AIDS and the Blood Bankers

Ross D. Eckert

SINCE DECEMBER 1982, when it became clear that Acquired Immune Deficiency Syndrome (AIDS) could be transmitted by blood transfusion, the blood bankers and their federal regulators have been unwaveringly optimistic that the spread of this lethal new disease by transfusion could be controlled. In June 1983, Edward Carr, the president of the American Association of Blood Banks (AABB) said "there is little or no danger to the general public." Then-Secretary of Health and Human Services Margaret Heckler announced that "there should be no fear among the public that they may develop AIDS through . . . blood transfusions."

Two-and-a-half years and over 250 cases of transfusion AIDS later, Secretary Heckler described a new blood test for the antibody to the AIDS virus (HTLV-III) as "the answer to the prayers of thousands of Americans facing surgery or otherwise requiring blood." The Centers for Disease Control (CDC), after analyzing the initial results of the test's efficacy, proclaimed it "just fantastic" and "a tremendous accomplishment," concluding that "people should not be concerned about accepting blood," and that "we have pretty much solved the transfusion-associated AIDS cases." According to the CDC, any new cases of transfusion AIDS would be those caused by infection before the antibody test became available.

From the start, the public has been skeptical. Within months after AIDS was linked to blood transfusions, patients began forming "blood clubs" and recruiting personal donors. In September 1985, a few months after the CDC's claims about the efficacy of the antibody test were publicized, a *Washington Post-ABC News* poll found that 67 percent of those surveyed remained fearful of getting AIDS via transfusion. In a January 1986 poll commissioned by the AABB, only 21 percent of those surveyed said they would trust information on the subject of AIDS from government officials and blood bankers.

Officials and blood bankers have tended to dismiss the public's concerns as unwarranted hysteria. But public concern about blood safety has been rational. AIDS is one of the few uniformly fatal diseases. It can incubate for up to seven years and be communicated before an individual is aware of having contracted it. And transfusion AIDS is growing both absolutely and relatively. While there was a total of 40 cases of transfusion AIDS documented prior to January 1984, there were 62 new cases reported in 1984 and 192 new cases reported in 1985. As of June 1986, transfusion AIDS cases totalled 396. This is a lower bound, however, as many blood recipients with documented exposure to the virus have not yet developed all the symptoms necessary to meet the CDC's definition, and some cases simply are not reported. Between 1984 and 1985, the ratio of reported AIDS cases attributable to transfusion to the total number of AIDS victims rose from 1 percent to almost 2 percent.

Transfusion AIDS is a potential risk for everyone. Over three million Americans receive

Ross D. Eckert is a professor of economics at Claremont McKenna College and Claremont Graduate School.

blood transfusions each year, and 95 percent of the population will have been transfused by age 72. While the antibody test is a major advance, its true effectiveness is still uncertain. In a tragic turn of events, the CDC announced in June that two individuals had developed AIDS from blood deemed safe to use. The blood had been collected and tested so soon after the donor was infected by AIDS that the test failed to detect antibodies to the virus.

AIDS is a tiny fraction of all transfusion disease. Hepatitis is estimated to strike about 10 percent of all transfusion recipients—roughly 1,000 per day—of whom a few die of hepatitis and perhaps 100 eventually develop cirrhosis. But the urgent public concern over the spread of AIDS has focused new attention on the safety of our blood supply, attention that is well placed because our blood is not as safe as it should be. Current federal policy encourages local monopolies or cartels in the supply of blood and discourages price competition in the blood bankers' acquisition of blood. Blood banks in almost every state are exempt from strict tort liability for collecting and distributing contaminated blood. These policies leave the blood bankers with seriously inadequate safety incentives. FDA regulation is a potential substitute for market competition and private liability, but in practice it is dominated by the interests of the blood bankers themselves. The result is that rates of transfusion AIDS and hepatitis are unnecessarily high. A different public policy would bring them down at low cost.

The Evolution of the Blood Cartels

Most blood banks in the United States operate as nonprofit monopolies or cartels. Some big-city hospitals collect a little blood from staff or families of patients, but they avoid soliciting donors openly in head-to-head competition with the blood bank in their region.

The American National Red Cross emerged from World War II with 35 regional centers where blood was collected for our armed forces. To sustain the size and enthusiasm of its volunteers during peacetime, the Red Cross began in 1948 to collect blood for civilian use. This effort had the support of the government, the American Medical Association, and public opinion.

