Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Chapter 12

A Prescription for the Next Health Care Crisis

BLOOD PRODUCT SAFETY

As long ago as 1975, the World Health Organization (WHO) promoted the development of national blood services based on voluntary non-remunerated donation of blood [1]. This action was prompted by a report that posttransfusion hepatitis was more likely if the blood came from paid donors [2]. Although blood banks switched to recruiting only volunteer donors, HIV-infected blood was still able to enter the blood collection and distribution system. In the wake of the acquired immunodeficiency syndrome (AIDS) epidemic, it became clear that additional measures were needed to prevent microbes from entering the blood supply, and blood banks adopted very extensive screening of donors and testing of donated blood. Potential donors now complete questionnaires and are deferred, or the blood is not used for transfusion if donors fall into any of the categories listed in chapter 3, page 33. Blood banks also increased the number of infectious agents included in their testing panels; the tests of donor blood currently required or recommended are likewise displayed in chapter 3, page 33. These efforts have been remarkably successful in preventing contamination of the blood supply, and the risk of contracting AIDS from a transfusion in the United States is estimated at less than 1 in every 2 million units transfused [3].

The Food and Drug Administration (FDA) is the main government agency tasked with safeguarding the nation's blood supply. It was established by the 1906 Pure Food and Drug Act and is a vast agency with four directorates overseeing medical products and tobacco, foods and veterinary medicine, global regulatory operations and policy, and operations. The principal regulatory agency with responsibility for the safety of blood and blood products is the Center for Biologics Evaluation and Research (CBER) within the Office of Medical Products and Tobacco. Its Blood Products Advisory Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of products derived from blood or biotechnology intended for use in the diagnosis, prevention, or treatment of human diseases. CBER regulates the collection of blood and blood components and establishes standards for the products themselves.

Linked by Blood: Hemophilia and AIDS. DOI: http://dx.doi.org/10.1016/B978-0-12-805302-7.00012-4

It evaluates scientific and clinical data submitted by manufacturers to determine whether products meet standards for approval, and it determines whether they have reasonable risks given the magnitude of the benefit expected and the alternatives available. In addition, it inspects blood establishments and monitors reports of errors, accidents, and adverse clinical events. It is responsible for identifying and responding to potential threats to blood safety, to develop safety and technical standards, and to help industry promote an adequate supply of blood and blood products. The agency is charged with providing up-to-date information to the public, health care professionals, the media, and product manufacturers through its Biologics web pages and Patient Network Newsletter.

The Institute of Medicine (IOM) in its 1995 report presented an analysis of the FDA and its Directorates, and concluded that there needed to be a "far more responsive and integrated process to ensure blood safety" [4]. They recommended the creation of a "Blood Safety Council" to assess and propose strategies for overcoming current and potential future threats to the blood supply and to educate public health officials, clinicians, and the public about challenges to blood safety and strategies for dealing with these challenges. They suggested that the Council could also alert scientists about the needs and opportunities for research to maximize the safety of blood and blood products. These IOM proposals were never implemented, but given the recent epidemics of previously exotic contagious diseases such as Ebola and Dengue hemorrhagic fever, and the emergence of SARS and MERS (severe acute respiratory syndrome and Middle Eastern respiratory syndrome, respectively), establishing an office to safeguard the blood supply would seem to be even more urgent now than when they proposed it in 1995. Blood banks do not currently test donors for these viruses, so there is the possibility that these organisms could be transmitted by transfusion. An even greater risk to the blood supply of the United States is the Chikungunya virus, which appeared in the Caribbean basin in December 2013. This virus causes fever and joint pains and has already infected approximately 15,000 persons. A group of French investigators screened plasma samples from 2149 blood donors from Martinique to find out if this virus is capable of gaining entrance to the blood supply [5]. The Chikungunya virus was found in the blood of four men; two never had symptoms of infection and the other two had fevers that began soon after their donations. Had their blood been used for the preparation of clotting factor concentrates or transfused into patients, it could have transmitted the virus to the recipients. This experience clearly shows that our blood supply remains vulnerable and requires continuous surveillance for new sources of contamination.[1]

Because people with hemophilia are major consumers of blood products, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia

1. In 2016, the W.H.O. issued an alert that the rapid spread of Zika virus posed a threat to the blood supply (Louis CS. W.H.O. issues guidance on blood in Zika areas. The NY Times, February 20, 2016, p. A5.

