically, some men infected their wives with HIV before they became aware that they had contracted the disease. We know of cases where unborn children in these circumstances were also infected.

The emotional toll on all of these families has been immense. Madam Speaker, the Federal Government cannot become involved in every tragic case that occurs in this country, but this case is unique. I believe the Federal Government can and should, for compassionate reasons, act to help the hemophilia community.

While we cannot right all the wrongs in the world, we should pass this legislation to acknowledge the unique responsibility of the government to protect the blood supply and provide some measure of compassionate assistance to these victims. While I am encouraged that a final class settlement between the people of hemophilia and the blood product manufacturing companies is in fact going forward, it does not change my view that government also must act.

As my colleagues know, and as the hemophilia community has learned firsthand, moving a bill through the legislative process is a slow, difficult, and sometimes frustrating experience, amen. When I first introduced the Ricky Ray bill, we had about two dozen cosponsors. Since then support for the bill has swelled to 270 cosponsors, and we have secured unanimous approval for all three committees with jurisdiction.

This incredible progress is the direct result of the courage, diligence, and hard work of the hemophilia community. Of particular notice is the work of a group of high school students from Robinson Secondary School in Fairfax, Virginia. For several years these kids, as part of a marketing education program called DECA, have lobbied to pass this bill. Their efforts have been extraordinary, and they show that democracy can and does work.

Finally, Madam Speaker, let me say thank you to the congressional staff that have worked with me through the years to research and understand this tragedy, explain it to the House, and get this bill moving.

Madam Speaker, for too long the hemophilia community has felt that government first let them down and later abandoned them. I sincerely hope that the House action today will provide some measure of reassurance that their voices do count, that the legislative process does work, and that we have not forgotten them or the tragedy that befell their community. I only wish we had a cure for AIDS.

I strongly urge my colleagues to support this important legislation.

Madam Speaker, I include for the RECORD the following CRS report.

The report referred to is as follows:

CSR REPORT FOR CONGRESS—BLOOD AND BLOOD PRODUCTS: FEDERAL REGULATION AND TORT LIABILITY

(By Diane T. Duffy and Henry Cohen, Legislative Attorneys, American Law Division)

SUMMARY

Part I of this report, by Diane Duffy, Legislative Attorney, provides an overview of the Federal government's regulation of blood products. Part II, by Henry Cohen, Legislative Attorney, examines tort liability for injuries caused by defective blood or blood products.

The Food and Drug Administration (FDA) regulates blood and blood products under two statutes which overlap to a certain degree: the Federal Food, Drug and Cosmetic Act [FFDCA] and the Public Health Services Act (PHSA). Regulations are issued in order to implement the provisions of these statutes. Current statutory and regulatory law operates to govern the licensing, production, testing, distribution, labeling, review and approval of all drugs and biologics. Specifically, under the FFDCA, drugs, which include biologics such as blood and blood components or derivatives, which are intended to cure, mitigate, or prevent disease, are regulated. The enforcement and penalties provisions of the FFDCA can be applied to biological product manufacturers. Within the agency, the Center for Biologics Evaluation and Review has jurisdiction over the regulation of these articles.

Tort liability for injuries caused by defective blood or blood products is a form of products liability, which is governed primarily by state law. Products liability is strict liability, which means that, to recover, the plaintiff does not have to prove that the defendant was negligent, but need prove only that the defendant sold a defective product and that the plaintiff's injury resulted from the defect. However, all 50 states—48 through ''blood shield'' statutes—provide that blood transfusions are not subject to strict liability. The primary rationale for this is the belief that holding suppliers of blood or blood products strictly liability would make blood transfusions too expensive.

Part I of this report, by Diane Duffy, Legislative Attorney, provides an overview of the Federal government's regulation of blood products. Part II, by Henry Cohen, Legislative Attorney, examines tort liability for injuries caused by defective blood or blood products.

PART I: FEDERAL REGULATION OF BLOOD PRODUCTS

Issues relating to the regulation of blood products have been raised in the context of individuals with hemophilia who contracted Human Immunodeficiency Virus (HIV), the virus which causes AIDS, through the use of contaminated blood products. In the 104th Congress, bills have been introduced by Rep. Goss and Sen. DeWine which would establish a trust fund to compensate hemophiliacs, their spouses or estates, who contracted HIV through tainted blood products. This part of the report summarizes Rep. Goss' bill (H.R. 1023, 104th Congress)[1]; discusses current Federal law that directs and authorizes the regulation of blood products; and discusses regulatory issues and events which are notable in this context. In particular, it focuses issues which tend to indicate that the regulation of blood products has been different than the regulation of other articles which are within the jurisdiction of the Food and Drug Administration (FDA).

Summary: The Ricky Ray Hemophilia Relief Fund Act of 1995

H.R. 1023, 104th Congress, introduced by Rep. Goss, establishes procedures for claims for compassionate payments with regard to persons with blood clotting disorders, e.g., hemophilia, who contracted HIV due to contaminated blood products. The bill, entitled the Ricky Ray Hemophilia Relief Fund Act of 1995, states that about half of all individuals in the U.S. who suffer from blood clotting diseases like hemophilia, were exposed to HIV through the use of blood clotting agents. The bill finds that the Federal government has a shared responsibility with the blood products industry for protecting the safety of the blood supply and for regulating blood clotting agents. H.R. 1023 finds that people with blood clotting disorders were at a very high risk of contracting HIV during the period beginning in 1980 and ending in 1987, when the last mass recall of contaminated anti-hemophilic factor (AHF) occurred. The bill states that it was during this period that the Federal government did not require the blood products industry to use means to ensure safety of blood products that were marketed for sale to people with blood clotting disorders. Moreover, it finds that the government did not require that all available information about the risks of contamination be dispensed and failed to properly regulate the blood products industry. Based upon these and other findings, the bill establishes a fund to compensate individuals in this circumstance. The fund is named after a child born with hemophilia who, like his two younger brothers and others, became infected with HIV through the use of contaminated blood clotting products.[2]

Footnotes at end of article.

Specifically, the fund provides for partial restitution to people who were infected with HIV after treatment, during the period of 1980–1987, with contaminated blood products. The fund is established in the Department of the Treasury, is to be administered by the Secretary, and is to remain viable for five years after the date of enactment. The bill authorizes to be appropriated to the fund $1,000,000,000, to be disbursed by the Attorney General. H.R. 1023 provides that any person who submits to the Attorney General written medical documentation that he has an HIV infection shall receive $125,000 if each of these conditions is met:

(A) 1. The person has any form of blood clotting disorder and was treated with blood clotting agency in the form of blood components or blood products at any time during the period of January 1, 1980 and ending December 31, 1987; or

2. The person is the lawful spouse of the infected person or is the former lawful spouse of the infected person at the time so described in the bill.

3. The person acquired HIV through perinatal transmission from a parent who is an individual described in the above paragraphs.

(B) A claim for payment is filed with the Attorney General.

(C) The Attorney General determines that the claim meets the requirements under this bill, if enacted.

The Attorney General is required to establish procedures for the claims and payments and must determine whether the claim meets all the requirements. Claims are to be assessed and paid, if appropriate, within 90 days of their filing. In the case of a deceased claimant, the payment is to be made to the deceased's estate or in the manner set forth in the bill. Payments made from the fund shall be in full satisfaction of all claims of or on behalf of the individual against the United States that arise out of both the HIV infection and treatment during the period of time noted. With regard to judicial review, any person whose claim is denied may seek judicial review in a district court of the U.S. The court shall review the denial on the administrative record and hold unlawful and set aside the denial if it was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.

Regulation of blood products

The Food and Drug Administration (FDA) regulates blood and blood products under two statutes which overlap to a certain degree: the Federal Food, Drug and Cosmetic Act [FFDCA][3] and the Public Health Services Act (PHSA)[4] and implementing regulations.[5] Current statutory and regulatory law operates to govern the licensing, production, testing, distribution, labeling, review and approval of all drugs and biologics. Under the FFDCA, drugs intended for the cure, mitigation, or prevention of disease, which include biologics such as blood and blood components or derivatives, are regulated.[6] Biological products are regulated by the FDA's Center for Biologics Evaluation and Review under the authority of the FFDCA, PHSA and implementing regulations.[7] The FDA is the primary agency for protecting the nation's blood supply and it is directed and authorized to regulate blood-banking, the handling of source plasma, and the manufacturer of blood products. Investigations of a new biological product is done under investigational new drug procedures found in the drug section of the FFDCA because the PHSA specifically regulates after the product is in the stream of commerce, not before. The enforcement and penalties provisions of the FFDCA can be applied to biological product manufacturers.

Under section 351 of the PHSA[8], blood products are regulated under the category of biological products. Current law provides that no person may sell, barter, exchange or offer to sell, barter, exchange or conduct interstate commerce of the same or bring from a foreign country any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic products, or analogous products applicable to the prevention, treatment, or cure of diseases or injuries of man unless the same has been propagated or manufactured and prepared at an establishment holding an unsuspended or unrevoked license, issued by the Secretary, to propagate or manufacture and prepare the biological product.

Moreover, the law provides that each package of the product must be plainly marked with the proper name of the product, the name, address and license number of the manufacturer and the expiration date. The statute prohibits the false labeling or marking of any package or container containing the biological product and authorizes department officials to inspect establishments. Current law governs licensing for both the establishment and the product. For example, the statute provides that licenses for the maintenance of the establishment are issued after a showing that the establishment and the products meet standards designed to insure the continued safety, purity and potency of the products. Further authority is provided for suspending and revoking licenses. Also, when a batch, lot or other quantity of a licensed product presents an imminent or substantial hazard to the public health, the Secretary shall issue an order, under 5 U.S.C. §554, immediately ordering the recall of the quantity. The assessment of civil money penalties is authorized for violations. Any person who violates this section or aids in the violation of this section may be punished upon conviction by a fine or imprisonment or both. In sum, the agency is authorized to enforce the law through various enforcement tools including, seizure, application for recall, injunction, criminal prosecution, or administrative techniques, e.g. suspension, revocation of license.[9]

Implementing regulations governing blood and blood products provide further detail. For example, 21 C.F.R. Part 600 addresses general standards for establishments that manufacture a product subject to licensing as a blood product. It defines critical terms, e.g., biological product, sterility, purity, establishment, etc. These regulations state that with respect to an establishment, a person shall be designated as the ''responsible head who shall exercise control of the establishment in all matters relating to compliance with the provisions'' of these regulations.[10] This part governs inspections with respect to time of inspection, duties of inspectors and more. In addition, regulations require other actions, for instance, the post-market reporting of adverse experiences.[11]

Part 601 governs two types of licensing: the establishment and the product.[12] The FDA is charged with issuing licenses only after all pertinent requirements and conditions are met. The agency is authorized to enforce provisions of current law through administrative measures to revoke or suspend a license. Provisions for review of the agency's decision regarding suspension or revocation are also addressed. Section 601.25 establishes the review procedures to determine that licensed biological products are safe and effective and not misbranded under prescribed, recommended or suggested conditions of use. Notably, Subpart E provides for the accelerated approval of biological products for serious or life threatening illnesses. This section permits the agency to approve products on a fast track to provide meaningful therapeutic benefit to patients over existing treatments, that is, to treat patients unresponsive to or intolerant of, available therapy.

To assist the agency in fulfilling its duty to evaluate the safety and effectiveness and labeling of biological products, Part 601 also authorizes the FDA to appoint advisory review panels to (1) evaluate the safety and effectiveness of biological products for which a license has been issued under §351 of the PHSA; (2) review the labeling of such biological products; and (3) advise the Commissioner on which of the biological products under review are safe, effective and not misbranded. The members of the panel shall be qualified experts, appointed by the Commissioner, and shall include persons from lists submitted by organizations representing professional, consumer, and industry interests. Such persons shall represent a wide divergence of responsible medical and scientific opinion. The Commissioner designates the chair of each panel (for each type of biological product) and minutes of all meetings must be made. Additionally, regulations provide that interested persons can participate in the advisory panels sessions to the extent that the FDA must publish a notice in the Federal Register requesting interested persons to submit, for review and evaluation by the advisory panel, published and unpublished data and information pertinent to the biological products.

To a certain extent, the industry regulates itself through the adherence to good manufacturing practices (GMPs). Part 606 sets forth these GMPs for blood[13] and blood components and provides uniform and industry-specific guidelines and requirements to insure safety, effectiveness, purity and other important features of blood products.[14] These regulations pertain to personnel of the establishment, e.g., requirement to designate person in control of establishment; facilities maintenance, e.g., adequate space, quarantine storage, orderly collection of blood, etc.; equipment, e.g., calibrated, properly maintained, etc.; and, supplies and reagents, e.g., storage in a safe, sanitary and orderly manner. The GMPs detail finished product controls, container labels, records and reporting procedures and importantly, the adverse reaction process.