At the time, hospitals collected blood in many communities. Blood was collected under the direction of hospital pathologists and distributed at prices based on fee-for-service, with charges levied for blood not replaced by patients. Hospitals were threatened by the Red Cross, which aimed to provide free of charge 100 percent of the blood supply of every community served. As stated in 1972, the Red Cross supports "a voluntary, nationwide, nonprofit blood service with uniform standards of operation—medical, technical, and administrative." In 1947, the AABB was formed by hospitals and other nonprofit blood collectors to oppose the Red Cross in some areas and pre-empt it in others.

For 30 years the Red Cross and the AABB contested some local markets and were rivals for national influence, but neither could establish a single nationwide system. Despite these rivalries both groups were committed to nonprofit status and to the collection of blood from volunteers without cash payment. They opposed competition from commercial blood banks, which by 1971 bought about 9 percent of the nation's blood from cash donors. Their opposition was strengthened by studies during the 1960s linking cash blood to higher rates of post-transfusion hepatitis. The idea that derelicts and poor people who sold their blood to commercial blood banks might lie about their health to get a few dollars, but that volunteer donors would not, was accepted by many physicians and health officials. It is worth noting, however, that from the standpoint of the blood banks, a policy of volunteers-only amounts to setting a uniform maximum price—zero—on a key factor of production; this eliminates price competition in a manner analogous to setting a minimum price on the output of rival suppliers.

In 1973, the Department of Health, Education and Welfare (HEW) declared a National Blood Policy intended "to encourage, foster, and support efforts designed to bring into being an all-voluntary blood donor system and to eliminate commercialism in the acquisition of whole blood and blood components for transfusion purposes." In 1978, the FDA required separate labeling of cash and noncash blood, which put hospitals and physicians using cash blood at greater liability risk and hastened the conversion to noncash blood. In California, it became a misdemeanor to use cash blood unless the attending physician certified that compatible noncash blood was unavailable.

HEW also sought to encourage the development of noncompetitive regional blood banks

committed to noncash blood. Believing this would reduce donor recruitment costs, it created the American Blood Commission (ABC) to cartelize regions where more than one nonprofit blood bank was entrenched. The ABC is a federation of blood banks, consumer and civic groups, and medical research charities, supported by member dues and federal and corporate grants. It promotes "regional associations" of local blood banks and hospitals to collaborate on donor solicitation and blood allocation. The ABC cannot restrict entry but tries to discourage it by mediating disputes over geographic markets (boundaries between regions become a problem if regions with many donors grow relative to regions with many patients) and similar issues. These efforts were assisted by HEW's implicit threat of direct federal action. By 1984 the ABC had "regionalized" almost half the nation's blood supply, and expected to cover three-quarters by 1992.

Transfusion AIDS is a potential risk for everyone. Over three million Americans receive blood transfusions each year, and 95% of the population will have been transfused by age 72.

The National Blood Policy is not a law or regulation, only a statement of goals. Cash blood is not illegal, only officially stigmatized. The FDA has not used its licensing authority over blood banks to establish rigid barriers to entry or marketing orders, as other agencies have sometimes done. Nevertheless, the direction of federal policy has been clear and its effects have been pronounced: Competition has been discouraged and cash blood has all but disappeared. By the late 1970s almost all commercial firms had switched from supplying cash blood to hospitals for direct transfusion to buying plasma for manufacture into various products for clinical or laboratory use. The cash plasma and blood products market remains exempt from the provisions of the National Blood Policy that stigmatize cash blood, and commercial firms dominate this market.

Until recently, hospitals that wanted better blood than that supplied by their regional blood banks have had few alternatives. Either they recruited and screened donors themselves or bought it from outside sources—which risked incurring the displeasure of their regional blood monopolies or cartels, and could be considered only by large hospitals in "weak" regions. In addition, the idea that cash blood is of lower quality became entrenched among physicians and nonprofit blood bankers even though hepatitis from noncash blood remained high. It took AIDS, a far worse disease spread by noncash blood from the established nonprofit blood banks, for some to reconsider the conventional wisdom.

