CHAPTER 15

OUTBREAK

The U.S. Centers for Disease Control and Prevention (CDC) serves as America's early-warning system for disease. This nondescript cluster of brick buildings nestled into the campus of Emory University is home to thousands of scientists working in some of the world's most high-tech biological-containment facilities. Established to investigate malaria prevention during World War II (Atlanta was chosen as the heart of America's malaria belt), the agency has since expanded its mission to monitor all forms of microbial invaders, from the familiar diseases of flu and hepatitis to the enigmatic outbreaks of legionnaire's disease and toxic shock syndrome. The agency played a key role in several historic triumphs, including the global eradication of smallpox and the defeat of polio in the U.S. The centers' researchers see themselves as a strike force against epidemics wherever they may emerge, from Africa to India, Arizona to New York.

One of the centers' less well known functions over the years has been to distribute certain vaccines and rarely used drugs. One such drug was pentamidine, a medication used against a rare form of pneumonia. Doctors had treated most pneumonia cases with sulfa drugs, but one form, Pneumocystis carinii pneumonia (PCP), resisted everything except pentamidine. Until fifteen years ago, fewer than one hundred cases occurred annually, and the CDC kept track of them.

In January 1982, Dr. Bruce Evatt, the CDC's specialist in hemophilia, got a call from a Miami physician whose patient had died of

Pneumocystis pneumonia. The patient was a sixty-two-year-old married hemophiliac who lived in New York but spent winters in Florida.

The mention of Pneumocystis pneumonia and hemophilia together sounded an alarm bell for Evatt. He knew that PCP cases had recently inexplicably jumped, particularly among gay men. In June 1981, five cases had been detected among "previously healthy" male homosexuals; since then the caseload had risen to more than one hundred. The disease seemed to travel in concert with other ailments, including a rare cancer known as Kaposi's sarcoma (KS). These "opportunistic" infections, as they came to be called, attacked people whose immune systems had been compromised, perhaps by anal intercourse. So stunning was the sexual connection that the syndrome became known as GRID—gay-related immunodeficiency disease.

Evatt suspected that the Miami patient, although heterosexual, had also died of GRID. Indeed, the case might show that hemophiliacs were also at risk for the syndrome, probably through their exposure to blood products. Hemophiliacs were well known to suffer high rates of blood-borne diseases; witness their towering rates of hepatitis. Indeed, with their massive exposure to blood products, they had become unintentional canaries in the cave. But Evatt needed more cases to prove the connection between GRID and Factor VIII. "If it's real there will be more of them," the agency's director had told him. Evatt's one wedge into cracking the mystery lay in the fact that, as the nation's sole distributor of pentamidine, the CDC could track where every dose went. He notified the CDC's pentamidine office to alert him the next time a request from a hemophiliac's doctor came in.

Half a year later, the disease struck two more hemophiliacs. They, like the Miami case, seemed to be average Americans—a fifty-nine-year-old man from Denver and a twenty-seven-year-old man from Ohio. They did not fit the known risk groups, or have anything in common other than that they used Factor VIII. Evatt sent Dr. Dale Lawrence out to examine them. When he returned with a diagnosis of GRID, Evatt felt they had made the connection.

Evatt immediately called the U.S. Public Health Service, the four major fractionators, and representatives of the National Hemophilia Foundation. He laid out his findings in the CDC publication *Morbidity and Mortality Weekly Reports.* (Set up as a rapid-response scientific publication, the *MMWR,* as it is called, is read throughout the world.) Evatt felt the cases raised two possibilities: that the pathogen probably moved through the blood, and that the agent was most likely a virus, since the process of making Factor VIII filters out anything larger. On July 16, 1982, he articulated his concerns to an emergency working

group of the U.S. Public Health Service, which included representatives of the CDC, the National Institutes of Health, the FDA, the National Hemophilia Foundation, and the major blood and plasma organizations.

By this time, GRID occurrences were forming the bell curve of a classic epidemic. The disease now afflicted more than 440 Americans overall. Doctors were astonished at the virulence of the syndrome—more than 50 percent of their patients had died. No one knew what caused the disease. Some disease experts thought that the pathogen had been transmitted by sperm; others suspected amyl nitrites, a stimulant then popular among gays. Some theorized that no single entity had caused the disease, but that the gay victims had been exposed to so many diseases—they had notoriously high rates of syphilis and hepatitis—that their immune systems had simply collapsed from the strain. With all these possibilities to choose from, the meeting participants were skeptical of Evatt's theory of blood-borne transmission, drawn from the data of just a few hemophiliacs. Most also did not want to believe the implications. Evatt's data would mean that the disease affecting gays in America could potentially infect the rest of the population. In a second meeting, later that month, the agencies set up a surveillance program to watch for new cases among blood recipients and hemophiliacs. They also agreed on a new name for the disease: acquired immune deficiency syndrome—AIDS.

Throughout the fall of 1982, with the number of hemophilia-AIDS cases rising, Evatt and his colleagues embarked on a campaign to warn the nation's medical establishment. The CDC was undergoing budgetary cutbacks, so Evatt used his own money for the travel. He worried that, given a lag time of several months before the symptoms appeared, a blood donor could have AIDS and not even know it. The safest course of action, he felt, would be to exclude the people most likely to carry AIDS—mainly, homosexuals—whether or not they exhibited the symptoms.

During his travels from one meeting to another, he received "mixed" responses to his unsettling news. Blood bankers, besieged with economic problems and continual shortfalls, did not want to add another crisis to their list—at least not until the evidence was definitive. Nor were they willing to exclude their gay donors. At a time of waning sense of community and declining blood donations, gays represented one of the most loyal donor groups. Generally well educated and civic-minded, they provided about a fifth of the Irwin Blood Bank's supply in San Francisco, for example. No one wanted to lose the best donors, or contribute in any way to antigay prejudice. "It was

as though someone had wandered in from the desert and said, 'I've seen an extraterrestrial,' " Evatt recalled. "They listened, but they just didn't believe it."

The National Hemophilia Foundation, though alarmed at his findings, gave him a decidedly mixed response as well. Dr. Louis M. Aledort, codirector of the foundation's Medical and Scientific Advisory Board, had pioneered the concept of hemophilia therapy. Having seen his patients literally climb out of their wheelchairs, he was loath to abandon the therapy. Years before, he had developed the nation's first "comprehensive-care" center at New York's Mount Sinai Hospital; later, he lobbied Congress to fund a national network of hemophilia treatment centers. Still later, Aledort formed a consortium among treatment centers in the New York area to leverage the best prices from the drug companies and provide reliable quantities to patients. With such a large market at his command, he became a power in the medical-pharmaceutical world, attracting tens of thousands of dollars in grants every year. Aledort felt that he needed more data before recommending that patients change their treatment; after all, Evatt had found only three cases among the nation's twenty thousand hemophiliacs. He knew the good that the therapy could do, and worried about an overreaction. As Evatt understood it, "Here they were dealing with a strange disease that they really didn't want to believe existed."

Others in the National Hemophilia Foundation could not ignore Evatt's findings. After he spoke to the foundation in October, it passed a resolution urging the drug manufacturers to exclude from their plasma pools groups with a relatively high incidence of AIDS, including gays, IV drug users, and Haitians. At the same time, it presented a reassuring face, issuing a series of advisories that the risk of AIDS in Factor VIII was minimal and that hemophiliacs should continue their infusions as before.