Foundation (NHF) has submitted to the FDA a number of recommendations for improving the quality of the plasma used for preparing clotting factor concentrates [6]. Among these are suggestions that the plasma pool size should be limited to 15,000 donors, very sensitive tests should be used to detect viral contamination, and improved techniques should be implemented for eliminating infectious agents. In addition, NHF requests that manufacturers should promptly report suspected infections associated with their products; any such products should be assumed to be implicated in disease transmission and removed from the distribution path and patients' homes. Another recommendation is that the FDA should communicate promptly with consumer organizations such as NHF whenever there is a recall or voluntary withdrawal, because these actions could have an impact on the supply and availability of clotting factor concentrates. They also suggest using bar-coding to identify coagulation products; adopting this method would facilitate accurate tracking and dispensing, as well as usage in the hospital and at home. Furthermore, NHF urges that expedited regulatory review should be extended to all products offering incremental safety and efficacy advantages.

On December 2, 2014, the FDA announced that it intended to establish a general program to monitor the safety of the blood supply in collaboration with the National Heart, Lung, and Blood Institute. In addition, the FDA plans to engage in public discussions about the donation of safe blood and to review the effectiveness of the blood donor history questionnaire. Although these actions are commendable, I believe that the FDA needs to have an office specifically devoted to safeguarding blood safety.

Recommendation 1: Establish an Office of Blood Product Safety Within the FDA

This Office is needed to provide oversight for the many tasks related to the procurement, availability, and safety of blood and blood products. In addition to the functions recommended by the IOM and the NHF, the Office of Blood Product Safety (OBPS) could collect and review reports received by the FDA regarding the safety and availability of blood and blood products. The OBPS would assess the appropriateness of public dissemination of these reports; if they were deemed relevant to the health and welfare of our citizens, then OBPS personnel would interpret and translate them into lay language. This material would be posted on a CBER website specifically designed for communicating important issues to the public. Paper copies of the material would be made available for persons without computer access, and the information would also be sent to nonprofit groups such as the NHF and the American Thrombosis and Hemostasis Network. These organizations have registries of people with bleeding disorders; therefore, they could be instrumental in ensuring that the information is distributed to these individuals. This method of disseminating information about product safety would replace the current piecemeal notification systems used by the NHF and other consumer organizations.

The OBPS might also address the important issue of spotty geographic availability of clotting factor concentrates. As noted, these concentrates are vital for the well-being of persons with bleeding disorders, which is why they maintain a supply of these products in their home or office. However, there are times when hemophiliacs have hemorrhages while traveling for business or pleasure. A visit to the nearest emergency department often brings the unwelcome news that the facility does not stock clotting factor concentrates. Surprisingly, even trauma centers designated level I (most capabilities) might not have coagulation products. Such facilities must either call a distribution center and request immediate delivery of the concentrate or transfer the bleeding patient to a treatment center that has the appropriate material. The lack of immediate accessibility to clotting factor creates delays in the provision of care, and the bleeding that continues unabated exacerbates the damage in whatever organ has been the site of the hemorrhage, be it the brain, joint, or other tissue. The OBPS might mandate that adequate supplies of clotting factor concentrate must be physically present in all level I trauma centers and other facilities that serve communities where persons with hemophilia and other bleeding disorders reside.

The FDA appears to recognize that its communication with the bleeding disorders community has been suboptimal. It has announced a new Patient-Focused Drug Development Initiative whose purpose is to provide opportunities for affected individuals to inform FDA officials about the treatments they consider most valuable. The FDA believes its rule-making will be enhanced if it understands patients' tolerance for benefit/risk tradeoffs. The proposed OBPS could serve as the vital interface between the FDA and the consumers of blood products, obtaining input from persons with bleeding disorders as well as disseminating information about the safety and availability of clotting factor concentrates and other coagulation products.

CONTROLLING THE COSTS OF HEMOPHILIA THERAPY

The major improvements in blood safety in recent years have been accompanied by large increases in the price of a transfusion. There is no cost for the blood itself; donors are not financially compensated for donations given for the benefit of those who are ill. However, the recipients of blood must pay a steep price for transfusions. While the cost to hospitals to purchase a unit of blood is usually $225–240, patients might be charged $1000 or more [7]; this is often loosely justified by claiming expenses for blood administration, inventory losses, and liability insurance, although formal cost-accounting is rarely available.[2] The monies collected for blood have made blood banking a multibillion-dollar enterprise, often generating large annual surpluses [8].