The Incentives of Blood Bankers

Blood is not free. The nonprofit blood banks collect blood from volunteer donors without cash compensation, but they generally sell blood to hospitals and blood products to commercial manufacturers for a price. Hospitals pay "cost recovery fees" to cover donor recruitment, testing and preparation, and storage and delivery, which are in turn shifted to patients. Fees vary markedly among blood banks due to differences in costs, cost-allocation rules, and demand. Manufacturers pay for blood plasma either directly from cash donors or from blood banks as a by-product of noncash donations. This plasma is used to manufacture coagulants, albumin, gamma globulin, and many other products. The Red Cross contracts with a blood bank and several manufacturers to produce pooled products from donated plasma, which are sold at the market price and carry the Red Cross label.

Having foresworn paying for blood, the blood bankers must beg for it, which is a difficult way to do business. Many donors respond to altruistic appeals, but not as many as the bankers would like. Under a regime such as this, blood bankers naturally want to reject as few donors as possible.

Blood banks are staffed with laboratory technologists, donor-center personnel, and physicians to handle the expected volume of donations. Donations decline during summer vacations and at Christmas, but a permanent drop in inventories is a blood banker's greatest fear. A marked and prolonged drop in donations or the amount fit for transfusion would raise the prospects of staff layoffs, smaller organizations, and blood shortages. Such a development could lead hospitals to shop for new suppliers or form blood banks themselves. Evidently, the fewer donors disqualified, and the fewer units of blood

that do not meet testing standards, the less likely it is that this fear will come true.

For most goods and services, consumers can switch producers to indicate dissatisfaction with price or quality. But patients who want to shop for blood that is safer than what their regional monopoly or cartel provides potluck may have to switch regions as well as physicians or hospitals. This is out of the question for emergencies and too costly for many illnesses. The incentive for blood bankers to offer the quality consumers want is thus weak.

Another reason blood bankers' safety incentives are weak is that they are exempt in almost every state from strict liability in tort for transfusion diseases. In those states, blood banks are liable for death or disease caused by transfusion only if plaintiffs can prove they were negligent—blood transfusion is exempt from strict liability (where only causation need be proved) by statute or common law, usually by declaring that blood is a "service" rather than a "product." Because courts usually determine negligence by asking if a defendant's practices conformed to the "custom of the trade," blood banks and manufacturers of blood products can usually escape liability by showing that they conformed to FDA licensing regulations and followed the prevailing blood testing and donor screening half-measures which are described below.

Most exemptions date to the 1960s before the first blood test for hepatitis was discovered. They were justified on the grounds that blood banks (nonprofit and for-profit) should not be liable for transmitting a germ that could not be detected. This justification, doubtful in the 1960s, is thoroughly obsolete today. It lives on, and has even been extended to cover transfusion AIDS, due to political pressures from the blood bankers and the misapprehension by judges and legislators that exemption is necessary to maintain an adequate supply of blood.

The blood banks do take precautions, some of them quite elaborate, to prevent transfusion injuries that are immediately lethal and hence inexpensively traceable. For example, one horrible transfusion outcome, rarer than AIDS or hepatitis, is an acute hemolytic reaction—death by transfusing blood that is not compatible with the patient's blood. Death is rapid and the cause is clear; careful and costly procedures are standard. But in the case of transfusion injuries that are delayed and therefore less certain, the blood banks do not take many of the precautions they would take in a competitive market under appropriate liability standards, and which the FDA could require them to take.

FDA Transfusion Standards

The FDA sets minimum standards for screening potential donors for risk of AIDS and for testing blood for contamination. For advice on how to set these standards, the FDA generally relies on the blood bankers. As a result, when trade-offs must be made between the health interests of blood consumers and the convenience and privacy interests of blood donors, the latter often prevail. To appreciate this, consider the recent development of FDA blood-screening standards.

In late 1982, CDC epidemiologists first suggested that AIDS was a virus, transmissible by blood. This was met by strong skepticism from many blood bankers—despite the early warning signals. Hepatitis was known to be viral and transmitted by blood, intravenous drug abuse, and sexual promiscuity, and AIDS was attacking people in these same risk groups.

As more cases of AIDS developed in which transfusion was the only identifiable risk factor, the FDA and the three blood-collecting organizations (AABB, American Red Cross, and Council of Community Blood Centers) changed their tune. And in March 1983, the FDA announced new recommendations to reduce the risk of transfusion AIDS. The new donor-screening criteria, which described the groups from whom blood should not be collected, consisted of two half-measures.