Ironically, the most cooperative early response came from the profit-oriented drug companies (although some later would try to stall, as we shall see). Tom Drees, president of Alpha at the time, said he was "knocked off [his] chair" when Evatt addressed a group of fractionators. He immediately made plans to exclude high-risk donor groups, despite potential charges of discrimination. His and other companies also accelerated their research to find a way to decontaminate the product.

The companies did not react solely out of altruism. Living in the worlds of medicine, regulation, public relations, and law, they recognized certain hard, even cynical, realities. They, like the blood bankers, prized their gay donors—not for their civic-mindedness, but as prime

sources of hepatitis B antibodies. During an early meeting with industry leaders, Dr. Dennis Donohue, director of the FDA's Division of Blood and Blood Products, had asked them if they could turn away high-risk donors from certain "hot spots," such as San Francisco, Los Angeles, and New York. "He is not basing this request on scientific concerns that such plasma or coagulation by-products transmits AIDS but believes the action is a political necessity to prevent national adverse publicity and . . . undue concerns in the hemophilic population," wrote Cutter official John Hink in an internal company memo. After informally surveying his competitors and finding that most intended to go along with the request, Hink concluded that Cutter should agree, for "political, moral and liability reasons." Meanwhile, in patient advisories and brochures, Cutter (and other drug companies) continued to describe the AIDS risk as minimal.

By late in the winter of 1982, the number of hemophilia-AIDS cases had risen to eight—more than a doubling in less than six months. Now came the first report of a blood-related AIDS case. A baby in San Francisco had died of the disease more than two years after receiving multiple transfusions of blood and blood products. Looking back through their records, officials at the Irwin Blood Bank discovered that one of the donors was a gay man who, seemingly healthy at the time, later died of AIDS. This information closed the case as far as Evatt was concerned. He and other public-health officials called for a summit meeting to discuss what to do about AIDS in the blood supply.

More than two hundred representatives of the blood industry, doctors, gay groups, and patient and hemophiliac groups came to the day-long session at CDC headquarters in Atlanta on January 4, 1983. After two preliminary presentations, Evatt laid out his most recent data. He told the assemblage that, in addition to the eight known hemophilia AIDS cases, he strongly suspected two more. Furthermore, a survey he had taken of more than one hundred hemophilia centers turned up thirty-seven more cases he planned to investigate. Thus, he said, the epidemic curve for AIDS in hemophiliacs was looking more and more as it had among gays, gathering momentum, and about to rise sharply. Furthermore, he confirmed details of the blood-related AIDS case of the San Francisco baby and said that two more transfusion cases were under study. Now that the problem was known, he said, the question was how to protect the blood system. It was especially crucial to act as soon as possible: With a known lag time of more than a year, someone who passed all the medical exams could still carry the disease and pass it on through blood or plasma.

The next speaker, Dr. Tom Spira of the CDC, presented some options. One thing that struck epidemiologists, he said, was the correlation between AIDS and hepatitis B—in fact, nearly 90 percent of the known AIDS sufferers in America had been exposed to hepatitis B. With such a tight correlation between hepatitis and AIDS, hepatitis could serve as a "surrogate marker" for AIDS—an indication of those who might harbor the disease. Blood banks routinely tested for hepatitis by screening for an antibody to the virus's surface coating, a test that only detected recent exposures. Spira found that another antibody—one that reacted to the virus's core—remained in the body for years. Thus, though no AIDS test existed, blood banks could provide an interim measure of safety by using the hepatitis B core test.

Evatt believed that he and his colleagues had presented a complete package—the disease, the risk groups, and the methods to exclude them. "We went into that meeting expecting it to be a snap," he recalled. "How could anybody doubt the data we'd accumulated, the *trends?* We thought it was a no-brainer."

He could not have been more mistaken. Gay representatives immediately objected that labeling them as unacceptable donors would trample their human rights. Roger Enlow of the National Gay Task Force said that the community had been educating its members and could be counted on to behave responsibly. To exclude them legally from donating, however, would put the stamp of approval on homophobia. Dr. Bruce Voeller, a member of the gay group Physicians for Human Rights, argued that, since AIDS seemed limited to promiscuous "fast-track" gays, excluding gays in general would "stigmatize . . . a whole group, only a tiny fraction of whom qualify as the problem. . . ." For that reason, he favored the use of the hepatitis B core test, since it relied on a laboratory procedure rather than invasive questioning. Enlow agreed: "We think screening blood, not people, is the way to go."

"I don't think anyone should be screened for donating blood on the basis of sexual preference," said Dr. Donald Armstrong of the Memorial Sloan-Kettering Cancer Center in New York. "I think that is wrong."

The drug companies disagreed. With their paid donors and enormous processing pools, they had to act quickly to check the contamination. A representative from Alpha said the company already had begun excluding gays, Haitians, and drug users, "because frankly, we don't have anything else to offer at this time." Seizing the public-relations advantage, he added, "I would hope everyone in the industry would

follow suit." Other drug manufacturers agreed to the principle, which the National Hemophilia Foundation had been pushing for months. Commenting later to a medical publication, Aledort said, "I disagree vehemently with the National Gay Task Force. They may want to protect their rights, but what about the hemophiliacs' right to life?"

There was plenty of reason for everyone to feel defensive at the CDC meeting. For one thing, the setting put everyone on edge. The visitors had expected a scientific exchange, a sober and considered policy discussion. But when they entered the conference room with the horseshoe-shaped tables, they found themselves blinded by television klieg lights and battered with questions from aggressive reporters. This was hardly the stetting for a rational discussion of the delicate topics of blood, blood products, and sexual orientation, hardly the place for secrets to be revealed. When a couple of people raised the question of prison plasma, the Pharmaceutical Manufacturers' Association "stonewalled" it as "immaterial to the discussion," according to a memo by a drug-industry representative. In a postmeeting memo, one Cutter official wrote, "To exclude such plasma from the manufacture of our coagulation product . . . would presage further pressure to exclude plasma collected from the Mexican border and the paid donor."

Dr. Oscar Ratnoff, a renowned hemophilia physician from Cleveland, suggested that hemophiliacs sidestep the problem by suspending their use of Factor VIII. They could resume using safer cryoprecipitate, made from pools of ten donors or less. "Sure it'll cost more, but not as much as a funeral or the lawsuits we're going to get after more hemophiliac deaths," he said. The drug companies and other hemophilia doctors opposed him, arguing that after a large number of exposures to cryoprecipitate hemophiliacs would probably contract the disease anyway. (They turned out to be wrong, as we shall see.)

Many harbored doubts about the hepatitis core tests. Dr. Aaron Kellner, director of the New York Blood Center and engineer of the Euroblood program, complained that the test would cost his center $5 million a year and force his and other blood banks to turn away 5 percent of their donors. "This is a very serious problem," he stated, "but we ought not to do things that would jeopardize the community's blood supply."