Part 607 requires the registration of establishments which include human blood and plasma donor centers, blood banks, transfusion services, other blood product manufacturers and independent laboratories that engage in quality control and testing for registered blood product establishments. The regulations also provide special standards for human blood and blood products, some of which apply directly to those being treated for hemophilia. For example, Part 640 addresses the product known as Cryoprecipitated AHF, a preparation of antihemophilic factor which is obtained from a single unit of plasma collected and processed in a closed system. The source material for this product is plasma which may be obtained by whole blood collection or plasmapheresis.[16] The regulations establish procedures pertaining to the suitability of donors; the collection of source material; the testing of blood; processing; quality control; and further requirements. With specific regard to donor testing, the regulations provide that the blood from which the plasma is separated must be tested as prescribed in §§610.40 [Test for hepatitis B], 610.45 [Test for HIV] and 640.5 [Test for syphilis, blood group, and Rh factors]. The test must be conducted on a sample of the blood collected at the time of donation and the container must be properly labeled. Manufacturers of this product are responsible for testing and record-keeping. Moreover, quality control tests for potency of the antihemophilic factor must

be conducted each month on at least four representative containers of Cryoprecipitated AHF. The results must be maintained at the establishment for inspection and review by the FDA.

As soon from the above examination of statutory and regulatory law, the legal requirements and procedures, as well as industry GMPs, create a complex and far-reaching regulatory structure for biological products and blood products in particular. To a certain extent, under the FFDCA and the PHSA, the licensing of biologics is more restrictive than that for other regulated articles, e.g., new drug. For example, a new drug under the FFDCA needs an approved new drug application (NDA), however, a new biologic needs to fulfill higher requirements. A generic biological product such as a serum must be approved by the FDA under the PHSA for its purity, potency and effectiveness based upon data submissions.[16] The PHSA states that licenses for new products may be issued only upon a showing that meets these express standards.[17] Additionally, related regulations and GMPs must be fully satisfied to ensure compliance.

Second, manufacturers of the product are individually licensed as capable of making the product on the particular manufacturing site.[18] Regulations at Part 607, discussed above, must be fully met for each establishment and for each product. Enforcement and inspection authority under the Act may be triggered to address alleged violations of the law or regulations or to insure ongoing compliance. Inspectors are authorized to examine records of the licensed establishments while GMPs guide recordkeeping, facility and equipment management, personnel regulations and similar procedures. Moreover, the FDA inspectors are granted special inspection authority for biological products and special procedures apply. For instance, as noted above, a specific person must be designated as being in control of the facility for regulatory and compliance purposes.[19] Moreover, and particularly with regard to blood clotting agents for hemophilia, extensive and frequent testing of lots and batches is required after initial production. The FDA may exercise its enforcement authority under the FFDCA and PHSA to suspend or revoke the license for either the product or the establishment, to seize, to seek recalls, injunctions, assess penalties, and to exercise a range of impressive enforcement tools.[20]

The entire licensure process is complex and intended to insure purity, potency and prevent misbranding. Some view it as the functional equivalent to a NDA for a new drug. Regulation of biological products is more restrictive in scope and has appeared to evolve to meet the unique needs and characteristics of biological products. While there are many similarities in the regulation of the drugs, devices, and biological products during premarket and post-market phases, there appears to be a greater emphasis on regulatory standards and requirements for biologics at the manufacturing level. Commentators have noted that the unique and separate histories of the regulation of drugs and biologics may account for the difference in regulatory approach.[21] One reason may be attributed to the fact that the Biologics Act[22] predates the FFDCA and that it was not enforced by the FDA until 1972, when jurisdiction for these matters was transferred to the FDA from the National Institutes of Health. Extensive government involvement and regulation of the manufacturing process grew out of early tragic incidents when it was determined that microbes contaminated vaccines.[23] Thus, where the primary focus is on the final product for drugs and devices, for biologics, it was determined that government regulation was needed much earlier and more strictly than for other articles under the various pertinent statutes.

Additionally, blood and blood products are the subject of an articulated national policy. Other articles under the FFDCA and PHSA have not been focused upon nationally in such a way. In 1973, the National Blood Policy was announced and the Public Health Service, including the CDC, the FDA and NIH, was charged with responsibility for protecting the nation's blood supply. The Policy recognized that reliance on ''commercial sources of blood and blood components for transfusion, therapy . . . contributed to significantly disproportionate incidence of hepatitis, since such blood is often collected from sectors of society in which transmissible hepatitis is more prevalent.''[24] The Policy encouraged efforts to establish an all-volunteer blood donation system and to eliminate commercialized acquisition of blood and blood components.

The Policy listed four goals: to provide an adequate supply of blood; to ensure a higher quality of blood; to facilitate maximum accessibility to services; and to achieve total efficiency.[25] According to the Institute of Medicine's [IOM] 1995 study, the first actions under the policy included adoption of an all-volunteer blood collection system; coordination of costs; regionalization of blood collection and distribution; and, an examination of standards of care for hemophiliacs and other special groups. The Policy did not address the commercialization of plasma, the preparation and marketing of plasma derivatives, and the commercial acquisition of blood for diagnostic reagents.[26]

Contaminated blood products and brief overview of Government actions during the 1980's

In the context of blood products regulation and the government's focus on the nation's blood supply, events occurred in the 1980s which led hemophiliacs and others to contract HIV from contaminated blood and blood products. The IOM study indicates that in September of 1982, of the 593 cases of AIDs reported to the CDC, 3 were hemophiliacs. Later, the CDC noted that the hemophilia patients who had AIDS had all received large amounts of a commercially manufactured anticoagulant known as AHF (antihemophilic factor)[27] Evidence seemed to indicate that children with hemophilia were at risk for the disease.[28] As more cases were reported, the IOM report states that a national survey indicated that 30% or more of all hemophiliacs had abnormal immunological tests. By January 1983, evidence from CDC investigations strongly indicated that blood and blood products transmitted AIDS and that it could be transmitted through sexual contact. It appeared that AIDS was occurring in individuals with hemophilia who had received AHF concentrate.[29] In March, 1983, the PHS issued its first formal recommendations on the prevention of AIDS and with regard to hemophiliacs, the recommendation stated that work should continue toward development of safer blood products for use by hemophiliac patients.[30] H.R. 1023 states that thousands became infected with HIV through the use of contaminated blood clotting products.[31]

The IOM report indicates that numerous measures were publicized and taken with regard to blood and plasma donations, collection and use, e.g. quarantine and disposal. The FDA announced that it approved a heat treatment to inactivate viruses in AHF concentrate, which purported to help protect individuals with hemophilia from Hepatitis B, and perhaps, AIDs.[32] The IOM report states that: ''Government and private agencies identified, considered, and in some cases adopted strategies for dealing with the risk of transmitting AIDs through blood and blood products. The recommended safety measures were limited in scope. . . .''[33]

In 1983, the FDA's Blood Product Advisory Committee (BPAC) met to reconsider blood and blood products policies. One company recalled AHF concentrate when it determined that the concentrate was made from pools containing plasma from a person diagnosed with AIDs. However the IOM report notes that this recall was expressly not viewed as a recall of all such products and that the agency did not initially initiate a nationwide call of the concentrate.[34] The BPAC stated in mid-1983 that the criteria for deciding to withdraw lots of AHF concentrate should be based on evidence that plasma from a donor with AIDs had been present in the pooled plasma from which the lot was manufactured and recommended to the FDA a case-by-case decision regarding withdrawal for each lot that included plasma from a person who had AIDS or was suspected of having AIDS.[35] Some physicians switched from AHF concentrate to cryoprecipitate in those with less severe hemophilia. The IOM concluded ''[b]lood safety policies changed very little during 1983 [and that there] were missed opportunities to learn from pilot tests to screen potentially infected donors or implement other control strategies that had been rejected as national policy.''[36] Inaction relating to donor screening and surrogate marker testing was emphasized in the report.[37]

BPAC served as an advisory committee for the FDA and was the forum for industry and interested entities to participate in and influence the FDA's policy regarding blood products regulation.[38] According to the IOM report, BPAC's membership included blood and plasma organization representatives, scientists, and physicians.[39] The report concluded that valuable screening measures were not recommended by the BPAC due to uncertainties regarding scientific data, i.e., data from CDC, and ''pressures from the blood industry and special interest groups.''[40] Thus, options that could have reduced infection were not pursued. HIV testing and additional donor screening procedures were implemented in 1985. The IOM concluded that the FDA relied too heavily on BPAC and did not independently assess its recommendations and statements, and did not observe principles for proper management of advisory committees.[41] Moreover, IOM concluded that the membership of BPAC limited the information and points of view expressed to the agency and found possible issues relating to conflicts of interest. The report focused on the agency's role as being responsible for protecting the nation's blood supply, providing leadership and communication of information to those at risk.[42]

Conclusion to Part I

In sum, the blood and blood products regulation under the FFDCA and PHSA are restrictive and complex, governing primarily licensing of products and sites, as well as the final product, and authorize extensive enforcement actions. The FDA is the lead agency responsible for regulation of these articles and was charged with this responsibility in 1972. The products themselves seem to have been accorded special status, to a certain degree, under the statutes for regulation. Moreover, blood and blood products have been part of an articulated National Blood Policy. Events of the 1980s resulted in individuals with hemophilia, and many others, to contract HIV through the use of contaminated blood and blood products. This spurred intense examination of the FDA, its regulatory actions, and the use of its advisory committee BPAC, during this period. H.R. 1023, and S. 1189, were introduced to provide for payments from a trust fund to those with

blood clotting disorders who contracted HIV at this time.

PART II: TORT LIABILITY FOR INJURIES CAUSED BY DEFECTIVE BLOOD OR BLOOD PRODUCTS

''Products liability'' refers to the liability of a product manufacturer or subsequent seller for damages resulting from an injury caused by a product defect. Products liability is governed primarily by state common (i.e., court-made) law, as modified by state statute, although federal statutes occasionally preempt aspects of state products liability law. For example, prior to filing suit under state law for injuries caused by defective vaccines, one must file a claim under the National Children Vaccine Injury Act of 1986, as amended.[43]

Products liability differs from most other liability for non-intentional torts because products liability is strict liability, which means that, to recover, the plaintiff does not have to prove that the defendant was negligent (i.e., failed to exercise due care). All the plaintiff generally must prove in a products liability action is that the defendant sold a defective product and that the plaintiff's injury resulted from the defect.[44]

Products liability suits sometimes also allege a breach of warranty, on the theory that the fact that the product was defective constitutes a breach of the implied warranties that goods shall be merchantable (fit for ordinary purposes) and fit for any particular purpose for which they are required. These implied warranties arise under Uniform Commercial Code §§2–314 and 2–315, which has been enacted into law in every state but Louisiana. A suit for breach of warranty is similar to one for strict liability in tort in that in neither type of case need the plaintiff prove negligence. Breach of warranty suits predate strict tort liability suits, which came into being only in the 1960s.

One situation in which strict liability is generally not applied is in suits involving unavoidably unsafe products, among which, as noted below, some courts include blood. Restatement (Second) of Torts §402A comment k, which courts generally follow, provides: ''There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. This is especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging side effects when it is injected. Since the disease itself inevitably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it *unreasonably* dangerous'' [emphasis in original].

Case law

The seminal products liability blood transfusion case was *Perlmutter* v. *Beth David Hospital,* decided by the New York Court of Appeals in 1954.[45] It was a breach of warranty case (as it predated strict tort liability), and the issue was whether a transfusion constituted the sale of a product, in which case a transfusion of contaminated blood would constitute a breach of warranty, or whether it constituted the provision of a medical service, in which case the plaintiff would have to prove negligence to recover. This distinction was critical because there was no means to detect the presence of the hepatitis virus in blood, nor a practical method to treat the blood to eliminate the danger of hepatitis. Therefore, if the court deemed the transfusion a sale, it would turn hospitals into insurers of the risk of contaminated blood, but if it deemed it a service, then plaintiffs in most cases would go uncompensated because of the difficulty in proving negligence.

The court held that the transfusion should be treated as a service, because, ''when service predominates, and the transfer of personal property is but an incidental feature of the transaction, the transaction is not deemed a sale. . . .''[46] The *Perimutter* decision was widely followed by the courts, and extended to blood banks as well as hospitals. In *Community Blood Bank, Inc.* v. *Russell,* however, a Florida court found it ''a distortion to take what is, at least arguably, a sale, twist it into the shape of a service, and then employ this transformed material in erecting the framework of a major policy decision.''[47] This policy decision, of course, is whether ''the social utility of an abundant blood supply outweighs the risks to individuals''[48] The Florida court, needless to say, found the transfusion to be a sale, and a transfer of contaminated blood to be a breach of warranty.