The first was a recommendation to issue a pamphlet to donors informing them about who was at risk for AIDS, the signs and symptoms of the disease and how it was spread. Those at risk included persons with signs or symptoms of AIDS, sexually active homosexual or bisexual men, immigrants from Haiti (later removed from the list), persons who were frequently transfused, past or present abusers of intravenous drugs, and sexual partners of any of these persons. Other potential AIDS carriers—such as symptomless homosexual men who were not highly promiscuous, people who had had venereal diseases, persons with liver abnormalities that could be detected by routine blood tests, and persons transfused since AIDS emerged in 1977—were believed to be acceptable if they met

other donor health criteria. Many blood banks asked donors to sign a statement indicating they had read the pamphlet.

The second half-measure was to let donors screen themselves. After reading the pamphlet, donors would decide, privately and confidentially, if they were promiscuous or for other reasons at high risk. As a matter of practice, staff nurses in donor centers answered questions and asked donors about possible AIDS symptoms or exposure to patients with AIDS, but not about sexual preferences or promiscuity. Affidavits about sexual preferences and penalties for donating with the knowledge of exposure to AIDS were thought to be counterproductive.

At that time, the three blood-collecting organizations argued that tighter screening was unjustified because "the cause of AIDS is unknown and . . . evidence for its transmission by blood is inconclusive" and "still unproven." The FDA was more candid in explaining that it set weaker standards for noncash donors at nonprofit blood banks than for cash donors at forprofit plasma banks and that the standards "were carefully developed with the major organizations responsible for blood supply and . . . [were] intended to limit the adverse impact on blood availability."

Introduction of the AIDS antibody blood test in the spring of 1985 provided evidence that some donors either had not understood from reading the self-screening pamphlet that they belonged in one of the high-risk groups or did not appreciate the importance of belonging to one of these groups. In one study, the Red Cross reported that out of a small group of 41 "regular blood donors" who were found to have positive antibody tests, 36 were homosexual or bisexual males, female sexual partners of drug abusers, persons heterosexually active with prostitutes in Africa, and recipients of transfusions in the previous six to 30 months.

These findings led the CDC to acknowledge that "there are people out there who have been donating blood and who have not considered themselves at risk for AIDS and who were a potential source of transmitting this disease." Accordingly, in September 1985, the FDA extended its definition of high-risk donors to include "any male who has had sex with another male" even once—a decision which would have been timely about 32 months earlier. Such a time lag has tragic consequences. The giant blood bank serving the New York metropolitan area announced in July that it was trying to identify 700 people who might have been infected by the AIDS virus before the antibody test was implemented. These were people who received blood between 1977 and 1985 from donors who were not screened out by prevailing measures but have since tested positive to the antibody test.

If undetected, screening lapses have the capacity to infect many persons. Most patients are transfused not with whole blood but with one of several extracted components. Any particular donor pint may be used, therefore, to treat several patients. The plasma components, which are pooled from several thousand donors, make batch products used to transfuse many people.

The new blood test is a big step forward but no substitute for vigorous donor screening. The test detects antibodies to the HTLV-III virus, not the virus itself. Because the antibody response takes time (as many as six months in some individuals) a person infected by HTLV-III can donate blood before enough antibodies develop for the test to register positive—as illustrated by the two individuals the CDC recently announced had contracted AIDS from infectious blood that had not registered positive on the antibody test.

In one study, the Red Cross reported that out of a group of 41 "regular blood donors" who were found to have positive antibody tests, 36 were homosexual or bisexual males, female sexual partners of drug abusers, and persons heterosexually active with prostitutes in Africa.

A study published in *Lancet* in December 1984, coauthored by the American discoverers of HTLV-III, found that in a group of 96 healthy, symptom-free, high-risk individuals, four had the virus but no antibody. If the antibody test now used in blood banks misses four infective persons for each one hundred it finds, I estimate with conservative assumptions that 80 new AIDS cases could occur each year. This estimate is uncertain because: the true efficacy of the antibody test remains uncertain; people exposed to AIDS are developing the disease at an uncertain rate; and AIDS is spreading in the heterosexual popu-

lation (including many individuals who would not be identified as high risks by donor screening) at an uncertain rate.