Kellner and others felt that Spira's core test was not specific enough. It certainly *correlated* with most cases of AIDS, but it did not specifically *detect* the disease. What about those people who falsely tested positive, who had previously been exposed to hepatitis but were at no risk for AIDS? Imagine a donor's horror after he has been rejected by a surrogate AIDS test. As Dr. Joseph Bove, director of the Yale University

Blood Bank and then president of the AABB, later testified: "This was a major worry, that in a time of this AIDS concern, hysteria, whatever you want to call it, one out of twenty individuals walking into the blood bank . . . would be told 'You can no longer donate blood because your blood is positive by the core antibody test. Yes, that is the test we're using to screen out people that might—but don't worry, you don't have AIDS.' " The point, Kellner argued, was that the data were not strong enough. "What do we have in the way of evidence?" he asked. "Three cases at most and the evidence in two of these cases is very soft. . . . Don't overstate the facts." Added Bove: "We are contemplating all these wide-ranging measures because one baby got AIDS . . . and there may be a few other cases."

Evatt tried to explain that when a disease appears suddenly and spreads rapidly it meant that they were witnessing the birth of an epidemic.

Yet how could they take actions against a syndrome, some argued, when they had not even identified a cause? These immune deficiencies could be triggered by many things. "I'm concerned about the concept that we are convinced it is an agent . . . ," said Aledort. "We could be doing something through transfusion that causes it . . . or something in the patients' immune complex. Now in another six months we may . . ."

At that point Dr. Donald Francis erupted. Francis, assistant director of the CDC's hepatitis lab in Phoenix, Arizona, could not believe what he was hearing. He had chased epidemics from India to Zaire, but had never seen bureaucratic resistance like this. Pounding his fist on the table, he shouted, "How many people have to die? Is three enough? Is six? Is ten? Is a hundred enough? Just give us the number so we can set the threshold!"

Years later, still seething about the incident, Francis said, "I just couldn't believe these guys. It was something like having a bend in the train track and sitting there and you hear the whistles and the signals are blinking and the tracks are beginning to shake, and they're saying, 'There's no train coming.' "

"I think they were listening, but I just don't think they wanted to believe it," Evatt reflected. "The implications were so catastrophic for the whole industry they just wanted it to go away."

Certainly denial lay behind the resistance—the implications of a contaminated blood supply were virtually unthinkable—but blood bankers had reasons to doubt the CDC. For one thing, the recommendations they heard that day were by no means *official.* The suggestions about donor questionnaires and hepatitis core testing came from a few

individuals *within* the CDC, whose superiors had not endorsed them at the meeting. (In the public-policy world, this small difference assumes galactic proportions.) Furthermore, the agency had cried wolf in the past. Many recalled how CDC experts had deeply embarrassed the Ford administration by sounding an alarm for the swine-flu epidemic that never came and pushing for a vaccine program that probably killed more people than it protected. They also knew that the agency faced budget cuts. As an American Red Cross official wrote in a post-meeting memo: "It has long been noted that CDC increasingly needs a major epidemic to justify its existence. This is especially true in light of Federal funding cuts and [the] fact that AIDS probably played some positive role in CDC's successful effort . . . to fund a new $15,000,000 virology lab. This CDC perspective is also obvious from the general 'marketing nature' of the January 4, 1983 Atlanta, [meeting, with the] abundant press. . . . In short, we can *not* depend on the CDC to provide scientific, objective, unbias[ed] leadership. . . ."

Beneath those reasons lay even deeper issues. Even though they were citizens of the same country, the adversaries in this discussion came from two different cultures, with contrasting sets of values and views. Francis and his colleagues were a fast-acting lot, sensitive to the slightest hint of a trend. These were the kind of people the CDC attracted—activist, Peace Corps types, ready to move, react, and respond. In contrast, the blood-banking culture resembled the business world. Its leaders, though scientists, concerned themselves with businesslike issues of inventory, quality control, and supply. Describing themselves as constitutionally conservative, they were loath to make quick decisions on scanty data.

This divergence of perspective gave the two groups radically different views of the AIDS-epidemic curve. To the CDC workers who had tracked it from the beginning, with the case rate doubling every six months, the response time was *now.* To the blood bankers who administered tens of millions of transfusions, these half-dozen or so cases were a blip, a troubling anomaly—certainly worth tracking but not enough to upset traditional collection methods. It is not surprising, then, that the meeting produced no decisions. Afterward, Francis wrote of his disappointment in a memo to his superiors. "I feel there is a strong possibility that some post-transfusion AIDS and much post–factor VIII receipt AIDS will occur in this country in the coming two years. . . . For hemophiliacs I fear it might be too late."

Two days after the meeting in Atlanta, the country's major blood-banking organizations (the American Red Cross, the AABB, and the

Council of Community Blood Banks) set aside decades of feuding about policy and territory and convened a Joint Task Force against AIDS. On January 13, the group issued its first Joint Statement on Acquired Immune Deficiency Syndrome Related to Transfusion. It was a conservative document, insisting that the case for blood-borne transmission was inconclusive, and offering several "reasonable" measures for blood banks and physicians to follow. These included educating donors about AIDS, allowing "autologous donations" in which patients could set aside their own blood for future use, and discouraging donations among groups "that may have a high incidence of AIDS." The statement did not recommend surrogate testing. The blood bankers added, "Direct or indirect questions about a donor's sexual preference are inappropriate."

Publicly the statement seemed reasonable, cautious, and reassuring. Privately, though, Bove harbored doubts. He hoped that the statement would "buy time" with the public while blood bankers figured out what they should do. "There is little doubt in my mind that additional transfusion related cases . . . will surface," he wrote in a memo to the AABB executive board. "Should this happen, we will be obliged to review our current stance and probably to move in the same direction as the commercial fractionators. By that I mean it will be essential for us to take some active steps to screen out donor populations who are at high risk for AIDS. For practical purposes this means gay males. . . ."

The fractionators had by now begun screening gay donors, but the National Hemophilia Foundation pushed them even harder. At a summit meeting with the industry in mid-January, the foundation stepped up pressure for tough donor screening—"lapel-grabbing, finger-pointing questions," as an industry veteran put it. They also asked companies to consider surrogate testing. The organization issued a dozen recommendations to hemophiliacs and their physicians designed to cut back the risk of overusing Factor VIII should it prove to carry an infectious agent. They urged hemophiliacs to postpone elective surgery, and physicians to use cryoprecipitates for newborns and other patients without previous Factor VIII exposure. Meanwhile, however, they continued to advise most hemophiliacs to keep using their factor as before.

The plasma companies agreed with the Hemophilia Foundation on the issue of screening, although some preferred a less confrontational, self-exclusion approach. They felt less sanguine about the foundation's demand for surrogate testing, which could cost $5 a test and eliminate 10 percent of the paid donors. Nor did they want to switch to small

plasma pools, which would raise the price to prohibitive levels. ABRA, the plasma-industry trade group, urged all collectors to intensify their screening by requiring donors to read informational brochures about AIDS and to certify they did not belong to any risk groups. They did not recommend the hepatitis core test.

Through the early months of 1983, as the first halting steps were taken to protect the nation's blood supply, fear and indecision rose in tandem. Provocative articles appeared about the threat to the blood products. A story in *Rolling Stone* asked readers to "think about the unthinkable: Are our blood banks already contaminated? Is AIDS going to flow into your veins the next time you need a blood transfusion?" On Long Island, New York, the Roslyn Country Club Civic Association established its own members-only donor list. In San Diego, a group of lesbian donors formed the Blood Sisters Project; if gays and their partners harbored the infection, then lesbian blood would be unusually clean, since they never had sexual contact with men. (The group later received a national award.) Donations declined as some people worried they could catch AIDS by merely *giving* blood; by midsummer in New York, for example, donations had dropped by 25 percent.