''*Community Blood Bank* thus paved the way for the greatest assault on the *Perlmutter* citadel, which came in *Cunningham* v. *MacNeal Memorial Hospital,*[49] where the defendant once again was a hospital, not a blood bank.''[50] The plaintiff, who had contracted serum hepatitis from defective blood supplied by the hospital during a transfusion, asserted a claim in strict liability and won, with the court refusing to allow the hospital the defense that there was no means to detect the existence of serum hepatitis in whole blood. The court wrote: ''To allow a defense to strict liability on the ground that there is no way, either practical or theoretical, for a defendant to ascertain the existence of impurities in his product would be to emasculate the doctrine and in a very real sense return to a negligence theory.''[51]

Some courts, even if they treated a transfusion as the sale of a product and not as a service, found for the defendant under Restatement (Second) of Torts §402A comment k, mentioned above. They ''considered whether liability without fault was applicable in view of a claim that blood containing hepatitis is a product which is unavoidably unsafe and thus is not an unreasonably dangerous product for which the blood bank could be held liable without fault. With some authority to the contrary, the courts have reasoned that blood infected with hepatitis virus is such an unavoidably unsafe product, since there is a great need for blood for operations and surgical procedures, but the possibility of blood being infected with hepatitis cannot be totally eliminated despite due care being taken, and therefore they have held that a blood bank cannot be held liable without fault for injuries to a patient who contracted hepatitis from the blood it supplied.''[52]

Blood shield statutes; negligence suits

The Illinois legislature responded to the *Cunningham* decision by enacting a statute that provides, in part: ''The procuring, furnishing, donating, processing, distributing or using human whole blood, plasma, blood products, blood derivatives and products, corneas, bones, or organs or other human tissue for the purpose of injecting, transfusing or transplanting any of them in the human body is declared for purposes of liability in tort or contract [i.e., breach of warranty] to be the rendition of a service . . . and is declared not to be a sale of any such items and no warranties of any kind or description nor strict tort liability shall be applicable thereto, except as provided in Section 3 [which imposes liability for negligence].''[53]

A subsequent Illinois case upheld the constitutionality of this statute, writing: ''[I]t was predicted at the time *Cunningham* was handed down that the imposition of liability without fault on the distributors of blood would cause the cost of transfusions to skyrocket. . . . Moreover, implicit in the legislature's declaration of public policy is the fear that the imposition of strict tort liability would cause the financial considerations arising out of increased exposure to tort litigation to impinge on the exercise of sound medial judgment in a field where an individual's life might be at stake.''[54]

Illinois' approach is now the approach of all 50 states, with 48 states having enacted blood shield statutes, and Minnesota, New Jersey, and District of Columbia courts having reached the same result on their own.[55] Blood shield statues ''expressly characterize blood transfusions as services or explicitly state that blood transfusions will not be subject to strict liability.''[56] A 1990 Washington case articulated the policy justifications for blood shield statutes: ''First, the societal need to ensure an affordable, adequate bloody supply furnishes a persuasive reason for distinguishing between victims of defective blood and victims of other defective products. Second, strict liability cannot provide an incentive to promote all possible means of screening the blood for HIV. Third, although the producers may be in a better position to spread the costs, it is not in society's best interest to have the price of a transfusion reflect its true costs.''[57]

Blood shield statutes do not preclude all lawsuits alleging injuries caused by contaminated blood. Even in a state with a blood shield statute, one commentator notes, ''It seems likely that an action in express warranty or innocent tortious misrepresentation would lie if a supplier of a blood product misrepresented the product's safety, and a plaintiff relied on the misrepresentation to his detriment in the purchase of use of the product.''[58]

Another commentator addresses a different situation in which strict liability may remain: ''So blood shield statutes were expressly enacted to address only the threat of serum hepatitis, and it was not until after it was discovered that the HIV virus was transmittable through blood that legislatures amended these statutes to deal with potential AIDS liability. Courts have held that these amendments are not to be applied retroactively. Consequently, plaintiffs who received contaminated transfusions before the amendment are not barred by the blood shield statutes from bring strict liability actions.''[59]

A blood shield statute was also held inapplicable in a suit against a pharmaceutical company where the relevant statute (Indiana Code 16–41–12–11) applied to the distribution of blood by a ''bank, storage facility, or hospital.'' The Indian Court of Appeals wrote: ''[W]e simply cannot conclude that our legislature intended to include a pharmaceutical company, which commercially produces blood products for mass distribution, as an entity within the same class described as an organ or a blood ''bank or storage facility.'' The manufacture and distribution of blood products by pharmaceutical companies is better characterized as the sale of a product rather than the provision of a service. . . . It is quite unlikely that our legislature intended to include pharmaceutical companies in its definition of ''bank or storage facility'' simply because the manufacture or production of blood products incidentally involves their storage.''[60]

Finally, blood shield statutes do not, of course, preclude suits for damages caused by negligence, and, ''[w]ith strict liability effectively eliminated as a possible remedy [in transfusion cases], negligence remains the only viable alternative.''[61] ''To recover under a negligence cause of action a transfusion-related AIDS victim must prove that

a standard of care existed, that the defendant's conduct fell below that standards, and that this conduct was the proximate cause of the plaintiff's injury. Plaintiffs who have contracted AIDS through transfusions of blood and blood products have alleged negligence in both blood testing and donor screening.''[62]

It is relevant to note here that, in 1985, the Food and Drug Administration (FDA) licensed the enzyme-linked immunsorbent assay (ELISA) test, which ''has proven 98.6% effective in detecting exposure to AIDS [in blood], and when coupled with a second test, the Western Blot Analysis, the rate of detection rises to 100%.''[63] The existence of this test enables plaintiffs to argue that a failure to use this test constitutes negligence. A federal court of appeals wrote: ''We believe that the FDA's recommendation of February 19, 1985, that blood facilities begin testing all donated blood as soon as testing supplies become commercially available imposed a duty on [the blood bank] to test all its blood supplies for antibodies to the AIDS virus.''[64]

One commentator reports: ''As the rampant spread of AIDS continues and its devastating effects, both socially as well as personally, are being publicized, courts are weighing the consequences of the AIDS epidemic against the necessity of assuring an adequate supply of blood. . . . In the past several years, courts have started to rethink their position on denying recovery to victims of AIDS-tainted transfusions. Several approaches [to proving negligence] have been utilized with some success. These approaches include: (1) failure of the blood supplier or doctor to adequately warn the blood recipient of the inherent dangers associated with a blood transfusion [thus denying] the patient the opportunity to make an informed choice; (2) inadequate screening of blood donors [thus] allowing high-risk individuals to continue donating blood; and (3) using a blood transfusion when an alternate, safer method of sustaining life was available.''[65]

Selected recommendations in the legal literature; The National Childhood Vaccine Injury Act of 1986

One commentator writes: ''Although absolute protection for these entities [blood banks and blood product manufacturers] may have been logical or desirable when the HIV virus was undetectable in blood, the better view based on current medical and scientific knowledge would be to allow post-1985 recipients of contaminated transfusions to recover under the theories of strict liability and breach of warranty. This would place the burden on the blood banks and blood products manufacturers to ensure the safety of the products they distribute.''[66]

The same writer adds: ''Moreover, court and legislatures should distinguish between hospitals, blood banks, and blood products manufacturers. Blood banks, and especially blood products manufacturers, are active players in the economic marketplace, selling goods rather than providing services.''[67]

These views are echoed by another commentator: ''While hospitals may be characterized as service-providers, it is merely a legal fiction to so characterize blood and blood products providers. To hold them liable only in negligence—and then to allow the blood industry itself to set the standard of care accepted in the community, thus requiring innocent plaintiffs to shoulder an extraordinary burden of proof—violates all notions of fair play. It is time that blood products purchased for a price, and particularly manufactured blood derivative products, be recognized for the products they are. Even under the 402A comment k exception for ''unavoidably unsafe'' products, it would be unthinkable to term blood contaminated by the HIV virus as not ''unreasonably dangerous.'' It would be hard to think of anything more unreasonably dangerous.''[68]

An advocate of the blood shield statutes could respond to these arguments by quoting the justifications various courts have proffered for the statutes.[69]

Finally, one commentator proposes: ''The National Childhood Vaccine Injury Act (NCVIA) should serve as the structural model for ''alternative legislation.'' . . . [P]otential claimants should seek capped [no-fault] compensation in a court of claims on waiver of potential tort claims against blood products manufacturers. Petitions should receive compensation from a fund financed by both congressional appropriations and revenue raised through an industry tax based on the sale of blood products.''[70]

The National Childhood Vaccine Injury Act of 1986,[71] was enacted because Congress feared that some vaccine manufacturers might leave the market, which could create a genuine health hazard in the United States. The Act provides federal no-fault compensation to persons who suffer injury or death from specified vaccines. It allows more limited recovery than is generally allowed against manufacturers under state tort law, but it was hoped that ''the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation.''[72]

The Act established a National Vaccine Injury Compensation Program funded by a manufacturers' excise tax on certain vaccines. Persons injured by a vaccine administered after October 1, 1988, with claims of more than $1,000, may not sue the vaccine administrator or manufacturer unless they first file a petition in the United States Court of Federal Claims for compensation under the Program. Upon the filing of a petition, the court must issue a decision within a specified period. Under the Program, compensation is limited to actual reimbursable expenses, up to $250,000 for pain and suffering and emotional distress, $250,000 in the event of a vaccine-related death, actual and anticipated loss of earnings, and attorney's fees and other costs, but no punitive damages.

A petitioner dissatisfied with his recovery under the Program may reject it and file a tort suit (state statutes of limitations are stayed during the pendency of the federal petition), which is governed by state law, with some limitations, such as that there are rebuttable presumptions that manufacturers who comply with federal regulations are not subject to failure to warn suits or to punitive damages.

Treatment of blood and blood products in 104th Congress products liability legislation

On May 2, 1996, President Clinton vetoed H.R. 956, 104th Congress, the Common Sense Product Liability Legal Reform Act of 1996. On May 9, the House failed to override the veto.[73] The vetoed bill had been agreed upon in a House-Senate conference, which adopted the Senate version of the provision that dealt with blood and blood products.

Both the House and Senate versions addressed blood and blood products in their respective definitions of ''product.'' Section 108(8)(B) of the House-passed bill provided: ''The term [''product''] does not include . . . ''human tissue, human organs, human blood, and human blood products.''

Section 101(13)(B) of the Senate-passed bill, by contrast, provided: ''The term 'products' does not include . . . tissue, organs, blood, and blood products used for therapeutic or medical purposes, except to the extent that such tissue, organs, blood, and blood products (or the provision thereof), are subject, under applicable State law, to a standard of liability other than negligence. . . .''

The Senate bill, in others words, did apply to blood and blood products in strict liability and breach of warranty actions, although these actions are precluded by all state laws, except apparently in the limited instances noted on page 15 of this report.[74] The Senate-passed bill did not apply in blood and blood products that are the subject of negligence actions. The House-passed bill did not apply in any suits involving blood or blood products.

The committee report that accompanied the House bill states merely, with respect to the exclusion: ''Tissue, organs, blood, and blood products—that are human in origin— . . . are explicitly excluded from the product definition.''[75] The committee report that accompanied the Senate bill goes into more detail:[76] ''Claims for harm caused by tissue, organs, blood and blood products used for therapeutic or medical purposes are, in the view of most courts, claims for negligently performed services and are not subject to strict product liability.[77] The Act thus respects state law by providing that, in those states, the law with respect to harms caused by these substances will not be changed.[78] In the past, however, a few states have held that claims for these substances are subject to a standard of liability other than negligence, and this Act does not prevent them from doing so.[79] See, e.g., *Cunningham* v. *MacNeal Memorial Hosp.*, 266 N.E.2d 897 (Ill. 1970) (overturned by Ill. Ann. Stat. Ch. 111½, sections 2 and 3).[80] Such actions would be governed by the Act. . . .''[81]

The conference committee version of H.R. 956, as noted, adopted the Senate provision that dealt with blood and blood products (renumbered as § 101(14)(B)). The joint explanatory statement of the conference committee, did not, however, discuss the provision.[82]

Recent settlement[83]

On August 14, 1996, a federal judge gave preliminary approval to a settlement between hemophiliacs infected with AIDS and four pharmaceutical companies that allegedly had manufactured blood clotting products contaminated with HIV.[84] Judge John F. Grady of the U.S. District Court for the Northern District of Illinois tentatively certified a settlement class, preliminarily approved the settlement agreement, and authorized the parties to begin notifying class members.

The plaintiffs contended that the companies sold tainted blood clotting products from 1978 until 1985, when new heat sterilization procedures came into practice. Under the settlement, each class member would receive $100,000, regardless of the number of class members; the total number of class members reportedly could range as high as 10,000. A fairness hearing is scheduled before Judge Grady on November 25, 1996.