Clearly the AIDS antibody test has not "pretty much solved" the AIDS transfusion problem as the CDC initially concluded. The American Red Cross, in an unusual and little noticed departure from its practice of coordination with the other major blood-banking organizations, recently voiced concern about the antibody test. Testifying before a Senate appropriations subcommittee on September 26, 1985, a vice president of the Red Cross stated that measuring an antibody response "has both theoretical and practical defects" and that we need tests that directly identify infective blood. He is right, but what can be done in the meantime? The important questions are whether superior, cost-effective screening and testing procedures are currently available and, if so, whether the blood bankers can be induced to use them.

What Can Be Done?

Four urgently needed measures would enhance the quality of the blood supply at relatively low cost. They could be introduced either by increased direct safety regulation by the FDA, or by less regulation and a change in the market and legal environments in which the blood banks operate. I will first describe what the FDA could and should do immediately, then explain why I believe nonregulatory changes would accomplish the same results.

• **Donor Registries.** Presently, blood banks attempt to maximize the number of donors through media solicitations and by mobile donor centers sent to businesses and shopping malls. The average donor gives only about 1.5 times a year; in a normal year about 8 million Americans donate 12 million pints of blood. Blood banks try to solicit repeat donors by telephone, but this is usually insufficient. In some urban areas 25 percent of the pool consists of first-time donors. Such pools are too large, recruited too randomly, and turn over too quickly to contain the spread of disease.

Safer blood requires more frequent donations from low-risk persons, even if this means fewer donors. To achieve this end, the FDA should require all licensed blood banks to maintain registries of permissible donors including only individuals who: (1) are known to be in good health; (2) have not been transfused since at least 1977; (3) agree to an extensive and confidential medical history, including questions not currently asked about venereal diseases and multiple sex partners; and (4) agree to have their blood tested not only for syphillis, which is now routine, but also for surrogate markers which indicate possible exposure to infections transmissible by blood.

Registries may cost more than random solicitation, but they have been successful at reducing disease. In the 1970s, registries of cash and noncash donors at the Mayo Clinic in Rochester, Minn., had rates of hepatitis B virus marker well below those of the nonprofit blood bank in the same region. (The registries are still in use today, although Mayo now collects mainly noncash blood.) The position of the nonprofit blood banks, that registries can work in rural Minnesota but not in big cities, has never been put to the test. It is also inconsistent with the procedures commonly followed to prevent acute hemolytic reactions—maintaining a rare-donor registry of persons asked to donate only when called. If rare donor-registries are cost-effective, then standard registries, offering the prospect of avoiding far more transfusion infection and death, are likely to be cost-effective as well.

• **Cash Blood.** Getting enough low-risk, registered donors may require compensating donors for their time and expenses. Commercial blood banks once were popular. They kept bigger inventories, were open on weekends, and gave hospitals faster service than nonprofits. They were in downtown areas where the big hospitals and inexpensive donors were.

Unfortunately, paid blood still suffers undeservedly from the reputation it got in the 1960s. Critics alleged that skid row donors would lie about their health to get five dollars even if this put patients at risk. It is true that many cash donors were unhealthy, so the quality of much cash blood in this era was poor, and some of it was awful. But partly this was due to the concentration of blood banks in inner cities and partly it was due to the nature of hepatitis—many hepatitis carriers never have jaundice or other overt symptoms that would make them aware they have the disease (this was before the blood test was developed to screen for hepatitis).

What at first was not recognized, and later discounted, was that cash blood collected through registries like the Mayo Clinic's was superior to some noncash blood. A 1976 study of

hepatitis rates among various groups of cash and noncash donors by the General Accounting Office—the most thorough published study of its kind—showed that the key determinants of blood quality were the donors' characteristics and the blood bank's location, not whether blood was sold or donated. Closing off the supply of cash blood has not ended post-transfusion hepatitis, and transfusion AIDS has spread almost entirely by noncash blood.

I do not propose buying blood from those who are down-and-out or in poor health as in the 1960s. It should be bought selectively from healthy low-risk people who may not be altruists, whose employers do not pay wages while they donate, and whose time is relatively valuable.

A GAO study of hepatitis rates among cash and noncash donors showed that blood quality was determined by the donors' characteristics and the blood bank's location, not whether blood was sold or donated.

Cash could be used, among other things, to attract more women donors. AIDS overwhelmingly occurs among men. Hepatitis predominantly occurs among men. But only about a third of all donors are women. Some pathologists have acknowledged that women donors are now safer as a rule (the exception is nurses and hospital workers, who have a higher incidence of hepatitis exposure). Male donors outnumber females in part because women often are underweight or have inadequate blood iron. In addition, to minimize cost per donation, the blood bankers send mobile donor units mainly to employers where men predominate. They do not offer travel or child care services for women who work at home or consider taking less than full pints from women who can safely give smaller amounts.