Threatened by shortages and public hysteria, the leading blood banks gave contradictory messages. Kellner openly scoffed at the risk of blood-borne AIDS transmission. Yet, even as he did, his staff began an experimental program in which, after an interview, the donor could check a box on a form reading "my blood is only for studies" if he felt that he belonged to a high-risk group. In San Francisco, Dr. Herbert Perkins, medical director of the Irwin Blood Bank, rebuffed a public plea from a group of AIDS specialists at the University of California, San Francisco, to consider using the core antibody test. Perkins argued that there was no "rational evidence" it would effectively screen AIDS, and that it would eliminate enough blood to jeopardize the region's supply. Later, under increasing public pressure, Perkins agreed to try the test. Many centers added more searching inquiries about AIDS-related symptoms to their donor questionnaires. No one really knew what do to. No leadership was coming from the Reagan administration, which had not even officially acknowledged the epidemic.

Finally, on March 4, 1983, the U.S. Public Health Service issued its first official AIDS-related recommendations. By now more than twelve hundred cases had been detected, including eleven among hemophiliacs and about half a dozen possible transfusion cases. The Public Health Service statement urged citizens to avoid sex with multiple partners or with "persons known or suspected of having AIDS." It also asked members of high-risk groups—including "sexually active homo-

sexual or bisexual men with multiple partners"—to refrain from donating plasma or blood. A few weeks later, the U.S. Food and Drug Administration issued specific guidelines for the blood industry with self-exclusion procedures to weed out members of high-risk groups. These generally took the form of informational materials, one-on-one interviews, and statements for recipients to sign saying they understood the risk of AIDS. Neither directive recommended surrogate lab tests or direct sexual questioning.

Those who had been tracking the epidemic believed that the government had done the absolute minimum, merely endorsing the existing consensus. (The Public Health Service had rejected an earlier draft prepared by the CDC including the surrogate blood test and the exclusion of gay donors, promiscuous or not.) But to Evatt the action marked a turning point—the beginning of the end of the period of denial. "I think it was gradual; but the fact that something actually came out [of the government] made a lot of people think, 'This really is happening.' Things began to change after that."

Evatt was right: Things had begun shifting, at least in terms of public policy. In terms of the physical resource, however, change came at the pace of making a U-turn with the *Titanic*. Millions of units of blood, plasma, and clotting factor collected the old way remained in use all over the country—in blood banks and drug companies; in hospitals and warehouses; in boxes and storage bins up and down the chain of distribution. Thousands upon thousands of infected bottles sat in the refrigerators of thousands of hemophiliacs, who would use them at the next sign of bleeding.

In the tiny rural town of Dolores, Colorado, forty-five-year-old Susie Quintana had just come home from some hiking and target practice in the woods. Hers was a bucolic existence, built around her husband, children, grandchildren, and community. Everyone in town knew Susie, and liked her. She had grown up in Dolores, met her husband at a dance, and gained some renown with her prize-winning crocheting. She was admired for her levelheadedness and cheerful personality. Returning from her hike on May 27, 1983, she was putting away her .22 rifle when it discharged, wounding her in the side. Later, at the hospital, her son Ron asked the doctors if the family could provide blood. Like millions of families throughout America, the Quintanas had heard news of the AIDS epidemic, and discussed it around the dinner table. They had all agreed that, if any of them ever needed blood, the others would provide it. Ron and his father had the same blood type as Susie. But the doctor dismissed him, telling him that the local

blood was perfectly safe. "There are no gays or homosexuals in the county," he said.

Aside from the ignorance of the doctor's assumption, what he neglected to tell Ron was that the blood did not come from their county, or their state. The hospital purchased blood from the nation's second-largest blood-banking conglomerate—United Blood Services, based in Arizona. On April 18, the company had staged a blood drive at a school in Santa Fe, New Mexico. The collectors knew about the Public Health Service advisory and took it seriously, carefully examining and interviewing the donors. They distributed printed sheets, asking members of the high-risk groups, including "homosexually active males with numerous contacts," to refrain from donating. One donor, a teacher who happened to be gay, read the sheets and answered the questions. The phrase "numerous contacts" did not apply to him, so he gave blood with a clear conscience and the best of intentions. He had no way of knowing that he might be carrying AIDS. One month later, in a small hospital in rural Colorado, doctors infused his blood into Susie Quintana.

At a charity basketball game in Tennessee, Dana Kuhn, a forty-year-old seminary student and father of two, fell after jumping for a rebound, and broke one of the bones in his foot. Kuhn was a mild hemophiliac, and had never injected Factor VIII before. But doctors infused him, just to be safe.

In Los Angeles, Corey Dubin, a radio journalist and severe hemophiliac, was watching the evening news as he gave himself a Factor VIII injection. A hulking man with a Pancho Villa mustache and a savage intensity, Dubin had been infusing since he was a boy; he was among the first group of patients on whom Hyland had tested the product in the late 1960s. It had changed his life utterly, giving him the freedom he craved to hike the Muir Trail in the mountains of California and bushwhack through the jungles of Costa Rica. Now, as he infused another of the thousands of doses he had taken since childhood, he turned to his wife and said, "Shit. I just *know* I'm shooting myself up with AIDS."

Outside America, the issue of AIDS in the blood supply stirred up a complicated mixture of concern and denial. Many in other countries saw AIDS as an American disease; it had, after all, blossomed there first. "The initial reaction was that whatever happened in America won't happen here. After all, we don't have gay bathhouses," recalled David Watters, director of Britain's National Haemophilia Society. Yet, just as in the United States of a year or so before, cases were increasing

among European gays, and had begun to appear among blood recipients and hemophiliacs. Deny it as they might, nations throughout the world would have to reconsider the safety of their blood systems. They would also face the uncomfortable reality that they imported most of their plasma products from a country with the world's highest AIDS numbers.

In Britain, concern about AIDS sparked yet another call for plasma self-sufficiency. The failure of England to reach Factor VIII independence had become an old and dreary news item by now. The government had set and missed numerous deadlines to modernize and expand the fractionation plant at Elstree. If they had succeeded, critics argued, it might have been possible to make safer clotting factors from small lots taken from well-screened British donors. What some critics found especially galling was that, just north of the border, the Scottish National Transfusion Service ran a clean, modern plant with excess capacity. The English could have collected plasma from their own donors and sent it for processing in Scotland. Doing so would have meant putting the facility on round-the-clock shifts and negotiating overtime pay with the unions—out of the question under the Conservative Thatcher government. And so the Scottish plant sat idle for a portion of each day while the English increased their imports from America. By the spring of 1983, when the first hemophilia AIDS cases began appearing in Britain, English hemophiliacs were getting about half their Factor VIII from commercial American firms.