FOOTNOTES

[1] Sen. DeWine's bill is substantially similar to H.R. 1023.

[2] The bill indicates that Ricky Ray died at age 15 of hemophilia-associated AIDS.

[3] 21 U.S.C. §§301 et seq.

[4] 42 U.S.C. § 262.

[5] FDA regulations pertaining to blood products are set forth at 21 C.F.R. Parts 600 [Biological products; general]; 601 [Licensing]; 606 [Good manufacturing practices for blood and blood products]; 607 [Establishment registration and product listing for manufacturers of human blood and blood products]; 610 [General biological products standards]; and, 640 [Additional standards for human blood and blood products].

[6] 21 U.S.C. § 321(g)(1) [Definitions; drug].

[7] According to an intra-agency agreement that differentiates drugs and biologics, biologics include: vaccines, allergens and in vivo diagnostic allergenic products; human blood and blood derived products; immunoglobulin products; products composed of or intended to contact intact cells or intact microorganisms including viruses, bacteria, fungi, etc.; non-

antibiotic products that are proteins, peptides, or carbohydrate products produced by cell culture; protein products produced in animal body fluids by genetic alteration of the animal; venoms and their constituents; synthetically produced allergenic products intended to specifically alter the immune response to a specific antigen or allergen; and certain drugs used in conjunction with blood banking or transfusion. ''FDA's Intercenter Agreement,'' Treatise on Food and Drug Administration, James O'Reilly, §13.21 [Biological Products].

[8] 42 U.S.C. §262.

[9] The FDA is not authorized to mandate recalls.

[10] 21 C.F.R. §600.10.

[11] 21 C.F.R. §600.80.

[12] This also includes the licensing of foreign establishments and products.

[13] Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

[14] Component means that part of a single donor unit of blood separated by physical or mechanical means.

[15] Subpart F; 21 C.F.R. §640.50.

[16] 42 U.S.C. §262(d).

[17] Id.

[18] Id.; Food and Drug Regulation, James O'Reilly, §13.22.

[19] 21 C.F.R. Part 606.

[20] The FDA is authorized to act via the misbranding and adulteration sections of the FFDCA and can take various actions for enforcement under 21 U.S.C. §357.

[21] See, for example, Regulation of Biologics Manufacturing: Questioning the Premise, Food and Drug Law Journal, Vol. 49, No. 1, 1994, pp. 213, 216.

[22] The Act was originally enacted in 1902 and reenacted in 1944 when the PHSA was enacted; codified at 42 U.S.C. §262.

[23] FDLJ, infra, at 216.

[24] Reprinted in the Institute of Medicine's [IOM] ''HIV and the Blood Supply,'' National Academy of Sciences, 1995, p. 41.

[25] Id.

[26] Id.

[27] IOM, at p. 68.

[28] Id.

[29] Id., at p. 70. AHF concentrate is manufactured from pools containing plasma from donors.

[30] Id., at p. 73.

[31] H.R. 1023, §2 (10).

[32] Id., at p. 73.

[33] Id., at pp. 73–4.

[34] Id., at p. 74.

[35] Id., at p. 75.

[36] Id., at p. 75–6.

[37] IOM, at pp. 101–133.

[38] The FDA is authorized, or at times directed, to use advisory committees. The Federal Advisory Committee Act, FACA, is applicable to the FDA and defines ''advisory committee'' as any committee, board, commission, counsel, conference, panel task force or, other similar group . . . which is established by a statute, established or used by the President, or established or utilized by the one or more agencies in the interest of obtaining advice or recommendations.'' 5 U.S.C. App. §3. As discussed above, FDA regulations provide additional and specific requirements for advisory committees, how they are constituted, meetings, participation by interested persons, and similar issues.

[39] IOM, at p. 121.

[40] Id., at p. 127.

[41] IOM, at p. 213.

[42] Id., at p. 215.

[43] 42 U.S.C. §§300aa et seq., discussed infra, at pp. 18–19.

[44] To recover in a products liability suit, the plaintiff must prove that the defect was present at the time it left the hands of the defendant. If a defect was present at the time of manufacture, but a plaintiff sues a seller instead of the manufacturer, then the seller may recover from the manufacturer any damages it pays to the plaintiff. In the past decade, almost half the states have enacted statutes making product sellers other than manufacturers strictly liable only when the manufacturer cannot be sued or would be unable to satisfy a judgment. See Fifty-State Surveys of Selected Products Liability Issues (CRS Report No. 95–300 A).

[45] 123 N.E.2d 792 (N.Y. 1954).

[46] Id. at 794.

[47] 185 So.2d 749 (Fla. Dist. Ct. App. 1966), aff'd as modified, 196 So.2d 115 (Fla. 1967).

[48] Terri S. Hall, Bad Blood: Blood Industry's Immunity From Liability For Transfusion-Borne Disease, 12 Journal of Products Liability 25, 33 (1989).

[49] 266 N.E.2d 897 (Ill. 1970).

[50] Hall, supra note 48.

[51] Cunningham, supra note 49, at 902.

[52] Annotation, Liability of Blood Supplier or Donor for Injury or Death Resulting from Blood Transfusion, 34 ALR4th 508, 513.

[53] 745 Ill. Compiled Stat. Ann. 40/2 (Smith-Hurd).

[54] Glass v. Ingalls Memorial Hospital, 336 N.E.2d 495, 499 (Ill. 1975).

[55] Andrew R. Klein, Beyond DES: Rejecting the Application of Market Share Liability in Blood Products Litigation, 68 Tulane Law Review 883, 915 (1994). The citations to 44 of the 48 state blood shield statutes appear in M. Stuart Madden, PRODUCTS LIABILITY (2d ed. 1988 & Supp. 1993) §6.19 n.1. Minnesota repealed its statute, Minn. Stat. §525.928, in 1991.

[56] Dana J. Finberg, Blood Bank and Blood Products Manufacturer Liability in Transfusion-Related AIDS Cases, 26 University of Richmond Law Review 519, 524 (1992).

[57] Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 817 (Wash. 1990).

[58] Robert E. Cartwright and Jerry J. Phillips, PRODUCTS LIABILITY (1986 & Supp. 1992) at §4.03 (Supp. p. 127). Of course, a blood supplier may avoid this liability simply by not making warranties or representations as to a product's safety.

[59] Finberg, supra note 56, at 525–526.

[60] JKB, SR., and VB v. Armour Pharmaceutical Company, 660 N.E.2d 602 (Ind. App. 1996).

[61] Kathryn Glasgow Lofti, Suppliers of AIDS-Contaminated Blood Now Face Liability, 34 Howard Law Review 183, 196 (1991).

[62] Finberg, supra note 56, at 533.

[63] Id. at 521.

[64] Kirkendall v. Harbor Insurance Co., 887 F.2d 857, 861 (8th Cir. 1989).

[65] Lofti, supra note 61, at 200, 197.

[66] Finberg, supra note 56, at 537.

[67] Id.

[68] Hall supra note 48, at 43.

[69] See, text accompanying notes 54 and 57, supra.

[70] Klein, supra note 55, at 931, 932–933. The author of this proposal, however, would not allow a petitioner to use the no-fault compensation scheme unless he first ''demonstrate[d] a diligent, but unsuccessful, effort to prove which manufacturer produced the product that caused his infection. Thus, only plaintiffs unable to prove traditional cause in fact would use alternative legislation.'' Id. at 933.

[71] 42 U.S.C. §§300aa et seq. The summary of the Act that follows draws heavily from Lester S. Jayson, Handling Federal Tort Claims: Administrative and Judicial Remedies §1.25 (1996).

[72] H.R. Rep. No. 99–908, Part 1, 99th Cong., 2d Sess. 13 (1986).

[73] For additional information see The Products Liability Conference Committee Bill (CRS Rep. No. 96–276 A).

[74] See, text accompanying note 48, supra.

[75] H.R. Rep. No. 104–64, Part 1, 104th Cong., 1st Sess. 30 (1995).

[76] The footnotes that accompany the following quotation are all by the author of this memorandum; they do not appear in the Senate report.

[77] This, of course, is because the blood shield statutes generally preclude suits except in negligence.

[78] This statement does not explain the reluctance to change negligence actions involving tissue, organs, blood, and blood products, when there is no reluctance to change negligence actions involving other products. Section 102(a)(1) of the bill provides that the bill would apply to any product liability action (with exceptions not relevant here), and section 101(14) defines ''product liability action'' as ''a civil action brought under any theory [i.e., including negligence] for harm caused by a product.''

[79] This is true, but does not explain why the bill would apply to strict liability actions involving tissue, organs, blood, and blood products, but not to negligence actions involving those products. Whether the bill would apply to a particular type of suit is unrelated to the question of whether that type of suit may be brought. This is because the bill would affect only particular aspects of products liability suit; it would not alter their nature as negligence, breach of warranty, or strict liability suits.

[80] This statute was renumbered as indicated in note 53, supra.

[81] S. Rep. No. 104–69, 104th Cong., 1st Sess. 24 n.86 (1995).

[82] H.R. Rep. No. 104–481, 104th Cong., 2d Sess. (1996).

[83] The following is based on an article in 24 Products Safety & Liability Reporter 761 (Aug. 16, 1996).

[84] Walker v. Bayer AG (N.D. Ill., MDL No. 93–C–7452).

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HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING

(By Lauren B. Leveton, Harold C. Sox, Jr., and Michael A. Stoto)

EXECUTIVE SUMMARY

A nation's blood supply is a unique, life-giving resource and an expression of its sense of community. In 1993, voluntary donors gave over 14 million units of blood in the United States (Wallace, et al. 1993). However, the characteristic that makes donated blood an expression of the highest motives also makes it a threat to health. Derived from human tissue, blood and blood products can effectively transmit infections such as hepatitis, cytomegalovirus, syphilis, and malaria from person to person (IOM 1992). In the early 1980s blood became a vector for HIV infection and transmitted a fatal illness to more than half of the 16,000 hemophiliacs in the United States and over 12,000 blood transfusion recipients (CDC, MMWR; July 1993).

Each year, approximately four million patients in the United States receive transfusions of approximately 20 million units of whole blood and blood components. The blood for these products is collected from voluntary donors through a network of nonprofit community and hospital blood banks. Individuals with hemophilia depend upon blood coagulation products, called antihemophilic factor (AHF) concentrate, to alleviate the effect of an inherited deficiency in a protein that is necessary for normal blood clotting. The AHF concentrate is manufactured from blood plasma derived from 1,000 to 20,000 or more donors, exposing individuals with hemophilia to a high risk of infection by blood-borne viruses.

The safety of the blood supply is a shared responsibility of many organizations including the plasma fractionation industry, community blood banks, the federal government, and others. The Food and Drug Administration (FDA) has regulatory authority over plasma collection establishments, blood banks, and all blood products. Since 1973, the FDA has established standards for plasma collection and plasma product manufacture and a system for licensing those who met standards. The Centers for Disease Control and Prevention (CDC) has responsibility for surveillance, detection, and warning of potential public health risks within the blood supply. The National Institutes of Health (NIH) supports these efforts through fundamental research. During the 1950s and 1960s, blood shield laws were adopted by 47 states. These laws exempt blood and blood products from strict liability or implied warranty claims on the grounds that they are a service rather than a product. The laws were developed on the premise that given the inherently risky nature of blood and blood products, those providing them required protection if the blood system was to be a reliable resource.

As a whole, this system works effectively to supply the nation with necessary blood and blood products, and its quality control mechanisms check most human safety threats. The events of the early 1980s, however, revealed an important weakness in the system—in its ability to deal with a new threat that was characterized by substantial uncertainty. With intent to prepare the guardians of the blood supply for future threats concerning blood safety, the Department of Health and Human Services commissioned the Institute of Medicine to study the

transmission of HIV through the blood supply. The Committee to Study HIV Transmission Through Blood and Blood Products undertook this assignment fully aware of the advantages and dangers of hindsight. Hindsight offers an opportunity to gain the understanding needed to confront the next threat to the blood supply. The danger of hindsight is unfairly finding fault with decisions that were made in the context of great uncertainty.

HISTORY

The Risk of AIDS

Starting with the identification of 26 homosexual men with opportunistic diseases in June 1981, the CDC's *Morbidity and Mortality Weekly Report* became the source for reports of the epidemic. By July 1982, enough cases had occurred with common symptomatology to name the new disease ''acquired immune deficiency syndrome'' (AIDS). By January 1983, epidemiological evidence from CDC's investigations strongly suggested that blood and blood products transmitted the agent causing AIDS and that the disease could also be transmitted through intimate heterosexual contact. The conclusion that the AIDS agent was blood-borne was based on two findings. First, AIDS was occurring in transfusion recipients and individuals with hemophilia who had received AHF concentrate; these patients did not belong to any previously defined group at risk for contracting AIDS. Second, the epidemiologic pattern of AIDS was similar to hepatitis B, another blood-borne disease.