2. The University of Utah Health Care is one of the few hospitals with a computer program to cost-account items for patient care (Kolata G. What are a hospital's costs? Utah system is trying to learn. NY Times September 8, 2015, pp. A1, A18).

A more enlightened system would have the costs of collecting, processing, and administering blood borne by the general public, and the prices for blood and blood products regulated by the government. Controlling the costs of transfusion and spreading the expense over the entire population would ease the financial burden on those who are ill and least able to afford this expense. Such a paradigm has been adopted by many other countries and should be incorporated into our health care system. Most other developed countries provide free care and supplies for people with chronic diseases, reasoning that diseases select their targets at random [9]. Also, they negotiate with drug and device makers to reduce list prices. For example, the British National Institute for Health and Care Excellence (NICE) is charged with assisting health and social care professionals by providing guidance on delivery of the best possible care based on the available evidence [10]. NICE conducts technology appraisals, publishes clinical guidelines, and performs cost-effectiveness analyses. It utilizes the quality-adjusted life year to measure health benefits; if the benefit is less than a designated threshold for the cost of a new drug or procedure, then the treatment is not recommended. Once the value of a therapy is established, NICE negotiates price with the manufacturer. The costs of drugs in the United States are higher because most other countries apply price controls and we do not; we rely on a competitive marketplace, but the fact is that many pharmaceutical products do not have competitors.

At present, health insurance plans are able to restrain drug prices by forcing pharmaceutical companies to compete regarding price when there are several medicines with similar indications [11]. Sometimes, drugs with significant advantages over their competitors are more expensive, or there are no competing products; in this situation, the health plan might decide that the products are too expensive and refuse to list them on its formulary. If patients wish to have such drugs, they are obliged to pay their full price out-of-pocket. This creates a double standard of care, with wealthy individuals and those with expensive insurance policies getting top-of-the-line products and others receiving only older, lower-quality material. Recently, in response to a complaint that people with HIV were subjected to restrictions on certain medications, an insurer agreed to limit the out-of-pocket costs for some of these agents [12], but this action was taken by only one company in one state. Two members of the US House of Representatives have introduced a bill (H.R.1600) to prevent private health insurance plans from imposing higher premiums for specialty drugs, but the fate of this legislation is uncertain.

Generic drugs are usually less costly than brand name medications, but prices can skyrocket if there are drug shortages, supply disruptions, or consolidations within the generic drug industry [13]. For the products used by hemophiliacs, insurers might demand that the few companies that make concentrates lower their prices, but this tactic will not be successful if all the manufacturers agree to hold the line on prices. Because hemophiliacs must have these drugs, and because third parties are obligated to pay for them, the prices are impervious to price escalation or “inelastic” [14].

Recommendation 2: Establish a New Office for the Control of Pharmaceutical Prices Within the Department of Health and Human Services

To make the care of hemophilia more affordable to patients and third-party payors, an office for the Control of Pharmaceutical Prices (COPP) should be established within the Department of Health and Human Services. It would be modeled after the Office of Price Administration (OPA) that was established by Executive Order at the start of World War II. The OPA was formed "to prevent price spiraling, rising costs of living, profiteering, and inflation resulting from market conditions caused by the diversion of large segments of the Nation's resources to the defense program, by interruptions to normal sources of supply, or by other influences growing out of the emergency" [15]. It included a Price Administration Committee that was charged with making findings and submitting recommendations for setting maximum prices, commissions, margins, fees, charges, and other elements of cost or price of materials or commodities. The OPA was successful in keeping consumer prices relatively stable during turbulent times.

Although we are not on a wartime footing, the situation with regard to many pharmaceutical products is similar; drugs indispensable for the well-being of citizens are available from only a few sources and at highly inflated prices. There is no marketplace or competition to determine the cost of many such drugs; their price is set by the manufacturers and health insurers. For the manufacturers, the considerations used to determine prices are return on investment and willingness of third parties (insurance, government) to accept the costs of the drugs (in other words, what the market will bear). Health insurers can assign some drugs, such as those used to treat HIV infection, to the highest payment tier for midlevel plans, requiring patients to contribute 40% of the cost of the drug [16]. Sick individuals are compelled to assume a heavy monetary burden at a time when their income is often substantially decreased by illness. There are few remedies for patients when insurance companies charge hefty premiums for vital medications. In addition, our government does not negotiate price with pharmaceutical companies; if fact, such negotiations were barred by Congress when Part D Medicare was enacted. As noted by Elizabeth Rosenthal, "we approve drugs and devices without considering cost-effectiveness, or even having a clue about price. We don't ask for estimates and then are surprised when the nation is stuck with a $2.7 trillion annual health care bill" [17].