Physicians watched the situation with dread, for they fully understood the hazards of the imports. In 1975 and 1978, for example, Dr. John Craske of the Public Health Laboratory in Manchester had published two studies implicating American clotting factor with hepatitis B outbreaks among British hemophiliacs. He and others knew that it was only a matter of time before AIDS, which followed the same routes as hepatitis, began to endanger hemophiliacs as well. But the AIDS risk was uncertain and the dangers of untreated hemophilia were clear. So, as they watched for the signs of a rising epidemic, doctors told their patients to keep using the clotting factors, imported or not. Someday, they hoped, safer products would become available. Until then, said Dr. Carl Rizza, chief of the Oxford Haemophilia Centre, the fate of hemophiliacs was "in the lap of the gods."

The Germans had plenty of early warning about AIDS. Not only had the federal health authorities been in close touch with the American CDC, but as early as May 1982 a patient at the Bonn clinic died of what appeared to be AIDS. The diagnosis, if accurate, would represent the world's second case of hemophilia-linked AIDS (after the January

case reported by Bruce Evatt), and came at a sensitive time for the Bonn center. After all, Dr. Hans Egli and Hans Hermann Brackmann had built the center's reputation on the massive use of Factor VIII, which they were now being forced to defend against the insurance companies. This was also the time when German tax authorities were launching an investigation against the center's chief procurement officer, Dr. Etzel, in relation to his arrangements with the importers from Switzerland. It was not surprising, then, that Brackmann and his colleagues at the Bonn center hotly disputed the diagnosis, arguing that the patient had actually died of alcoholism and hepatitis. More cases inexorably followed. By the fall of 1983, the number in Germany had risen to six.

In Strasbourg, the Council of Ministers of the Council of Europe urged its member nations to react to the disease. Even though "no formal proof" linked AIDS and the plasma supply, the council urged its member nations to avoid blood products derived from commercial (i.e., American) donors, and try to eliminate imports altogether.

Germany could never hope to comply. It led the world in its prescription of the factor, the vast portion of which came from the United States. In November 1983, a special working group of federal health authorities, hemophilia treatment providers, and industry representatives debated the wisdom of continuing to prescribe high levels of clotting factors. Some doctors argued for an immediate cutback, but others, principally Brackmann, insisted that a virus did not cause the disease, that there must be some other "co-factor" at work. Brackmann and his colleagues prevailed in the end, and the Federal Health Authority (Bundesgesundheitsamt, or BGA) concluded that "a limitation of imports" was "out of the question."

During this time, the hundreds of Bonn patients received no indication of the ongoing debate. All they knew about the safety of their factor was what their doctors kept telling them in a reassuring series of "Dear Family" letters. The July 1983 greeting, for example, described hemophiliacs with AIDS as having been found "exclusively in America" and stated that "no patient who has been treated at our center has been affected," thus ignoring the death of at least one of their patients. One patient, Dr. Werner Kalnins, recalled that the center's attitude at the time was a strange mixture of blind faith and cynicism:

> As soon as I heard about AIDS, I said, "Doctor, wouldn't it be safer if I took European products, say from Immuno [the Austrian fractionator]?" He said, "It doesn't matter. They all get their plasma from America anyway."

> If they had given me the chance to take cryoprecipitate, I must say I would have taken it. I would have said, "OK, I'll be careful and play no sports for one or two years . . . ," but I would have taken it.

Years later, Professor Hans Egli would testify in Parliament that three-quarters of his patients with severe hemophilia had become HIV-infected—a number he found "surprisingly large . . . alarmingly large." One was Werner Kalnins. Another was Frank Schnabel, the founder and president of the World Federation of Hemophilia, who, having lavishly praised the Bonn center for years, died of AIDS in 1987.

One of the pivotal events of the early AIDS years was the World Hemophilia Federation's annual meeting in June 1983. Convened at the Karolinska Institute in Stockholm and attended by delegates from all over the world, the conference embraced a wide-ranging program, from the "Psychosocial Effects of Hemophilia" to "Possibilities to Increase Yield of Factor VIII." To all who attended, though, the underlying agenda was clear. They had been hearing the rumors, and watching developments in the U.S.; this meeting would be their first chance to assemble as a group and compare notes about AIDS. Indeed, part of their purpose was to produce a resolution that they all could take back to their home countries for guidance.

Bruce Evatt had been invited to speak, but he felt himself set up in a way. Though Aledort was supposed to give a brief introduction, instead he swung into a lengthy discourse on how little scientists knew about the disease. Evatt, when his turn came, felt he had to defend how much they *did* know. By now he and his colleagues felt certain that the agent was a virus, transmitted though sexual contact and blood products. The only reason they had not observed more cases was that the disease displayed a mysterious lag time, but they had no doubt that more cases would come. It would be "prudent," he suggested, in the courtly language of scientific conferences, "to take measures to reduce the risk of acquiring and transmitting AIDS via blood and blood products. This may be especially pertinent to the Hemophilia patients."

A couple of days later, the group prepared to vote on a resolution. Dr. Shelby Dietrich, a member of the federation's medical-advisory board, had written the draft. Dietrich had a complicated experience with AIDS. As head of the hemophilia department of the Los Angeles Orthopedics Hospital, she was an enthusiastic Factor VIII proponent, having introduced home therapy to the West Coast. When AIDS came along, she reacted responsibly, suspending elective surgery for all the

hemophiliacs under her care. After several months with no cases, however, she lifted the suspension and urged her patients to continue their infusions. At the same time, she continued to use cryo with "virgin" patients and small children. She had come to the meeting with a six-page summary of what scientists in America knew about AIDS. Given the uncertainty, she concluded, it really boiled down to a simple decision of whether patients would risk more by discontinuing their factor and suffering the known consequences of hemophilia, or by continuing their treatments and incurring the unknown risk of AIDS. She suggested, in part, the following resolution: "There is insufficient evidence to recommend, at this time, any changes in the treatment of hemophilia, therefore present treatment should continue with whatever blood products are available. . . ."

The wording outraged the Dutch representatives. Cees Smit, head of the Dutch Hemophilia Society, had extensively researched the international plasma trade, and what he found had scared him. Having helped a Dutch journalist named Piet Hagen research his 1982 book, *Blood: Gift or Merchandise,* Smit could see how a virus could spread through the global blood-products system, be it hepatitis or AIDS. Indeed, early in 1983 he had convinced Dutch medical authorities to curtail severely the use of imported Factor VIII. Now he and his countrymen tried to persuade the World Federation to take a more cautious approach to the use of the factor. Rather than give approval, for example, the federation could urge patients to use clotting factors only in cases of life-threatening emergencies, such as a brain bleed, or to revert, for a time, to cryoprecipitate. Granted, these measures would be inconvenient, but they might, in the end, save a few lives. "There was certainly enough proof to at least have warned the hemophilia community about what was going on," Smit later said. But almost no one supported the Dutch, and the resolution passed as originally worded.

The decision was tragic. Dietrich may have meant for the resolution to stand as an interim measure—to continue provisionally while doctors gathered more evidence—but many delegates took it as a *carte blanche* for the continued and unfettered use of Factor VIII. Indeed, some nations, including Britain, France, and Japan, escalated their use after the conference. As a result, thousands of hemophiliacs throughout the world freely infused themselves with a product that they should have been regarding with utmost suspicion.