Immediate Responses to Evidence of Blood-Borne AIDS Transmission

In the first months of 1983, the epidemiological evidence that the AIDS agent was blood-borne led to meetings and public and private decisions that set the pattern of the blood industry's response to AIDS, starting with a public meeting convened by the CDC in Atlanta on January 4, 1983. Later that month, the leading blood bank organizations, and, separately, the National Hemophilia Foundation (NHF) and the blood products industry, issued statements about preventing exposure to AIDS. In March 1983, the Assistant Secretary for Health promulgated the first official Public Health Services (PHS) recommendations for preventing AIDS, and the FDA codified safe practices for blood and plasma collection.

The government and private agencies quickly identified, considered, and in some cases adopted strategies for dealing with the risk of transmitting AIDS through blood and blood products. The recommended safety measures, however, were limited in scope. Examples include: questions to eliminate high-risk groups such as intravenous drug users, recent immigrants from Haiti, and those with early symptoms of AIDS or exposure to patients with AIDS; direct questions about high-risk sexual practices were generally not used. These questions reflected a lack of consensus about the magnitude of the threat, especially among physicians and public health officials who had trouble interpreting the unique epidemiological pattern of AIDS. The recommendations also reflected uncertainty about the benefits of identifying and deferring potentially infected blood and plasma donors, treatment of blood products to inactivate viruses, recall of products derived from donors known to have or suspected of having AIDS, and changes in transfusion practice and blood product usage. The costs, risks, and benefits of these and other potential control strategies were uncertain.

Opportunities to Reformulate Policy

In the interval between the decisions of early 1983 and the availability of a blood test for HIV in 1985, public health and blood industry officials became more certain that AIDS was a blood-borne disease as the number of reported cases of AIDS among hemophiliacs and transfused patients grew. As their knowledge grew, these officials had to decide about recall of contaminated blood products and possible implementation of a surrogate test for HIV. Meetings of the FDA's Blood Products Advisory Committee in January, February, July and December 1983 offered major opportunities to discuss, consider, and reconsider the limited tenor of the policies.

Despite these and other opportunities to review new evidence and to reconsider earlier decisions, blood safety policies changed very little during 1983. Many officials of the blood banks, the plasma fractionation industry, and the FDA accepted with little question estimates that the risk of AIDS was low (''one in a million transfusions''), and they accepted advice that control strategies (such as automatic withdrawal of AHF concentrate lots containing blood from donors suspected of having AIDS, or a switch from AHF concentrate to cryoprecipitate in mild or moderate hemophiliacs) would be ineffective, too costly, or too risky. During this period, there were missed opportunities to learn from local attempts to screen potentially infected donors or implement other control strategies that had been rejected as national policy.

Research Activities

From 1983 through 1985, research on AIDS included epidemiological analysis to understand patterns of spread and etiology, the search for methods to control or eliminate the disease, and evaluation of the efficacy of potential safety measures such as surrogate tests for the infection. Related research on methods to inactivate hepatitis B virus in AHF concentrate had begun in the 1970s and came to fruition in the early 1980s.

Scientists at the Pasteur Institute in Paris first isolated the retrovirus now known as HIV–1 in 1983. Investigators at the National Institutes of Health (NIH) provided convincing evidence that HIV–1 was the causative infectious agent of AIDS in 1984, and were also able to propagate HIV–1 in the laboratory, thus providing the basis for a blood test to identify individuals infected by the virus. Scientists at NIH isolated and characterized HIV in 1984. Viral inactivation methods for AHF concentrate were developed in laboratories of the plasma fractionators, and the FDA licensed the new processes quickly. Although the pace of viral inactivation research had been slow, it accelerated in the 1980s, largely in response to hepatitis, and had identified effective strategies by 1984. However, research into other potential ways to safeguard the blood supply such as the use of surrogate tests was not pursued vigorously, and there was relatively little research on blood safety issues per se.

FINDINGS

The Committee framed its approach by examining four topics that are essential components of a focused strategy for ensuring the safety of the blood supply: blood product treatment, donor screening and deferral, regulation of removal of contaminated products from the market, and communication to physicians and patients.

Product Treatment

Plasma products can be treated by a variety of physical and chemical processes to inactivate viruses and thus to produce a product free from contamination and relatively safe for transfusion. Shortly after the development of the technology to manufacture AHF concentrate, it was recognized that these products carried a substantial risk of transmitting hepatitis B. Although some blood derivative products had been treated with heat to destroy live viruses since the late 1940s, Factor VIII and IX concentrates in the United States were not subject to viral inactivation procedures until 1983 and 1984. If this technology had been developed and introduced before 1980 to inactivate hepatitis B virus and non-A, non-B hepatitis virus, fewer individuals with hemophilia might have been infected with HIV.

Overall, the record of the plasma fractionators and the FDA with respect to the development and implementation of heat treatment is mixed. The Committee's analysis focused on whether the basic knowledge and technology for inactivating viruses in AHF concentrate had been available before 1980 and whether industry had appropriate incentives (from FDA, NIH, NHF, or others) to develop viral inactivation procedures. In the Committee's judgment, heat treatment processes to prevent the transmission of hepatitis, an advance that would have prevented many cases of AIDS in individuals with hemophilia, might have been developed before 1980. For a variety of reasons (e.g., concern about possible development of inhibitors and higher costs), however, neither physicians caring for individuals with hemophilia nor the Public Health Service agencies actively encouraged the plasma fractionation companies to develop heat treatment measures earlier. The absence of incentives, as well as the lack of a countervailing force to advocate blood product safety, contributed to the plasma fractionation industry's slow rate of progress toward the development of heat-treated products. Once plasma fractionators developed inactivation methods, however, the FDA moved expeditiously to license them.

Donor Screening and Deferral Policies

The purpose of donor screening and deferral procedures is to minimize the possibility of transmitting an infectious agent from a unit of donated blood to the recipient of that unit, as well as to ensure the welfare of the donor. Donor screening includes the identification of suitable donors; the recruitment of donors; and the exclusion of high-risk individuals through methods and procedures used at the time of donation, such as questionnaires, interviews, medical exams, blood tests, and providing donors with the opportunity to self-defer. Donor deferral is the temporary or permanent rejection of a donor based on the results of the screening measures.

By January 1983, in addition to suggesting that the agent causing AIDS was transmitted through blood and blood products and could be sexually transmitted, the epidemiological evidence also demonstrated that there were several groups who had an increased risk of developing AIDS. The highest incidence of the disease was in male homosexuals, who donated blood frequently in some geographic regions. The Committee found that organizations implemented donor screening measures in different ways at different times. Plasma collection agencies had begun screening potential donors and excluding those in any of the known risk groups as early as December 1982, and CDC scientists suggested in January 1983 that blood banks do likewise. Also in January, the blood-banking organizations (the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Center) issued a joint statement that recommended the use of donor screening questions to detect early symptoms of AIDS or exposure to AIDS patients. The statement, however, did not advocate directly questioning donors about their sexual preferences. Blood banks did institute some screening

measures in early 1983, but only a few asked potential donors questions about homosexual activities. At the same time, CDC scientists also suggested that all blood and plasma collection agencies employ an available surrogate test for hepatitis B core antigen (anti-HBc). Most blood and plasma collection agencies rejected this recommendation. Although the precise impact of these two actions is not known, earlier implementation of either probably would have reduced the number of individuals infected with HIV through blood and blood products. In March 1983 the PHS issued recommendations that identified high-risk individuals for AIDS and stated that these individuals should not donate plasma or blood.

Based on its review of the evidence, the Committee found that decisionmakers involved with donor screening and deferral acted with good intent in some instances. In other instances, however, preference for the status quo under the prevailing conditions of uncertainty and danger led decisionmakers to underestimate the threat of AIDS for blood recipients. The Committee concluded that when confronted with a range of options for using donor screening and deferral to reduce the probability of spreading HIV through the blood supply, blood bank officials and federal authorities consistently chose the least aggressive option that was justifiable. In adopting this limited approach, policymakers often passed over options that might have initially slowed the spread of HIV to individuals with hemophilia and other recipients of blood and blood products, for example, by screening male donors for a history of sexual activity with other males and screening donated blood for the anti-HBc antibody. The Committee believes that it was reasonable to require blood banks to implement these two screening procedures in January 1983. The FDA's failure to require this is evidence that the agency did not adequately use its regulatory authority and therefore missed opportunities to protect the public health.

Regulations and Recall

The FDA is the principal regulatory agency with authority for blood and blood products, but it exercises its authority largely through informal action. Recall—the removal of a product from the market—exemplifies the relationship between the FDA's potent formal powers and its informal modus operandi. Recall is a voluntary act undertaken by the manufacturer but overseen by the FDA, which has the authority to seize or revoke the license of a product. Regulation of blood and blood products has been generally based on establishing a scientific consensus. Because the FDA's resources are limited, it relies upon the blood industry and others for cooperation. The FDA's Blood Products Advisory Committee is a venue for consensus-building about blood regulatory policy. In an industry in which firm and product reputation is critical to market success, the FDA's collegial approach is usually effective.

The Committee analyzed the FDA's exercise of its regulatory powers by examining how it acted during four critical events: (1) letters issued by the FDA in March 1983 requiring particular practices related to donor screening and the segregation of high-risk plasma supplies; (2) a July 1983 decision not to recall plasma products ''automatically'' whenever they could be linked to individual donors who had been identified as having or as suspected of having AIDS; (3) a decision not to recall nontreated AHF concentrate when heat-treated AHF concentrate became available in 1983; and (4) a delay of years in the FDA's formal decision to recommend tracing recipients of transfusions from a donor who was later found to have HIV. For each of these, the Committee posed a series of hypotheses to explain the FDA's actions. These focused on the reach of the agency's legal powers, the information available at the time in relation to relevant public health considerations, the agency's resources, the FDA's institutional culture, the economic costs of particular actions, and the prevailing political climate.

The analysis of these four events led the Committee to identify several weaknesses in the FDA's regulatory approach to blood safety issues. The agency's March 1983 letters may have been unclear concerning whether all of their recommendations were required to be implemented by the addressed. Handling of the case-by-case recall decision suggested that the agency lacked both the capacity to structure its advisory process adequately and to analyze independently the recommendations that were made to it. In the Committee's judgment, these and other events indicate the need for a more systematic approach to blood safety regulation when there is uncertainty and danger to the public.

Communication to Physicians and Patients

As evidence accrued on the possibility that the blood supply was a vector for AIDS consumers of blood and blood products and their physicians found themselves in a complex dilemma about how to reduce the risk of infection. Restricting or abandoning the use of blood and blood products could lead to increased mortality and morbidity. On the other hand, continued use of these products apparently increased the risk of AIDS. The Committee investigated the processes by which physicians and patients obtained information about the epidemic and the costs, risks, and benefits of their clinical options.

A wide range of clinical options were available by late 1982 and might, in some instances, have reduced or eliminated dependence on AHF concentrate and there by reduce the risk of HIV transmission. As often happens in times of intense scientific and medical uncertainty such as in the early 1980s, individuals with hemophilia and transfusion recipients had little information about risks, benefits, and clinical options for their use of blood and blood products.

The dramatic successes of treatment with AHF concentrate in the 1970s provided a context in which thresholds for abandoning or radically restricting the use of these products for individuals with severe hemophilia were high. both physicians and individuals with hemophilia express reluctance about returning to the era of clinical treatment before the introduction of AHF concentrate. The National Hemophilia Foundation (NHF) and physicians, in their effort to find the right balance between the risks and benefits of continued use of AHF concentrate, tended to overweight the well-established benefits of AHF concentrate and underestimate the risks of AIDS, which were still uncertain.

In addition, the Committee found that prevailing assumptions about medically acceptable risks, especially regarding hepatitis, led to complacency and a failure to act with sufficient concern upon reports of a new infectious risk. Ultimately, assumptions about medical decisionmaking practices in which patient played a relatively passive role led to failures to disclose completely the risk of using AHF concentrate and thereby did not enable individuals to make informed decisions of themselves. As the potential dimensions of the epidemic among individuals with hemophilia became clear, communication between physicians and patients was further compromised by physicians' reticence to discuss the dire implications of widespread infection with their patients and families.

Institutional barriers to patient-physician communications and relationships between relevant organizations also impeded the flow of information. If the NHF had received input from a wider group of scientific and medical experts, more explicit and systematic dissemination of a range of clinical options might well have been possible. In addition, the financial and other relationships between the NHF and the plasma fractionation industry created a conflict of interest that seriously compromised the perceived independence of NHF's recommendations.