COPP would have as its primary function the establishment of ceilings on prices for products for which there is currently little or no marketplace competition; these products would include essential commodities such as drugs, medical devices, blood, and blood components that are currently under the purview of the FDA. It would adopt methods for assessing cost-effectiveness that are somewhat similar to those used by the NICE Institute, and it would negotiate prices with the manufacturers based on the safety and effectiveness of their products. It could recommend that Medicare refuse payment if prices were not

commensurate with the estimated value of the therapy. In that circumstance, COPP would recommend the next best alternatives. With regard to blood and blood components, it seems likely that the price of these essential substances will substantially increase in the future as methods are introduced to sterilize the final product. For example, two firms are developing a set of chemical compounds that will inactivate microbes contaminating blood [18]. Although these innovations should greatly enhance the safety of transfusion, the final blood product will undoubtedly be more expensive. We need an agency that will provide an independent assessment of the value of such a product and set limits on its price.

In addition, COPP should have the power to authorize subsidies for the production of certain pharmaceuticals that are absolutely necessary for people's health. Currently, there is little incentive for manufacturers to produce inexpensive drugs such as heparin and morphine, and even more mundane items like sterile saline and magnesium sulfate, resulting in periodic shortages of these indispensable materials [19]. Furthermore, pharmaceutical companies have little incentive for developing new classes of antibiotics, mainly because the monetary returns from such drugs are small in comparison to medicines used for chronic diseases such as cancer and diabetes. However, we desperately need new antimicrobials because of the emergence of bacteria resistant to the current drugs [20]. Vaccine production is another area frequently neglected by pharmaceutical companies because of a perceived lack of profitability. Margaret Chan, Director General of the WHO, criticized the drug industry for not developing an Ebola vaccine in advance of the current crisis. She said "A profit-driven industry does not invest in products for markets that cannot pay" [21]. Although the government has been encouraging antibiotic research by making funds available for drug development, and although Congress is considering legislation that would increase the levels of Medicare reimbursement for newer antibiotics [16], COPP could provide more immediate financial incentives for manufacturers to discover and produce novel antibiotics and vaccines. By controlling prices and ensuring the availability of essential health products, COPP would make a valuable contribution to global health care.

BUILD EDUCATIONAL PROGRAMS TO PROMOTE TOLERANCE AND INCREASE SUPPORT FOR RESEARCH

People become more tolerant when they are presented with factual information that is simple and readily understandable. Educational programs can be devised that clearly identify the cause of a particular disease (AIDS, Ebola), describe how it is spread, and indicate whether restrictions on movement or contacts are required. Most importantly, such information is essential for dispelling conspiracy theories that attribute evil intentions to health care workers, government, and others. Therefore, greater effort is needed to educate the public and remove the stigma associated with infectious diseases.

Recommendation 3: Educate the Public About Emerging Infectious Diseases

Health care agencies should enlist the assistance of professional spokespersons to broadcast educational messages, prepare videos, and write brochures that can be disseminated by electronic and print media to broad segments of the population. A major educational campaign might mitigate the stigma associated with these infectious diseases and overcome prejudicial attitudes. It might also encourage people infected by these viruses to seek medical assistance before their diseases progress and they infect others.

Many of the serious consequences of the HIV epidemic were due to prejudicial attitudes toward those with a different sexual orientation. The rampant spread of the AIDS virus among homosexuals was almost completely ignored by the media, and research into the causes and potential remedies was grossly underfunded by government [4]. This might have led blood bankers to underestimate the prevalence of HIV in donors because they failed to give attention to data derived from the homosexual population showing that infected persons might not have symptoms of AIDS for months to years. Likewise, medical experts advising the NHF were unaware that HIV infection had been fatal in almost half of those exposed to the virus and would be much worse than an untreated hemorrhage. Had these groups been better informed about what was happening in the homosexual community, they could have taken measures to limit the entrance of the virus into the blood supply and restricted the use of clotting factor concentrate, the product that infected the hemophilia community.