Dr. Takeshi Abe, vice-president of Teikyo University, near Tokyo, was one of the experts at the Stockholm conference. Abe was a legendary figure among hemophiliacs in Japan. In a culture where disability

meant disgrace, Abe treated his patients with dignity, extending to them the right to be rehabilitated, not scorned. When Factor VIII came on the market, he enthusiastically promoted it, becoming the nation's pioneer in home hemophilia care. He and a couple of colleagues had traveled the country, bringing the therapy to urban and rural populations alike. People still remember how Abe and a colleague, scouring the rural areas for hemophiliacs, came upon a little boy curled up in a barn, twisted from years of disfiguring joint bleeds, and brought him in for treatment.

It was no surprise then that Abe continued to promote Factor VIII, especially after the Stockholm conference. Others in Japan had come to value it too, and not only for therapeutic reasons. Its use had been climbing ever since the country's insurance commission began covering the cost of Factor VIII home infusion in February 1983. Indeed, as hemophilia doctors were debating the resolution in Stockholm, Factor VIII use in Japan had just begun to take off. But Abe had other things to consider as well. As leader of a newly formed government AIDS commission, Abe had to determine whether the epidemic would soon sweep into Japan, and if so how to act.

The Japanese had always prized their national purity, and considered AIDS an American disease. In July, a hemophiliac whom Abe had been treating died of multiple causes. Although suspicious that the man had died of AIDS, Abe hesitated to make a positive diagnosis, which would have meant acknowledging that the disease had arrived in Japan. That summer, when two American CDC specialists happened to be attending a conference in Japan, Abe met them and related the details. "We said that it seemed very similar to what we were seeing," recalled Dr. Tom Spira, one of the two. "We put it in the same context as the cases here." In other words, the patient had AIDS.

Meetings in Japan do not proceed under the same social rules as those in America. Fewer memos are exchanged; fewer formal agreements pass from hand to hand. With a cultural sense of shared understanding, corporate and policy decisions can move forward based on an assumed consensus, on a nod, a look, or a lack of objection. Therefore, the literal details of what happened next probably will remain somewhat obscure. According to witnesses in the Diet hearings that eventually followed, Abe initially agreed with the diagnosis. But when the media picked up on the story that AIDS had "landed" in Japan, Abe's commission voted to backtrack on the story and deny the patient had AIDS. Abe reportedly dissented, but for the sake of solidarity announced to the media that the patient had died of "quasi-AIDS" probably brought on by his use of steroids.

Thereafter the cover-up took on a life of its own. In August of 1984, after an experimental AIDS test had become available to scientists in America, Abe sent forty-eight blood samples from his patients to Dr. Robert Gallo of the U.S. National Institutes of Health. Twenty-three of the samples were HIV-positive. Abe informed the Health and Welfare Ministry, but for several months said nothing to his patients or to the public. Later that year, when another sampling showed that a high proportion of his patients had AIDS, Abe still kept the information quiet.

It is difficult to comprehend the extent of the medical establishment's denial in Japan. In 1983, when Japanese hemophiliacs asked the Ministry of Public Health about clotting factor, they were told, "Blood concentrates are safe, so the blood system does not have to be changed." In a "Proclamation of Safety" to Japanese hemophiliacs, Abe's commission pronounced: "The need to worry about AIDS is slight, so to worry about stopping the imports from the U.S. is probably too much. Imports will continue to be improved so hemophilia treatment will not be disrupted. . . . All of you are being saved because of blood products."

As far as the Japanese public was concerned, AIDS had not yet arrived in the motherland. And for all the hemophiliacs knew, their clotting factor was safe. Not until March 1985 did the Health Ministry's commission announce that they had found the first AIDS case, a man who had been living in New York but who after he got sick came home to Japan. They picked someone who was as atypical as possible. As sociologist Eric Feldman has written: "[He] was a homosexual, not a hemophiliac; an artist, not a salaried worker; a Japanese national living in the United States, not Japan; in short, a deviant, not an average Japanese, who was identified as the country's first AIDS patient."

Eventually Abe and the Japanese Health Ministry acknowledged that the first hemophiliac had indeed died of AIDS. By now, of course, hundreds had been infected and dozens diagnosed, most of whom had not been told of their condition. As late as 1988, in fact, Abe and at least some other hemophilia specialists did not tell their patients they had become HIV-positive. To a newspaper he explained: "Until we can have a procedure to conquer AIDS, we prefer to hide the real data from the HIV test. . . ." In one sense, this conformed to a Japanese paternalistic medical tradition of not directly telling patients that they have a terminal disease; the doctors generally tell close relatives instead. But in this case, the doctors told no one in the family. As a result, at least thirty HIV-positive hemophiliacs gave the infection to loved ones and spouses.

Thus, Japanese medical authorities kept secret the very existence of AIDS in Japan for two crucial years, from 1983 to 1985. During this period, their imports of Factor VIII and plasma continued to climb.

Jean Péron-Garvanoff was a living testament to the wonders of French hemophilia therapy. Born in Bulgaria, he emigrated to France after the war as a boy with his parents and two half-brothers. The move saved his life, for he had gone from one of the most backward nations in the treatment of hemophilia to one of the most advanced. In Bulgaria, there had been nothing for his bleeds except ice, improvised plaster wraps, and prayers. (Once, in order to stop a spreading hematoma, his parents had no choice but to throw him into the snow.) A new world opened up for him in France. There he received the most modern treatments. He remembered being treated by Dr. Arnault Tzanck, the father of French transfusion medicine, who, his kindly eyes twinkling, would sit next to the boy, turning the little crank on the arm-to-arm transfusion pump. After Tzanck died, Péron-Garvanoff became a patient of Dr. Jean Pierre Soulier, another luminary of French transfusion medicine. Soulier introduced him to the therapeutic marvels of plasma and cryoprecipitate.

Of all the doctors who helped him, however, he reserved his greatest affection for Dr. Jean-Pierre Allain. It was Allain who, as head of a school for hemophiliac boys, introduced hemophilia home therapy to France. Allain had impeccable credentials. In addition to doing pioneer work at the school, he had performed research at the University of North Carolina with Kenneth Brinkhous, the developer of Factor VIII. Allain later joined CNTS, where he became chief of anticoagulant research and development. Péron-Garvanoff found this therapy miraculous—not only for him and his two hemophiliac half-brothers, but also for their mother, who lived in anguish about the condition of her sons. It kept his joints supple enough to pursue his career as a boogie-woogie piano player. Furthermore, he *liked* Allain. With his rumpled appearance and boyish enthusiasms for tennis and jazz, Allain did not stand on the traditional pedestal; he even let his patients call him Jean-Pierre. Sometimes Péron-Garvanoff performed at the *soirées* Allain and his wife liked to host. The depth of Péron-Garvanoff's loyalty became apparent one night when an argument erupted between Allain and an unruly neighbor. The neighbor was becoming violent. Just as he reared back to lunge at the doctor, Péron-Garvanoff, risking a hemorrhage if anyone had struck him, threw himself between the doctor and his assailant, and shouted, "Don't touch this man! He's a saint!"

On June 19, 1983, Péron-Garvanoff heard a radio broadcast about a malady called AIDS among homosexuals and hemophiliacs in New York. "I remember that date because I wrote in my notebook," he later recalled. He called Allain and asked a simple question: Did he, as a hemophiliac, stand a risk of contracting the disease?