No organization stepped forward to communicate widely the risks of blood transfusions to potential recipients. Many blood bank officials during this period publicly denied that AIDS posed any significant risk to blood recipients. In this context, and because many transfusions occurred on an emergency basis, patients were typically not apprised of the growing concerns about the contamination of the blood supply. For both individuals with hemophilia and recipients of blood transfusion, physicians concern that their patients might refuse care deemed a ''medical necessity'' further contributed to failure to inform them of the risks.

CONCLUSIONS

Decisionmaking Under Uncertainty

The events and decisions that the Committee has analyzed underscore the difficulty of personal and institutional decisionmaking when the stakes are high, when knowledge is imprecise and incomplete, and when decisionmakers may have personal or institutional biases. The Committee attempted to understand the complexities of the decisionmaking process during this uncertain period and to develop lessons to protect the blood supply in the future. In retrospect, the system did not deal well with contemporaneous blood safety issues such as hepatitis, and was not prepared to deal with the far greater challenge of AIDS.

Although enough epidemiological evidence has emerged by January 1983 to strongly suggest that the agent causing AIDS was transmitted through blood and blood products and could be sexually transmitted to sexual partners, the magnitude of the risk for transfusion and blood product recipients was not know at this time. Policymakers quickly developed several clinical and public health options to reduce the risk of AIDS transmission. There was, however, substantial scientific uncertainty about the costs and benefits of the available options. The result was a pattern of responses which, while not in conflict with the available scientific information, were very cautious and exposed the decisionmakers and their organizations to a minimum of criticism.

Blood safety is a shared responsibility of many diverse organizations. They include U.S. Public Health Service agencies such as the CDC, the FDA, and the NIH, and private-sector organizations such as community blood banks and the American Red Cross, blood and plasma collection agencies, blood product manufacturers, groups like the National Hemophilia Foundation, and others. The problems the Committee found indicated a failure of leadership and inadequate institutional decision making process in 1983 and 1984. No person or agency was able to coordinate all of the organizations sharing the public health responsibility for achieving a safe blood supply.

Bureaucratic Management of Potential Crises

Federal agencies had the primary responsibility for dealing with the national emergency posed by the AIDS epidemic. The Committee scrutinized bureaucratic function closely and came to the following conclusions about the management of potential crises.

First, unless someone from the top exerts strong leadership, legal and competitive concerns may inhibit effective action by agencies of the federal government. Similarly, when policymaking occurs against a backdrop of a great deal of scientific uncertainty, bureaucratic standard operating procedures designed for routine circumstances seem to take over unless there is a clear-cut decision-making hierarchy. An effective leader will insist upon coordinated planning and execution. Focusing efforts and responsibilities, setting timetables and agendas, and assuming accountability for expeditious action cannot be left to ordinary standard operating procedures. These actions are the responsibilities of the highest levels of the public health establishment.

Second, the FDA and other agencies in the early 1980s lacked a systematic approach to conducting advisory committee processes. These agencies should tell their advisory committees what it expects from them, keep attention focused on high-priority topics, and independently evaluate their advice. Because mistakes will always be made and opportunities missed, regulatory structures must organize and manage their advisory boards to assure both the reality and the continuous appearance of propriety.

Third, agencies should not rely upon the entities they regulate for analysis of data and modeling of decision problems.

Fourth, agencies need to think far ahead. They must monitor more systematically the long-term outcomes of blood transfusion and blood product infusion to anticipate both new technologies and new threats to the safety of the blood supply. The Committee believes that the Public Health Service should plan what it will do if there is a threat to the blood supply. It should specify actions that will occur once the level of concern passes a specified threshold. The Committee favors a series of criteria or triggers for taking regulatory or other public health actions in which the response is proportional to the magnitude of the risk and the quality of the information on which the risk estimate is based. Taking on small steps allows for careful reconsideration of options, particularly as information about uncertain risks unfolds. Not all triggering events need lead to drastic action; some may merely require careful reconsideration of the options or obtaining new information.

RECOMMENDATIONS

The Committee's charge was to learn from the events of the early 1980s to help the nation prepare for future threats to the blood supply. From the record assembled for this study, the Committee identified potential problems with the system in place at that time and has identified some changes that might have moderated some of the effects of the AIDS epidemic on recipients of blood and blood products. The federal and private organizations responsible for blood safety and the public health more generally will have to evaluate their current polices and procedures to see if they fully address the issues raised by these recommendations.

The Public Health Service

Several agencies necessarily play important, often differentiated, roles in managing a public health crisis such as the contamination of blood and blood products by the AIDS virus. The National Blood Policy of 1973 charged the PHS (including the CDC, the FDA, and the NIH) with responsibility for protecting the nation's blood supply.

The Committee has come to believe that a failure of leadership may have delayed effective action during the period from 1982 to 1984. This failure led to less than effective donor screening, weak regulatory actions, and insufficient communication to patients about the risks of AIDS. In the event of a threat to the blood supply, the Public Health Service must, as in any public health crisis, insist upon coordinated action. The Secretary of Health and Human Service is responsible for all the agencies of the Public Health Service,[1] and therefore the Committee makes—Recommendation 1: The Secretary of Health and Human Services should designate a Blood Safety Director, at the level of a deputy assistant secretary or higher, to be responsible for the federal government's efforts to maintain the safety of the nation's blood supply.

To be effective in coordinating the various agencies of the PHS, 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 considering the history of the contamination of the blood supply with HIV and the current surveillance, regulatory, and administrative structures for ensuring the safety of our nation's blood resources, the Committee became convinced that the nation needs a far more responsive and integrated process to ensure blood safety. To this end, the Committee makes—Recommendation 2: The PHS should establish a Blood Safety Council to assess current and potential future threats to the blood supply, to propose strategies for overcoming these threats, to evaluate the response of the PHS to these proposals, and to monitor the implementation of these strategies. The Council should report to the Blood Safety Director (see Recommendation 1). The Council should also serve to alert scientists about the needs and opportunities for research to maximize the safety of blood and blood products. The Blood Safety Council should take the lead to ensure the education of public health officials, clinicians, and the public about the nature of threats to our nation's blood supply and the public health strategies for dealing with these threats.

The proposed Blood Safety Council would facilitate the timely transmission of information, assessment of risk, and initiation of appropriate action both during times of stability and during a crisis. The Council should report to the Blood Safety Director (see Recommendation 1). The Council would not replace the PHS agencies responsible for blood safety but would complement them by providing a forum for them to work together and with private organizations. The PHS agencies would be represented on the Council.

The Blood Safety Council should consider the following activities and issues: to deliberate the need for a system of active surveillance for adverse reactions in blood recipients; to establish a panel of experts to provide information about risks and benefits, alternative options for treatment, and recommended best practices (see Recommendation 13); and to investigate methods to make blood products safer, such as double inactivation processes and reduction of plasma pool size.

When a product or service provided for the public good has inherent risks, the common law tort system fails to protect the rightful interests of patients who suffer harms resulting from the use of those products and services. To address this deficiency, the Committee makes—Recommendation 3: The federal government should consider establishing a no-fault compensation system for individuals who suffer adverse consequences from the use of blood or blood products.[2]

For such a no-fault system to be effective, standards and procedures would have to be determined prospectively to guide its operations. There needs to be an objective, science-based process to decide which kinds of adverse outcomes are caused by blood-borne pathogens and which individual cases of these adverse outcomes deserve compensation. As with vaccines, such a system could be financed by a tax or fee paid by all manufacturers or by the ultimate recipients of blood products. However, had there been a no-fault compensation system in the early 1980s, it could have relieved much financial hardship suffered by many who became infected with HIV through blood and blood products in the United States. The no-fault principles outlined in this recommendation might serve to guide policymakers as they consider whether to implement a compensation system for those infected in the 1980s.

The Centers for Disease Control and Prevention

The CDC has an indispensable role in protecting our nation's health: to detect potential public health risks and sound the alert. In order to improve CDC's efficacy in this critical role, the Committee makes—Recommendation 4: Other federal agencies must understand, support, and respond to the CDC's responsibility to serve as the nation's early warning system for threats to the health of the public.

One way to begin to implement this recommendation is for the Secretary of Health and Human Services to insist that an agency that wishes to disregard a CDC alert should support its position with evidence that meets the same standard as that used by the CDC in raising the alert.

In order to carry out its early warning responsibility effectively, the CDC needs good surveillance systems. The Committee, believing that the degree of surveillance should be proportional to the level of risk inherent in blood and blood products and should include both immediate and delayed effects, makes Recommendation 5: The PHS should establish a surveillance system, lodged in the CDC, that will detect, monitor, and warn of adverse effects in the recipients of blood and blood products.

The Food and Drug Administration

The FDA has legal authority to protect the safety of the nation's blood supply, and it is the lead federal agency in regulating blood banking practice, the handling of source plasma, and the manufacture of blood products from plasma. The Committee's recommendations focus on decisionmaking and the role of advisory committees in formulating the FDA's response to crises.

In the Committee's judgment, a more systematic approach to blood safety regulation, one that is better suited to conditions of uncertainty, is needed. In particular, the Committee recommends (see Chapter 8) that the PHS develop a series of criteria or triggers for taking regulatory or other public health actions for which the response is proportional to the magnitude of the risk and the quality of the information on which the risk estimate is based. In order that the perfect not be the enemy of the good, the Committee makes—Recommendation 6: Where uncertainties or countervailing public health concerns preclude completely eliminating potential risks, the FDA should encourage, and where necessary require, the blood industry to implement partial solutions that have little risk of causing harm.

In all fields, decisionmaking under uncertainty requires an iterative process. As the knowledge base for a decision changes, the responsible agency should reexamine the facts and be prepared to change its decision. The agency should also assign specific responsibility for monitoring conditions and identifying opportunities for change. In order to implement these principles at the FDA, the Committee makes—Recommendation 7: The FDA should periodically review

Footnotes appear at the end of article.

important decisions that it made when it was uncertain about the value of key decision variables.

Although the FDA has a great deal of regulatory power over the blood products industry, the agency appears to regulate by expressing its will in subtle, understated directives. Taking this into account, the Committee makes—Recommendation 8: Because regulators must rely heavily on the performance of the industry to accomplish blood safety goals, the FDA must articulate its requests or requirements in forms that are understandable and implementable by regulated entities. In particular, when issuing instructions to regulated entities, the FDA should specify clearly whether it is demanding specific compliance with legal requirements or is merely providing advice for careful consideration.

In the early 1980s, the FDA appeared too reliant upon analyses provided by industry-based members of the Blood Products Advisory Committee (BPAC). Thus the Committee arrived at—Recommendation 9: The FDA should ensure that the composition of the Blood Products Advisory Committee reflects a proper balance between members who are connected with the blood and blood products industry and members who are independent of industry.

An agency that is well-practiced in orderly decisionmaking procedures will be able to respond to the much greater requirements of a crisis. This consideration leads to—Recommendation 10: The FDA should tell its advisory committees what it expects from them and should independently evaluate their agendas and their performance.

Advisory committees provide scientific advice to the FDA, but they do not make regulatory decisions for the agency. The FDA's lack of independent information and an analytic capability of its own meant that it had little choice but to incorporate the advice of BPAC into its policy recommendations. To ensure the proper degree of independence between the FDA and the BPAC, the Committee makes—Recommendation 11: The FDA should develop reliable sources of the information that it needs to make decisions about the blood supply. The FDA should have its own capacity to analyze this information and to predict the effects of regulatory decisions.

Communication to Physicians and Patients

One of the crucial elements of the system for collecting blood and distributing blood products to patients is the means to convey concern about the risks inherent in blood products. In today's practice of medicine, in contrast to that of the early 1980s, patients and physicians each accept a share of responsibility for making decisions.

In instances of great uncertainty, it is crucial for patients to be fully apprised of the full range of options available and to become active participants in the consideration and evaluation of the relative risks and benefits of alternative treatments. To encourage better communication, the Committee makes—Recommendation 12: When faced with a decision in which the options all carry risk, especially if the amount of risk is uncertain, physicians and patients should take extra care to discuss a wide range of options.

Given the inherent risks and uncertainties in all blood products, the public and providers of care need expert, unbiased information about the blood supply. This information includes risks and benefits, alternatives to using blood products, and recommended best practices. In order to provide the public and providers of care with information they need, the Committee makes—Recommendation 13: The Department of Health and Human Services should convene a standing 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.

One lesson of the AIDS crisis is that a well-established, orderly decisionmaking process is important for successfully managing a crisis. This applies as much to clinical decisionmaking as to the public health decision process addressed by earlier recommendations. As the narrative indicates, there are both public health and clinical approaches to reducing the risk of blood-borne diseases. The Blood Safety Council called for in Recommendation 2 would deal primarily with risk assessment and actions in the public health domain that would reduce the chance that blood products could be vectors of infectious agents. The primary responsibility of the expert panel on best practices called for in Recommendation 13 would be to provide the clinical information that physicians and their patients need to guide their individual health care choices. To be most effective, this panel should be lodged in the Blood Safety Council (see Recommendation 2) so that both bodies can interact and coordinate their activities in order to share information about emerging risks and clinical options.