An FDA requirement that blood banks adopt donor registries would oblige the nonprofits to consider the use of cash incentives. At the same time, the FDA should encourage more careful donor solicitation by repealing its labeling regulation and withdrawing its policy pronouncements against cash blood.

• **State-of-the-art Blood Testing.** Too little blood testing is undertaken at present, particularly for hepatitis. Post-transfusion hepatitis, which strikes many more people than AIDS, is caused by at least three viruses, of which only the marker for the hepatitis B virus has been identified and can be detected by blood tests. Hepatitis B is the most severe form, but accounts for only about 10 percent of all transfusion hepatitis cases. Non-A, non-B hepatitis accounts for the rest.

Roughly half of hepatitis victims have either no symptoms or symptoms so mild that the disease can be identified only by a blood test. Many hepatitis victims also become "symptomless carriers" of the disease via transfusion or household contacts. Carriers of non-A, non-B hepatitis viruses are widespread in our society, although the full magnitude of the problem is unknown.

Although non-A, non-B hepatitis viruses cannot be detected in blood, surrogate tests to spot mild hepatitis in symptomless transfusion recipients can be used to identify blood donors who do not realize they have been infected. Papers published in 1981 in the *Journal of the American Medical Association* and the *New England Journal of Medicine* showed that one surrogate test (for abnormal liver enzymes) could eliminate between 29 percent and 40 percent of non-A, non-B hepatitis cases, and half of the worst cases. Another study published in *JAMA*, in 1984, showed that this test was cost-effective, considering the cost of replacing discarded blood, but ignoring lost wages. A National Institutes of Health study published in *Annals of Internal Medicine* in 1986 showed that a second surrogate test (for the hepatitis core antibody) would cut non-A, non-B disease by 43 percent, and that both tests were justified since each detected infection in different donor populations. Each study involved noncash blood almost exclusively. The FDA should require both tests of all nonprofit blood banks and for-profit plasma collectors.

Identifying the AIDS virus (as opposed to its antibody) is too complicated for normal blood-bank operations at present. Nevertheless, the blood bankers are wrong in claiming that the AIDS antibody blood test currently in use is the best that can be done. There exists a test which detects abnormal ratios between T-helper cells (a type of white blood cell) and other kinds of T cells common in persons with AIDS or the pre-AIDS syndrome. As a surrogate test it is subject to error, including registering false-positives

among persons recovering from minor virus infections. However, the T-cell test provides a known method of screening blood to provide additional precaution against transfusing blood that might contain dangerous viruses.

The Stanford University Medical Center in 1983 became the first major hospital to implement the T-cell test. In so doing, Stanford was able to identify persons with AIDS who had donated at blood banks that screened only by the half-measures described earlier—a precaution criticized by some blood bankers as "distasteful" and a "marketing tool." Stanford is not a typical medical center—it is a tertiary center in a high AIDS area—but it has apparently found the T-cell test a cost-effective way to enhance the safety of transfused blood. The FDA should determine whether it would be cost-effective for other hospitals as well.

• **Designated Donations.** Many believe it has always been normal practice for blood banks to provide patients with designated blood donated by family and friends, but this is not so. Traditionally, all donations went into the regional inventory, from which potluck shipments were made to hospitals. Only recently have hospitals begun to permit patients to receive blood designated for their use by self-recruited donors. Most blood banks still refuse to permit designated donations, even if patients are willing to pay the cost.

The three major blood-collecting organizations claim there is no proof that designated donations are safer than potluck blood. This is true: The practice is still too recent and limited to provide conclusive evidence one way or the other. But it stands to reason that designated donors, because of their personal ties to patients, would provide an important degree of accurate self-screening on top of the current screening and testing procedures and the additional ones advocated here. And if patients are willing to pay the extra costs of customized blood, it is difficult to understand why it should not be provided.

The blood bankers also claim that donors who give for friends will donate less often for strangers, reducing inventories and leaving patients who cannot find donors out of luck. The evidence is against them here; hospitals allowing designations find that inventories grow because blood not used by the intended patients is available for strangers. The FDA should require blood banks to provide designations to patients willing to pay the costs.