Public attitudes toward persons with AIDS, whether they were homosexuals or hemophiliacs, were often characterized by hostility and lack of acceptance. This was probably best exemplified by the experience of Ryan White, a boy with hemophilia and AIDS, who said that he became the target of vicious jokes, his school locker was vandalized, and his folders were marked "FAG" [22]. This occurred because AIDS was identified by many as a "gay" disease, and discrimination against homosexuals was rampant in the small town in Indiana where he grew up. White and his family rejected the idea that he was an innocent victim, because that implied that gays with AIDS were guilty. In fact, gay men gave blood altruistically and were unaware that they were infected by HIV when they donated. White understood that AIDS was a disease, not a way of life, and he and his family were grateful for the assistance and advice they received from the gay community [23]. White was a strong proponent of education and research, noting that he faced discrimination, fear, and panic but became accepted when students and parents understood the facts of his illness.

In the three decades since the advent of the AIDS epidemic, treatment for HIV infection has progressively improved and HIV-related deaths in hemophiliacs are now rare in the United States. But isolated outbreaks of the disease still occur in nonhemophiliacs. A recent epidemic in rural Indiana illustrates how the sharing of contaminated needles disseminates HIV among people who abuse

drugs [24]. In this poor community, marked by abandoned homes and widespread unemployment, many individuals became addicted to an opioid painkiller called Opana (Endo Pharmaceuticals, Inc., Malvern, PA). Although this drug is meant to be taken orally, addicts crushed the pills in water and injected the slurry intravenously. They reused needles hundreds of times and shared needles with other drug abusers. HIV infection was first recognized in January 2014; there were 71 cases by December and 135 by April 2015 [25]. The transmission rate was estimated at 80%, meaning that infection occurred in 8 of every 10 individuals sharing needles with an infected person [26]. Other factors that might have contributed to the size of the epidemic are the misperception that only homosexuals could become infected by HIV and the general reluctance to undergo testing and treatment because of the stigma attached to the disease [27]. To overcome these barriers, Indiana officials instituted a program of needle exchange, offered free HIV testing, and provided clinic facilities for treatment. It is still unclear whether these measures will be effective in limiting this outbreak.

We are one society, and what happens to our neighbors affects us as well; for example, HIV can spread quickly from the homosexual to the heterosexual community, and from drug abusers to sexual partners. We need to be more tolerant of those who differ from us, whether those differences are religious, economic, or lifestyle-related. When we observe persons afflicted with disease, we need to support them and take active measures to relieve their suffering. This concern for the rights of those with AIDS was probably best expressed by Nelson Mandela, who vigorously fought against stigmatization and discrimination of infected persons [28]. We do not know who will be vulnerable to the next invasion by an infectious agent, but we must not let prejudice and irrational thinking prevent us from doing everything possible to identify and eradicate the contagion, no matter who is infected. Study of the AIDS epidemic in hemophiliacs is relevant because it shows that failure to adequately address diseases in minority populations inflicts a high cost on society as a whole; for example, it provides a convincing rationale for investing resources to control Ebola in West Africa before it is disseminated globally.

Recommendation 4: Greater Support for Basic and Applied Research

The final, and perhaps most important, component of this prescription is a plea for greater support for basic and applied research. We are on the cusp of major advances in the treatment of blood and bleeding disorders, and these breakthroughs will be accomplished if our support for the necessary research does not waver. There are at least three areas that exemplify current research progress: safer transfusion therapy, more effective clotting factors, and prevention of HIV infection.

With regard to transfusion therapy, we can never be absolutely certain that the blood of a donor is free of viruses or other microbes because of the evolution

and spread of new infectious agents, such as Chikungunya, Ebola, and Zika viruses. Several methods for sterilizing blood and blood products have been approved or are undergoing development, but none has yet been mandated by the FDA [29]. The procedures being investigated include filtration, addition of solvents, detergents, or other substances, and exposure to ultraviolet light or other light sources. The efficacy and safety of the methods are still unclear, and all would increase the cost of the product.