Recommendation 14: Voluntary organizations that make recommendations about using commercial products must avoid conflicts of interest, maintain independent judgment, and otherwise act so as to earn the confidence of the public and patients.

One of the difficulties with using experts to give advice is the interconnections that experts accumulate during their careers. As a result, an expert may have a history of relationships that raise concerns about whether he or she can be truly impartial when advising a course of action in a complex situation. One way to avoid these risks is to choose some panelists who are not expert in the subject of the panel's assignment but have a reputation for expertise in evaluating evidence, sound clinical judgment, and impartiality.

Financial conflicts of interest influence organizations as well as individuals. The standards for acknowledging, and in some cases avoiding, conflicts of interest are higher than they were 12 years ago. Public health officials, the medical professions, and private organizations must uphold this new, difficult standard. Failure to do so will threaten the fabric of trust that holds our society together.

REFERENCES

Centers for Disease Control, Morbidity and Mortality Weekly Report, July 23, 1993. Institute of Medicine, Emerging Infections. Washington, D.C.: National Academy Press, 1992.

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FOOTNOTES

[1] In the 1980s and now, the PHS agencies report to the Assistant Secretary of Health. As this report was being written, the Department of Health and Human Services has proposed to eliminate the office of the Assistant Secretary, so that the PHS agencies would report directly to the Secretary.

[2] One Committee member (Martha Derthick) abstains from this recommendation because she believes that it falls outside of the Committee's charge.

Mr. SCOTT. Madam Speaker, I yield such time as he may consume to the distinguished gentleman from Massachusetts (Mr. DELAHUNT).

Mr. DELAHUNT. Madam Speaker, I thank the gentleman for yielding me the time.

Madam Speaker, I, too, rise in strong support of H.R. 1023, the Ricky Ray Hemophilia Relief Fund Act. Before I begin my statement, I want to acknowledge and commend the fine work of my colleague, the gentleman from Florida (Mr. PORTER GOSS). He has truly provided outstanding leadership in this particular issue.

Let me ask Members to imagine that they are the parent of three fine sons, each of whom has inherited the gene for hemophilia. Now imagine, if you can, that each of your sons acquires the AIDS virus through a contaminated blood transfusion. Two brothers die before age 40, and the third is very sick. Among them, they have 9 children, your grandchildren, all of whom will be left fatherless.

At least one family in my district does not have to imagine what that would be like, Madam Speaker. They know, because this is precisely what is happening to them. Nor is their heartbreaking story, unfortunately, unique. I have received letters from people in Abingdon, Weymouth, Ducksbury, and other towns throughout Massachusetts who have lost family members and friends to hemophilia-associated AIDS.

Every death from AIDS is a tragedy that touches many lives. Yet, who can fathom the sheer devastation that is visited on families such as these? The enormity of their experience becomes still more compelling when one learns that the government, our government, could have acted to prevent it.

In 1980 when the first Americans began to fall ill from the mysterious ailment that would ultimately be called AIDS, the technology became available to pasteurize blood-clotting agents. Yet, for 7 years the government failed to require the blood products industry to make use of this technology, nor did the government require the industry to inform the public about the risks of contamination with HIV and other blood-borne pathogens.

□ 1230

As a result, at least 8,000 people with hemophilia and other blood-clotting disorders contracted HIV/AIDS from transfusions of contaminated antihemophilic factor or AHF between 1980 and 1987. This means that as many as 50 percent of all individuals who suffer from blood-clotting disorders were exposed to HIV through their use of AHF.

In 1995, an independent scientific review conducted by the Institute of Medicine concluded that this tragedy occurred because the government failed to take the steps that could have prevented it. Some might argue that we cannot afford to do anything about that, but I believe we have an obligation to acknowledge what happened and make restitution to the victims of this disaster and their families.

This bill will not compensate them for the terrible harm that was done to them, nor will it begin to cover their medical costs. But it will mean a great

deal to them to know that their country has not abandoned them. I am proud to be an original cosponsor of this bill and urge all of my colleagues to join in supporting it today.

Mr. HYDE. Madam Speaker, I yield 1 minute and 30 seconds to the gentleman Arizona (Mr. HAYWORTH).

Mr. HAYWORTH. Madam Speaker, I thank my colleague, the gentleman from Florida (Mr. GOSS), for his hard work on this legislation.

I am pleased to come to the well today to speak in behalf of passage of this legislation because, Madam Speaker, I had a chance to listen to a young man from my State recount the very real difficulties that he confronted from receiving a transfusion of HIV-tainted blood. His name, Jeremy Storms.

Jeremy lived the Scriptures in which he so fervently believed. He let his light shine among men and, despite all the medical difficulties he encountered, many times he traveled here to Washington to tell us of the challenges he faced. He had a wisdom beyond his years. He would joke, you know, I used to be upset that I was a hemophiliac. Now I wish it was the only problem I had.

Jeremy passed away a few short months ago, but he did not live in vain. For his mother and father and family and for countless other families, this House on this day at this hour acknowledges the role of the Federal Government in public health and, yes, in personal responsibility.

I would urge this body, adopt this legislation in memory of Ricky Ray, Jeremy Storms and so many others.

Mr. SCOTT. Madam Speaker, I yield 2 minutes to the gentlewoman from Texas (Ms. EDDIE BERNICE JOHNSON).

Ms. EDDIE BERNICE JOHNSON of Texas. Madam Speaker, I rise in support of this bill. Having functioned as a registered professional nurse, I have observed over the years persons who are afflicted and need frequent transfusions are more subjected to the risk of HIV than others on a normal basis. This has been one of the viruses that has come along in our history that we have not found any way to conquer it. That we must always be mindful of.

Nothing is more important than assuring a family that when they have a loved one that needs a transfusion it is free of viruses and any other bacteria. We have gone a long way in that. We have had to deal with the virus of the 1930s for pneumonia and the virus of polio for the 1950s. Now we are having to deal with another major virus, the HIV virus.

So many people are so unaware of their risk for this disease, for the disease which the virus will cause. We must do all that we can to protect the general public, and this bill goes a long way in protecting the hemophiliacs because they can not get around having the transfusions.

I have observed too many families, heterosexual, intact families be destroyed by contamination from the young children and some young adults getting transfusions, blood transfusions. I do think, and I agree with the gentleman that there is a public health responsibility of our Federal Government, and this is one of those major issues that, until we find medical breakthroughs, we as a government need to take the responsibility of ensuring the availability of safe, virus-free blood.

Mr. HYDE. Madam Speaker, I yield 3 minutes to the gentleman from Florida (Mr. BILIRAKIS).

Mr. BILIRAKIS. Madam Speaker, I, too, rise in strong support of H.R. 1023.

First and foremost, I want to commend my colleague, the gentleman from Florida (Mr. GOSS), for his tireless efforts to secure passage of this important measure.

As chairman of the Subcommittee on Health and Environment of the Committee on Commerce, I am pleased to be an original cosponsor of the bill.

As my colleagues have already noted, H.R. 1023 provides compassionate payments to individuals with blood-clotting disorders who contracted HIV due to contaminated blood products. The National Hemophilia Foundation estimates that nearly 8,000 individuals with hemophilia contracted HIV from the Nation's blood supply which became contaminated before the identification of and development of tests to detect its presence.

These individuals and their families were already burdened by the medical costs of treating their blood-clotting disorders, and many have been financially devastated by the costs associated with HIV infection. This is a tragedy, and I share the Foundation's view that passage of this bill will serve to rebuild trust in the Federal Government in its essential role of protecting the U.S. blood supply and blood products.

A number of my constituents, including Margie and Johnny Kellar of Palm Harbor, have contacted me to urge enactment of this critical legislation. I share the desire to secure prompt passage of the bill, and I am pleased that the House is considering it today under a suspension of the rules.

As Members know, provisions of H.R. 1023 which fall within the jurisdiction of the House Committee on Commerce were enacted last year as part of the balanced budget law. Those provisions exempted the private settlement funds from the calculation of income for the purposes of determining Medicaid eligibility. This language was designed to ensure that those who accepted the private settlement would not lose their eligibility under the Medicaid program.

My Subcommittee on Health and Environment has jurisdiction over the Medicaid provisions, and I was pleased to secure their enactment as part of the 1997 balanced budget law.

The measure before us today extends similar protections to recipients of Supplemental Security Income benefits.

Again, I want to commend the gentleman from Florida (Mr. GOSS) for his leadership on this issue and his diligent efforts in bringing H.R. 1023 to the floor. I urge all of my colleagues to lend their wholehearted support to passage of this important bill.

Mr. SCOTT. Madam Speaker, I reserve the balance of my time.

Mr. HYDE. Madam Speaker, may I inquire how much time remains?

The SPEAKER pro tempore (Mrs. EMERSON). The gentleman from Illinois (Mr. HYDE) has 5 minutes remaining.

Mr. HYDE. Madam Speaker, I yield 2 minutes to the gentleman from Florida (Mr. STEARNS).

Mr. STEARNS. Madam Speaker, I thank the gentleman for yielding me this time.

I commend my colleague the gentleman from Florida (Mr. GOSS) for his vigilance in getting this legislation to the floor. I also am an original cosponsor of the Ricky Ray Relief Act. I am deeply committed to seeing this bill become public law.

Madam Speaker, my involvement in this issue began back in 1994 when I, too, was contacted by Gale and Randy Ellman. The Ellmans lost their son Eric Brandon when he was 14 years old. Eric died as a result of infusing a clotting factor that was tainted with HIV. His death is a double tragedy because it could have been avoided.

While we cannot bring back Ricky or Eric, we can try today to rectify this wrong. According to best estimates, about 8,000 hemophiliacs have been infected with HIV. This represents half the hemophiliacs in the country. By passing this bill we are simply saying that we acknowledge the government's failure, through the FDA, to protect our Nation's blood supply and regulate the sale of blood products.

Will $100,000 make up for the pain and suffering these families had to endure? The answer is no. But what it will do is say to thousands of people so deeply affected by this tragedy that your government wants to right the wrong.

The Ellmans called my office this morning to express their heartfelt gratitude for my support for this legislation and for my other colleagues' support. I say to the Ellmans and the many other families so devastated by what has happened to them, it is the very least we can do.

The SPEAKER pro tempore. The gentleman from Virginia (Mr. SCOTT) has 11½ minutes remaining.

Mr. SCOTT. Madam Speaker, I reserve the balance of my time.

Mr. HYDE. Madam Speaker, I yield 2 minutes to the distinguished gentleman from Virginia (Mr. DAVIS).

(Mr. DAVIS of Virginia asked and was given permission to revise and extend his remarks.)

Mr. DAVIS of Virginia. Madam Speaker, I rise today to voice my strong support for H.R. 1023, the Ricky Ray Hemophilia Relief Fund Act.

As an original cosponsor in both this Congress and the 104th Congress, I am

enormously proud that we have been able to bring this bill to the floor in a bipartisan manner with the support and cosponsorship of over 270 Members.

The gentleman from Florida (Mr. GOSS) has done a tremendous job in garnering support for the Ricky Ray Act and ensuring that it come before the full House today.

I also express my appreciation to the chairman of the Committee on the Judiciary, the gentleman from Illinois (Mr. HYDE), as well.

I also want to recognize the hard work of the students at the Robinson Secondary School in Fairfax, Virginia, on behalf of the thousands of hemophiliacs suffering from AIDS. They have dedicated themselves over the past couple of years to winning passage of this legislation and are now witnessing that democracy does work.

As my colleagues know, this legislation is named for Ricky Ray, a young boy from Florida who died in 1992 of hemophilia-related AIDS that he contracted through the use of blood-clotting products. Approximately one-half of all hemophilia sufferers were infected with HIV through the use of blood-clotting products between 1980 and 1987. The Federal Government has a shared responsibility for this tragedy because it failed to fulfill its responsibility to protect the Nation's blood supply and to regulate the safety of blood products.

The Ricky Ray bill gives a one-time payment of $100,000 each to about 7,200 hemophiliacs, about half of whom are still surviving, who were infected with the AIDS virus from blood-clotting agents between July 1, 1982, and December 31, 1987. It also implements a sunset provision after 5 years from the date of the bill's enactment.

Passage of this legislation will mark a defining and critical moment in the lives of many innocent AIDS sufferers, not because of the relatively small amount of money they receive but because of the peace they and their families will have in knowing that their government has taken responsibility for what happened to them and is attempting to compensate them for their suffering to the extent that we are able to do so.

I strongly urge all of my colleagues to vote in favor of the Ricky Ray bill.

Mr. SCOTT. Madam Speaker, I yield 4 minutes to the gentlewoman from California (Ms. PELOSI).