Market Competition with Strict Liability

The regime described above, involving increased regulation in a basically noncompetitive environment, is inferior to a competitively organized blood market operating under strict liability. The first step in achieving this end is for the federal government to revise its current policies that discourage competition. The FDA's labeling requirement for cash blood should be rescinded and the National Blood Policy should be revised to favor competition over cartelization. Public financing of the American Blood Commission should be withdrawn and careful scrutiny should be given to the commission's regionalization arrangements and other industry behavior for possible cases of noncompetitive conduct. For example, on September 9, 1985, the executive director of the Red Cross Regional Blood Services for Los Angeles and Orange Counties cautioned hospitals about buying even some blood from lower-priced "outside sources." He quoted a remark by the AABB president that "a coordinated, cooperative blood-collection system is essential to maintain the public trust, rather than a competitive system fraught with frustration and suspicion." These appear to be invitations to avoid competition.

In addition, blood banks should be held strictly liable for damages caused by contaminated transfusions. Negligence liability is inappropriate for blood banking and results in too few safety precautions, as the economist Reuben Kessel argued in an authoritative 1974 article. In the language of tort law, contaminated blood is a "manufacturing defect" (where only manufacturers can take additional precautions to reduce injuries) rather than a "design defect," (where both manufacturers and consumers can take precautions). The professional consensus among leading tort scholars, including Richard Epstein, William Landes, Richard Posner, and Steven Shavell, is that strict liability is the correct standard for manufacturing defects, because manufacturers are in a much better position than consumers to minimize such defects. If blood bankers are held strictly liable for damages caused by contaminated transfusions, they will take all cost-justified precautions to reduce those damages—including, I am confident, the relatively low-cost, high-benefit screening and testing measures I have advocated. Those receiving blood are in a relatively poor position to distinguish defective from safe blood or to adjust their

use of blood according to their understanding of the risks involved.

It may appear anomalous to propose an expansion of tort liability in an era when many economists and lawyers believe that tort liability is already too expansive and is becoming a threat to public health, as in the case of side-effects from vaccines [*see* Edmund Kitch, "Vaccines and Product liability—A Case of Contagious Litigation,"*Regulation*, May/June 1985]. But the problem of excessive tort liability, in the case of vaccines and many other products, is different. It arises from imposing strict liability where manufacturers can do nothing to reduce risks (i.e., the product has neither a manufacturing defect nor a design defect), from imposing liability where causation itself is doubtful, and from awarding "punitive" and other damages in excess of actual damages.

The liability reform proposals now circulating in Congress deal with these problems; to my knowledge all maintain strict liability for manufacturing defects. If they do develop into proposals to eliminate strict liability for manufacturing defects, then the case of blood transfusion, where the blood bankers themselves have obtained statutory exemptions in many states, should stand as a precaution against altering the common law through the political process.

Fears that blood bankers or manufacturers will withdraw from production if they were held strictly liable for injuries caused by transfusion are baseless. A point often overlooked in the product liability debates is that consumers pay the costs of defective products—in the form of product price or injury costs—regardless of whether liability is strict or negligence. Under strict liability, state-of-the-art blood testing and donor screening would increase the costs of blood banking and manufacturing, but these costs would be far more than offset by lower costs of transfusion diseases and deaths.

My prediction is that in this more competitive setting, all blood bankers would be induced to use registries, and their current, implicit agreement to pay no more than a zero price for blood would break down. Blood would be bought only from low-risk people with good health records, and increasingly from women. In addition, competition would likely lead blood collectors to adopt the two surrogate tests for hepatitis and, in some urban areas, the T-cell surrogate test as well.

But market competition and private liability are more than indirect means of accomplishing what the FDA could accomplish directly. In a market environment blood bankers would be guided more by consumer demand and less by the institutionally cautious forces of the FDA and official medical research, and would be less able to control industry practices according to their own views and interests. This would foster a greater diversity of approaches to improving the blood supply, and probably result in innovations neither the FDA nor a private student of the industry such as myself would come up with. The supply responses to the next threat to the blood supply would surely be swifter than in the case of AIDS. Indeed, there is already evidence that the blood market, regimented as it currently is, is responding to the AIDS threat more quickly than the regulators.

In a market environment blood bankers would be guided more by consumer demand and less by the institutionally cautious forces of the FDA and official medical research, and would be less able to control industry practices according to their own views and interests.