The use of donor blood could be eliminated if it were possible to replenish the blood of anemic patients by growing their own red cells in tissue culture, but this would require the ability to generate sufficient cells to provide relief of symptoms. Investigators recently reported that functional red blood cells could be grown from the rare immature cells that normally circulate in the blood [30]. At present, the method is not clinically feasible because it produces only a limited number of red cells, is time-consuming, and uses a great deal of culture medium. But with continued research, it should eventually be possible to treat anemic patients by propagating their own cultured red blood cells and avoiding the use of other people's blood and the risk of blood-borne infection.

Another approach is to replenish hemoglobin, the oxygen-carrying protein found in the red blood cells. Such a product could be life-saving in situations in which there is massive bleeding and blood either is unavailable or cannot be typed and cross-matched in time to prevent death. Three hemoglobin products were extensively studied for this indication, but all had serious adverse effects and none received regulatory approval, although a related product has been approved for veterinary use. The current status of the various methods to limit or avoid transfusion of banked blood has recently been reviewed [31].

Research has also produced modified clotting factors that circulate for longer periods than the native factors; long-acting versions of both recombinant factors VIII and IX have recently been approved by the FDA [32]. These products have the advantage of providing protection against bleeding with fewer intravenous infusions. Although clotting factor replacement with recombinant factors has been the mainstay of hemophilia treatment, an ongoing problem is the development of resistance to the infused proteins. A current investigation is identifying sites on the clotting proteins that elicit the immune responses that destroy the infused therapeutic material [33]. By synthesizing clotting factors that lack these provocative areas, it might be possible to circumvent this treatment resistance. However, this approach will require a great deal of more basic research and probably several clinical trials to confirm the safety and effectiveness of these modified clotting proteins.

The prevention of HIV infection and AIDS is a worldwide problem that requires a global response; research has focused on behavioral modification, male circumcision, and pre-exposure prophylaxis [34]. A major research focus has been the development of a safe and effective vaccine, but this has been difficult because of the extensive variability in the envelope proteins of the virus and the fact that key sites on these proteins are masked from potential antibodies

elicited by a vaccine [35]. However, recent research has produced several novel antibodies that are able to neutralize diverse strains of HIV [36]. In addition to assisting in the design of a vaccine, some of these antibodies also target the cells harboring the virus. These cells are the factories for viral synthesis and their elimination might have a long-term beneficial effect on the treatment of the infection. Other investigators are trying to determine why some patients have a natural resistance to HIV infection, and they have discovered that genetic mutations in certain cell membrane proteins thwart the virus from entering those cells. These studies might eventually result in the development of drugs that simulate these mutant proteins and prevent the spread of the infection.

In addition to medical research, there is also a pressing need for behavioral studies focused on ways to change hostile public attitudes toward persons with alternative sexual orientations and those with mental or physical disabilities. In particular, people with hemophilia experience a lack of social support and are under-employed, resulting in a high prevalence of depression [37]. Studies have shown that their quality of life is reduced, but data are lacking on many of the psychosocial aspects of hemophilia [38]. Research is also needed to define the factors that engender hostility and avoidance of those who fall outside of the usual societal norms. The development and early implementation of educational programs focused on instilling tolerance might promote greater acceptance of homosexuals and hemophiliacs. This type of research has been underfunded in the past, but it needs to be addressed if we wish to better the lives of all members of our society.

In summary, this prescription for mitigating the next health care crisis due to blood-borne disease has four components:

- Create an Office of Blood Product Safety (OBPS) within the FDA to alert consumers about threats to the safety of blood and blood products, and ensure that there is an adequate supply of clotting factor concentrates for the needs of persons with bleeding disorders,
- Establish an Office for the Control of Pharmaceutical Prices (COPP) that would place caps on prices for blood, blood products, and essential medications, and authorize subsidies for the manufacture of selected products essential for human health,
- Enhance educational efforts to remove the stigma of infectious disease and instill tolerance toward those that are afflicted, and
- Invest in basic and applied research to improve the care and treatment of those requiring blood and blood products.

KEY POINTS

- The FDA should establish an Office of Blood Product Safety (OBPS) to communicate information on the safety and availability of blood and blood products to the public and health care professionals.
- Blood is freely given and should be freely received; the costs of collection, processing, and distribution should be borne by the public.

- Government should establish an Office for the Control of Pharmaceutical Prices (COPP) to set caps on the prices for blood, blood products, and essential drugs that is modeled after the wartime Office of Price Administration.
- Public investment in education and research will improve the safety and accessibility of blood and blood products for all our citizens.

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