Ms. PELOSI. Madam Speaker, I thank my colleague from Virginia for yielding me this time.

I rise in strong support of the Ricky Ray Hemophilia Relief Fund Act. I want to commend our colleague, the gentleman from Florida (Mr. GOSS), for his leadership and compassion in bringing this legislation to the floor as a sponsor of this bill.

The life of the boy who gave his name to this legislation should remind all of us of the many different tragedies and demonstrations of courage and compassion the AIDS epidemic has brought us.

In his short life, Ricky witnessed the prejudice and fear which surrounded hemophilia, AIDS particularly, in its first decade but which is still all too common today. He had hemophilia, but he contracted AIDS and was the victim of much discrimination. He and his family watched their home burn down because neighbors were afraid of his illness.

□ 1245

His family struggled with the tremendous financial burden of providing for a child with hemophilia and AIDS. Ricky's parents saw their son pass away as they confronted the limits of treatment to fight the HIV disease.

Each of these aspects of Ricky's life is important to remember today: The prejudice, the crushing financial burden, the hope for cures which have yet to come, and the inspiring courage and compassion of this young man, his family and friends. This was Ricky's story, and it is the story of thousands of other people, many of whom have died, many are living today with hemophilia, HIV and AIDS.

The resources that Congress can provide will not solve the tragedy of hemophilia and AIDS for Ricky Ray and others like him, but they will help individuals, families and communities begin to recover from the calamity that has befallen them. Whether the Federal Government acted appropriately to protect blood clotting products in the 1980s is not the issue today. At issue now is providing assistance to individuals and families who have been forced to confront a personal and financial crisis brought by two debilitating diseases.

The Federal Government must do many things to respond to the AIDS epidemic and to hemophilia. It must protect the Nation's blood supply; provide prevention interventions; in the case of HIV-AIDS, fund research to find a cure and a vaccine; and support health care and needed services for those who are ill.

But as with other major catastrophes, the Federal Government also must provide the resources which help families and communities take the first steps toward recovery. For that I am grateful to the gentleman from Florida (Mr. GOSS) for his leadership, to the gentleman from Virginia (Mr. SCOTT) for his participation in this, as well as the gentleman from Illinois (Mr. HYDE) and others, and I urge my colleagues to support H.R. 1023.

Mr. HYDE. Madam Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. SCOTT. Madam Speaker, I yield myself such time as I may consume just to thank the gentleman from Florida (Mr. GOSS) for his hard work on this, the gentleman from Illinois (Mr. HYDE) for his leadership, and the gentleman from North Carolina (Mr. WATT), whose subcommittee considered this.

Ms. CHRISTIAN-GREEN. Madam Speaker, I rise today in strong support of H.R. 1023, a bill to provide compassionate payments to individuals with blood-clotting disorders such as, Hemophilia, who contracted the HIV virus due to contaminated blood.

My colleagues, children, especially minority children, are one of the most rapidly increasing segments of our population being infected with HIV. And, in all cases they are the innocent victims. Any legislation which helps to improve the quality of life of these children is worthy of all of our support.

Prevention programs, while available to all, often do not reach out to the most needy populations. Where we most need to improve our effort in this regard, is in making sure that the treatments which have been developed and proven to improve lives and health, are made accessible to all who need it. This bill does it.

As a family physician who has treated several patients with hemophilia, I am pleased to support H.R. 1023 and urge all my colleagues to do so as well.

Ms. JACKSON-LEE of Texas. Madam Speaker, as Chair of the Children's Congressional Caucus, and a co-sponsor of this bill, I want to take a few minutes to speak about the importance of this issue and this bill.

H.R. 1023 is named after Ricky Ray, a child victim of hemophiliac associated AIDS. Like thousands of others, Ricky Ray became infected with HIV through the use of contaminated blood products. Ricky brought national attention to this tragedy before he died from AIDS at age 15, 1992.

The Ricky Ray Hemophilia Relief Fund Act will not only acknowledge the federal government's unique responsibility to protect the nation's blood supply, it will also provide recognition to and some small solace to those living with hemophilia related HIV and their families. Almost 50% of the U.S. hemophilia population has been infected with HIV through tainted blood products. This bill will also authorize a $750 million dollar fund to provide compassionate assistance to individuals struggling with the emotional and financial costs of this disease.

In my home state of Texas, AIDS was the sixth leading cause of death among young people aged 13–24, and currently worldwide approximately 775,000 Americans are infected with the HIV virus.

Although we can never fully compensate the victims and families of those who are living with hemophilia related AIDS and HIV, we must show our compassion and our recognition of their plight, through the legislation here today.

Ms. FURSE. Madam Speaker, I rise today in support of H.R. 1023, the Ricky Ray Hemophilia Relief Fund Act. I want to congratulate my colleague, Mr. GOSS, for his hard work and relentless efforts to pass this bill through the House.

In 1994, shortly after I was first elected to the House, a constituent of mine named Katherine Royer brought to my attention the plight of people with hemophilia who became infected with HIV through tainted blood products. Many of these people were children. Until I met Katherine, I had no idea that over 7000 people with hemophilia had become infected with HIV, and their already complicated lives were getting even more difficult. Her family's story was powerful, and Katherine has relentlessly pursued this issue in her community and with her elected officials.

I strongly support H.R. 1023 because it acknowledges that the government must protect

the nation's blood supply, and provides assistance to the victims of this tragedy. With yearly medical costs of over $150,000, and a lack of legal options, many of the affected families have been devastated financially. While this bill can not bring back loved ones, it can provide those who are still living with some degree of financial relief. In addition, it recognizes, finally, the tragedy that occurred and the impact it had on the entire hemophilia community.

I thank Katherine for bringing this issue to my attention, and am pleased that H.R. 1023 is finally on the floor of the House. I strongly urge all my colleagues to support it.

Mr. SHAW. Madam Speaker, I strongly support H.R. 1023, the ''Ricky Ray Hemophilia Relief Fund Act of 1998.''

H.R. 1023, sponsored by my friend PORTER GOSS, is named for Ricky Ray, a 15 year old Florida hemophiliac who died in 1992. This bill represents the best of what government can do to help needy families struggling to overcome personal tragedy. From some, including for the bill's namesake, H.R. 1023 comes too late to provide help. But for many others it will provide welcome relief, and I am proud not only to be an original cosponsor, but also to have helped H.R. 1023 progress through the Ways and Means Committee to the House floor today.

Even though the bill was first marked up by the Judiciary Committee, an important component is the promise H.R. 1023 would keep by continuing Supplemental Security Income (SSI) benefits to needy individuals, which falls under the jurisdiction of the Committee on Ways and Means and the Subcommittee on Human Resources that I chair. These critical benefits will remain available despite a recent settlement and also new federal funds that otherwise would disqualify hemophiliacs who contracted the AIDS virus through tainted blood products in the 1980s from continued SSI eligibility. There is ample precedent for SSI to ignore such payments, and I can scarcely think of a more worthy class than this limited number of hemophiliacs, many of them children at the time, who have been afflicted with the AIDS virus. The Congressional Budget Office has told us the cost is minimal, especially when compared with the tragedy these individuals and their families have already experienced.

Another important feature of the bill is that it would exempt the payments from federal income taxes. Chairman BILL ARCHER summarized the issue well when the Committee on Ways and Means unanimously approved H.R. 1023 last month: ''No amount of money in the world can fix this tragedy, but we want to make sure that the federal payments are treated as tax-free, as they should be, and that SSI benefits stay unchanged for these innocent victims. They've been through enough as it is.''

Madam Speaker, I commend Congressman GOSS for his diligence in pressing for passage of this important bill, and urge all of our colleagues to support it.

Mr. ARCHER. Madam Speaker, I rise today in support of H.R. 1023, the Ricky Ray Hemophilia Relief Act. As an original cosponsor to the legislation introduced by my friend and colleague, PORTER GOSS, I believe that H.R. 1023 takes a positive step in addressing a great wrong that was committed affecting seven thousand Americans; over half of the hemophilia community.

In 1995, the Institute of Medicine conducted an independent review which concluded that the system designed to ensure the safety of blood and blood products had been ill-prepared to deal with the dangers of blood-borne viruses and had failed to protect the public health. As a result, thousands of Americans with hemophilia became infected with HIV through the use of these contaminated blood products.

The portion of the legislation that came before the Ways and Means Committee ensures that payments to people with hemophilia who contracted HIV from tainted blood products will be tax-free and not threaten benefits under the Supplemental Security Income (SSI) system. While no amount of money in the world can fix this tragedy, Congress must do all it can to make certain that the SSI benefits of these individuals living with two chronic and expensive diseases remain unchanged.

Finally, I want to commend: Congressman GOSS; Chairmen HYDE and BLILEY; the National Hemophilia Foundation (NHF); Ray Stenhope, a Houstonian who is Past-President of NHF; Dr. Keith Hoots and the folks at the Gulf States Hemophilia Treatment Center at Hermann Hospital in Houston; and everyone else who worked long and hard to bring this legislation before the House of Representatives. While I realize that these courageous individuals and their families will have to continue to live with the horrors of this tragedy, I hope that this bill will at least bring them some comfort.

Mr. SCOTT. Madam Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mrs. EMERSON). The question is on the motion offered by the gentleman from Illinois (Mr. HYDE) that the House suspend the rules and pass the bill, H.R. 1023, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

The title was amended so as to read: ''A bill to provide for compassionate payments with regard to individuals with blood-clotting disorders, such as hemophilia, who contracted human immunodeficiency virus due to contaminated antihemophilic factor, and for other purposes.''.

A motion to reconsider was laid on the table.

VETERANS TRANSITIONAL HOUSING OPPORTUNITIES ACT OF 1998

Mr. STUMP. Madam Speaker, I move to suspend the rules and pass the bill (H.R. 3039) to amend title 38, United States Code, to authorize the Secretary of Veterans Affairs to guarantee loans to provide multifamily transitional housing for homeless veterans, and for other purposes, as amended.

The Clerk read as follows:

H.R. 3039

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Veterans Transitional Housing Opportunities Act of 1998''.

SEC. 2. LOAN GUARANTEE FOR MULTIFAMILY TRANSITIONAL HOUSING FOR HOMELESS VETERANS.

(a) IN GENERAL.—Chapter 37 of title 38, United States Code, is amended by adding at the end the following new subchapter:

''SUBCHAPTER VI—LOAN GUARANTEE FOR MULTIFAMILY TRANSITIONAL HOUSING FOR HOMELESS VETERANS

''§ 3771. Definitions

''For purposes of this subchapter—

''(1) the term 'veteran' has the meaning given such term by paragraph (2) of section 101;

''(2) the term 'homeless veteran' means a veteran who is a homeless individual; and

''(3) the term 'homeless individual' has the same meaning as such term has within the meaning of section 103 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11302).

''§ 3772. General authority

''(a) The Secretary may guarantee the full or partial repayment of a loan that meets the requirements of this subchapter.

''(b)(1) Not more than 15 loans may be guaranteed under subsection (a), of which not more than 5 such loans may be guaranteed during the 3-year period beginning on the date of enactment of the Veterans Transitional Housing Opportunities Act of 1998.

''(2) A guarantee of a loan under subsection (a) shall be in an amount that is not less than the amount necessary to sell the loan in a commercial market.

''(3) Not more than an aggregate amount of $100,000,000 in loans may be guaranteed under subsection (a).

''(c) A loan may not be guaranteed under this subchapter unless, prior to closing such loan, the Secretary has approved such loan.

''(d)(1) The Secretary shall enter into contracts with a qualified nonprofit organization to obtain advice in carrying out this subchapter, including advice on the terms and conditions necessary for a loan that meets the requirements of section 3773.

''(2) For purposes of paragraph (1), a qualified nonprofit organization is a nonprofit organization—

''(A) described in paragraph (3) or (4) of subsection (c) of section 501 of the Internal Revenue Code of 1986 and exempt from tax under subsection (a) of such section, and

''(B) that has experience in underwriting transitional housing projects.

''(e) The Secretary may carry out this subchapter in advance of the issuance of regulations for such purpose.

''(f) The Secretary may guarantee loans under this subchapter notwithstanding any requirement for prior appropriations for such purpose under any provision of law.

''§ 3773. Requirements

''(a) A loan referred to in section 3772 meets the requirements of this subchapter if—

''(1) the loan is for—

''(A) construction of, rehabilitation of, or acquisition of land for a multifamily transitional housing project described in subsection (b), or more than one of such purposes;

''(B) refinancing of an existing loan for such a project;

''(C) financing acquisition of furniture, equipment, supplies, or materials for such a project; or

''(D) in the case of a loan made for purposes of subparagraph (A), supplying such organization with working capital relative to such a project;

''(2) the loan is made in connection with funding or the provision of substantial property or services for such project by either a State or local government or a nongovernmental entity, or both;