What is Being Done

There have been many new developments bearing on the quality of the blood supply in recent months, largely as a result of AIDS. In general, the government is responding grudgingly and in some cases perversely, while the market is responding in ways that are, under the circumstances, helpful and encouraging.

Government Responses. The blood bankers and manufacturers have successfully lobbied three states to extend liability exemptions from hepatitis to AIDS (in many states the exemptions are already general enough to cover AIDS). They have also had some success in opposing state legislation to require them to provide designated donations when requested. As of June 1986, such a bill had been defeated in one state; similar bills had been adopted in two states and were under consideration in five states.

The blood bankers are also winning lawsuits

in which patients or their estates attempt to discover donors' names to determine if they were negligently screened. Recently, a Pennsylvania court rejected the American Red Cross's contention that donors had a constitutional right to privacy, but nevertheless barred discovery out of fear it would "chill . . . the flow of blood donations." The judge invoked a "balancing test" to weigh "the need for voluntary blood donations versus the protection of blood recipients from disease." Such rulings suggest it is unlikely that appropriate liability rules will come about through the common law so long as voluntary blood remains the market norm.

On the other hand, bills to forbid AIDS victims from donating knowingly are gaining ground. As of June 1986, such bills were under consideration in seven states and had been adopted in one. In addition, local regulatory diversity has been encouraged by a 1985 Supreme Court decision in *Hillsborough County, Fla.* v. *Automated Medical Laboratories Inc.* upholding ordinances subjecting for-profit plasma banks to quasi-registry rules stronger than the FDA's minimum regulations. Apparently, few parties are pleased by this sensible ruling. Neither blood banks nor for-profit plasma collectors want standard registries, and organizations of both types that collect in several states prefer a single nationwide requirement. (The Red Cross, for example, operates over 50 regional centers under a single FDA license.) The FDA may prefer that local communities impose minimum standards no stronger than its own.

In an important turn of events, the FDA's Blood Products Advisory Committee, at its meeting in February 1986, reversed its position of a year earlier and recommended that blood banks adopt both of the hepatitis surrogate tests described earlier in this article. But the committee's two Red Cross members wanted to defer recommending the two hepatitis tests, and later persuaded the committee to defer action on an additional recommendation to screen donors who had been transfused since AIDS emerged in 1977. Their clinching argument against additional screening was that it would result in "throwing away" 5 percent of the nation's blood supply, and that "We are talking about a serious problem if we are talking about limiting the blood supply even more in this country." The argument assumed that the supply of blood is fixed, which is incorrect and would certainly be seen to be incorrect if blood banking were competitively organized.

Market Responses. The most promising development in blood banking is the recent resurgence of competition in supply. Hospitals, increasingly subject to fixed-fee rather than cost-plus reimbursement for their services, are seeking business and cutting expenses. Price is now more important, and new blood suppliers are beginning to cut price. Loyalties to regional blood banks are weakening because of the widely held view that they have not done all they could to prevent transfusion AIDS.

In Tucson, Ariz., last year, United Blood Services, a nonprofit blood service that contracts with 835 hospitals in 18 states, undercut by 40 percent the prices that the Red Cross charged to the University of Arizona Hospital. The hospital's expected annual savings were $250,000. In other cities, United Blood Services has forced the Red Cross to cut prices to keep its business. The Red Cross blood center in Salt Lake City closed after losing business to a large hospital that collected blood for itself and other hospitals. Mergers are under discussion in several regions. A new nonprofit blood bank has recently been formed in the San Diego area. And competition has led to new practices in the San Francisco Bay area without new entry. Media attention over Stanford's use of surrogate testing allowed Stanford to attract patients from surrounding communities; blood banks in nearby San Francisco and San Jose then adopted surrogate testing as a defensive measure.

The blood bankers' failure to provide services consumers want has led to innovations that are reducing the demand for potluck blood. More hospitals are offering designated and autologous donation, where patients pre-deposit their own blood for planned surgeries. A new specialty for-profit blood center in Los Angeles offers transfusion materials from donors designated by patients or from its registry of select, repeat, cash donors. Registry donors are asked to sign affidavits that they are not in high-risk groups, and agree to screening and testing in excess of typical blood-bank standards. This development may suggest that registries will emerge even where transfusion liability is limited, as in California—not to reduce suppliers' liability exposure, but as a market signal of higher-quality blood.

(Continues on page 54)