Allain too had begun to worry about AIDS, which had just begun appearing in France. In Paris, with its exuberant lifestyle and mixture of populations, chances were high that this "gay" syndrome might infect hemophiliacs as well. Allain had already seen the first hints of an invasion: In a survey that he and a colleague conducted of twenty-three hundred hemophiliacs, six exhibited AIDS-like symptoms of swollen lymph nodes and dramatic weight loss. The study also told him that no products were risk-free, even those made solely from French volunteer donors. Concerned by the results, Allain was forming an AIDS Hemophilia Study Group, a collection of more than four hundred hemophiliacs in which he would try to pin down which products seemed to be carrying the disease. Yet he did not feel ready to alarm his patient. And so, rather than reveal his fears, he dismissed all the AIDS talk as "journalistic gossip." Something, however, rang hollow to Péron-Garvanoff. He wrote in his notebook: "*Je ne suis pas rassuré du tout*": I am not at all reassured.

Much has been written about France's notorious "contaminated-blood affair," in which four doctors were convicted for failing to protect the nation's hemophiliacs. But the scandal extends deeper and wider than the courts and the media have suggested. Far from affecting only hemophiliacs, negligence in the French medical establishment condemned thousands of French citizens to AIDS, hemophiliacs, and nonhemophiliacs alike. They did so in a slow-motion sequence of denial and deception that has never been publicly acknowledged.

The denial in France is easy to understand, given the country's transfusion history. Ever since the war, as we have seen, the country had collected its blood on the basis of a deeply held philosophy—*bénévolat, volontariat, anonymat*—blood freely, voluntarily, and anonymously given, with no profits earned anywhere along the way. The premise seemed sound enough on the face of it. After all, volunteer blood tended to be cleaner than paid blood, given the donors' social and medical backgrounds. Yet the French elevated that practical consideration to the level of dogma. They actually believed their blood was inherently safe, simply by dint of the *bénévolat* tradition. The assumption of purity extended to plasma products as well, since they too came from voluntary donors. Long after Paris became the AIDS capital of

Europe, bloodmobiles kept circulating through Beaubourg, the Latin Quarter, and Pigalle, collecting blood and plasma from their high-risk populations.

The first person publicly to question these practices was the most qualified man in the nation to do so—Jean Pierre Soulier, director general of CNTS. As he neared his retirement, Soulier could look back on a long and distinguished career. Trained by Tzanck in the early days of transfusion, he had become a professor, clinician, and internationally known researcher—discoverer of Factor IX, the missing protein in people with hemophilia B. Soulier had supported the Health Ministry's efforts to make the nation self-sufficient for Factor VIII. But now, with the specter of AIDS on the horizon, he began to worry about the pace of the program. He knew that benevolence did not ensure purity, even less so with pooled plasma products than with whole blood. Beyond that, he had always been a bit wary of clotting concentrates, or "comfort products," as the French had come to call them. "Every transfusion is a risk," he used to say, and hemophiliacs were infusing the equivalent of thousands. Now, as he saw the epidemic growing in America, he renewed his call for caution with Factor VIII, even to the point of using cryoprecipitate instead of the new concentrates. "It was a question of prudence," he would say later. He was not suggesting a return to the past; only a "retreat" for a couple of years until doctors could understand this new disease. In doing so, he joined other like-minded physicians, such as Oscar Ratnoff in Cleveland, Dr. Bernard Noël of the blood center in Chambéry, and most of the Belgian medical establishment. (The Belgian Red Cross, which distributed clotting factors, had cautiously stayed away from Factor VIII in favor of locally produced cryoprecipitate.)

Almost no one in France appreciated his suggestion. The Health Ministry frowned upon cryoprecipitates, which would draw plasma away from their showcase Factor VIII program. Hemophiliacs objected strenuously. They remembered the old days of feeling tethered to the hospital, waiting dreary hours for the liquid to infuse. Gone would be the ski weekends and soccer afternoons, the promise of a life without crippling and pain. In an angry rebuttal to Soulier's suggestion, André Leroux, president of the French Hemophilia Association, wrote in *L'Hémophile,* the association's journal, that patients should insist on receiving their products. If the transfusion service could not produce enough clotting factor, they should be forced to import it. If they still refused, then the patients should "protest to the point of threatening" the clinicians. Soulier argued that French hemophiliacs should "temper

their enthusiasm," because "mercenary" products imported from America carried a greater risk of transmitting viral disease. (Little did he know that the French products would become every bit as tainted.)

Meanwhile, Soulier was challenging complacency about whole blood as well. French blood bankers always had relied on what they called the "serological shield"—a battery of lab tests to screen out diseases such as syphilis and hepatitis—but they avoided asking personal questions. "Donors were like gods," said Claudine Hossenlopp, longtime secretary of CNTS. "No one would have wanted to offend them." Since AIDS could not yet be detected in a lab test, Soulier favored the only technique that was available at the time—the kind of sociological screening that the Americans had introduced with their pamphlets and questionnaires. If blood banks could not yet identify the pathogen, they could exclude those groups most likely to carry it. That was why the British, Swedes, and others were beginning to use such techniques as well. In May 1983, Soulier proposed the nation's first donor questionnaires for CNTS in Paris, asking donors to acknowledge whether they used intravenous blood or had multiple homosexual partners.

The move provoked an immediate backlash from human-rights advocates and gays. "Faggots—an Undesirable Blood Group?" mocked a headline in the leftist newspaper *Libération.* Soulier tried to explain that homosexuals do not constitute a blood group, simply "a group of individuals at risk," but his argument did nothing to quell the storm. Bureaucrats complained that, though his intentions were laudable, the wording of his new questionnaire—with its references to tattoos, drugs, and multiple gay liaisons—was simply too "rough" for the general public.

A month later, the Health Ministry attempted a "smoother" approach. In a "circular" to the directors of the nation's nearly 170 regional and local blood centers, Director General of Health Jacques Roux gently suggested that they begin to consider the lifestyles of their donors. The notice did not go to the donors directly—only to the blood-center directors, whom he took great pains not to alarm, describing the AIDS risk through transfusion as "minimal." Roux did not require the exclusion of high-risk donors, or even the filling out of questionnaires; he simply left the matter to the directors' discretion.

Roux knew that he had little power to enforce such an edict, no matter how tactfully he worded it. Under French law, Roux, as director of the Health Ministry's policy office (the Direction Générale), could set prices and policies, but he lacked the authority to enforce them. Whatever policies he formulated were largely at the behest of the Consultative Commission, an advisory body consisting mainly of blood bankers.

(Indeed, the circular itself resulted from a decision by the Consultative Commission, which had viewed Soulier's experiment favorably.) As one government study later described it, the nation's blood system resembled less a centralized medical network than a "feudal system consisting of multiple baronies."

It was no surprise, then, that few paid attention to Roux's circular. Most blood-center directors saw AIDS as something foreign—an American disease, or perhaps a Parisian one. The mere suspicion of a "minimal" risk was not enough to force them to embarrass their donors, so they collected unscreened blood, just as before. So, at a time when other nations were taking the logical measures to contain the epidemic, lifestyle screening was "systematically forgotten," according to French sociologist Michel Setbon. A year and a half passed, during which only about half the nation's blood banks had instituted procedures. Finally, in January 1985, Roux issued another notice urging the "immediate and strict" application of screening, and warned the directors that they could be held legally responsible for the transmission of AIDS. Even though additional blood centers obeyed him, donor questionnaires never became rigorously enforced.

An excess of faith in the government's blood system and the purity of "benevolent" donors had set the stage for the spread of AIDS through the French blood system. Now an additional factor would come into play that would make a national public-health calamity inevitable.

For decades, French blood bankers had been staging collection drives in prisons. Born in the flash of postwar idealism, and expanded during the reforms of the 1960s, the program was thought to have "redemptive" significance; social scientists felt it humanized the prisoners by making them part of the larger social compact. Prisoners who gave blood enjoyed it, since it gave them a break from the monotony, with wine, sandwiches, and a brief change of scenery. Wardens felt it had a palliative effect. Blood bankers appreciated the custom as well, not so much for the quantities involved (prison blood never exceeded .5 percent of the national total) as for the fact that they could collect blood during traditional lean times of holidays and vacations.

As the first AIDS cases appeared in France, a few doctors began to question the collections. In March 1983, Dr. Luc Noël, director of the Versailles regional transfusion center, examined 212 of his volunteer prison donors. Subjecting them to several diagnostic procedures, including the hepatitis core antibody test, he found that 31.5 percent tested positive, making them prime candidates to transmit hepatitis and possibly AIDS. Astonished at the proportion, Noël wrote that to continue taking blood from these men was "ethically and economically

inconceivable." He also alerted the Health Ministry. "They ignored me," he later recalled. Later that spring, Dr. Michel Garretta, of the Paris-based CNTS, ended his center's prison collections. Still later, the doctors at the regional transfusion centers in Strasbourg and Toulouse found high viral markers among prisoners they studied.

Despite these early warnings about prison blood, the nation kept using it as freely as before. All but a few of the blood centers kept visiting the prisons. Indeed, during the two years when AIDS found a foothold in France and matured into an epidemic, discussion of prison blood never became part of the national agenda. It remained conspicuously absent from ministry meetings and those of the Consultative Commission. Roux's famous "circulars" about high-risk donors in 1983 and 1985 made no mention of prisoners, the riskiest group of all.

Meanwhile, a bureaucratic sideshow in the Department of Justice threatened to make the situation even worse. In late 1982, the regional blood center in Marseilles, running short of blood, had petitioned the Justice Ministry to allow them to collect more often from the local prison. The ministry, which was responsible for the health of the prisoners, had restricted blood collections to three times a year for male prisoners (twice for female prisoners). The request from Marseilles drifted for a while in the ministry bureaucracy, until it landed on the desk of the Justice Ministry's prison director, Myriam Ezratty. Ezratty knew nothing about risks of prisons and AIDS, nor, as the months passed and the evidence accumulated, had anyone bothered to inform her. She knew nothing about the Health Ministry's circular, of Garretta's decision, or of Noël's disturbing study. And so, when the time came to make her determination, she not only granted the request to Marseilles, but applied it to all prisons in France, increasing the limit on annual donations from each prisoner to five. Her edict went into effect on January 13, 1984. By 1985, as the AIDS epidemic crested and broke, collections in prisons reached an all-time high.

From his office at the prison hospital overlooking the *grand quartier* of the prison in Fresnes, a suburb of Paris, Dr. Pierre Espinoza thought little about the export of prison blood, even with collections taking place almost under his window. Espinoza had become director of the prison hospital as part of a national penal-medicine reform. Dedicated to the cause of prisoners' health, he was struck by the uniformity of his patients, who all seemed to be former drug addicts. Indeed, in recent years drug addicts had flooded French prisons. His task became more complicated in the spring of 1984, when he heard about AIDS and its relation to intravenous drug users. Deciding to conduct "a little public-health research," Espinoza surveyed the hospital's more than two hun-

dred patients. He found that a dozen had come down with the disease, and sounded the alarm that prisons would become the next hotbed of AIDS.

At that point, Espinoza was not even thinking about blood; his only concern was to provide his patients with adequate care. Several months later, he received a visit from the local blood-center director, Dr. Najib Duedari. Duedari told him that a civilian patient had contracted AIDS. Working back through the patients' transfusion records, Duedari found that the infectious unit had come from a prisoner at Fresnes.

The two doctors decided to survey the prison donors, using every screening tool at their disposal, including medical exams, questionnaires, and hepatitis B tests. It would take weeks to do so, but at least this would give them a handle on the problem. Meanwhile, they conveyed their suspicions to prison director Ezratty, and asked her to suspend prison collections. She asked Director General of Health Roux to attend a meeting of health, transfusion, and prison officials. Roux declined, dispatching a few subordinates instead, along with some disdainful handwritten instructions that the local transfusion-center directors "are adults" and should be able to work things out for themselves.

They could not. During the meeting, chaired by Ezratty, Espinoza said AIDS was running rampant in penitentiaries, and described the risks of giving prison blood to the general population. Roux's representative, Dr. Jean-Baptiste Brunet, an epidemiologist who became known as "Mr. AIDS" in France, agreed. Two other representatives from the Health Ministry worried more about causing a "rupture" in blood supplies. Ezratty limited her position to expressing the concern that suddenly halting the program would cause prisoners to panic. In the end, the officials decided to leave the program as it stood. They made one concession to safety, however: They requested the Health Ministry's director general's office to telephone regional blood centers with "appropriate recommendations" about the use of prison donors. It was never determined exactly how many centers were called, what they were told, or how they responded.

Ten days after the committee's decision, Espinoza and Duedari completed their survey. Two hundred sixty-four inmates had volunteered as donors. Of those men, more than 40 percent represented "populations at risk," including drug addicts, men who tested positive for hepatitis B, those who failed detailed questionnaires, and those who transferred and could not be traced. This represented an overwhelming proportion—more than sixty-seven times higher than from the "hottest" neighborhoods of Paris. The doctors mailed their results to Ezratty and

Roux. From this point forward, no one could pretend that blood drives in prison could possibly be safe. Meanwhile, throughout France, the "benevolent" collection of prison blood continued.

At Stanford University in California, Dr. Edgar G. Engleman had become fed up with his American colleagues. As director of the university hospital's blood bank, he had been following the AIDS debate since its inception. By now he had lost patience with the blood-banking establishment, with their false confidence and wait-and-see attitude about finding the perfect screening test. The time had come for action, not promises. Because of its long lag time, fatal consequences, and corrosive effects on public confidence in the blood supply, AIDS could not be dealt with like other diseases, by waiting until all the data were in. It was time to *do* something, even if that meant using a partial solution. Working at a research center gave Engleman access to a large number of reagents and equipment. He picked one procedure, the T4/T8 ratio test, which detected a white-cell abnormality typical among presymptomatic AIDS patients. The test was not perfect—it did not identify all cases and gave a small percentage of false positives—but he felt it would have to do. Each test cost his center $10. To offset the cost partially, he charged hospitals an extra $6 per pint.

To Engleman's surprise, the blood-banking establishment castigated him. How could he rely on such a test, they demanded, when the contamination of whole blood had not even been proved? Beyond that, the test was expensive, at least by the standards of the time. Ten dollars a pint might be affordable for a small blood bank like Stanford's but hardly for large ones like Irwin or New York. When Engleman submitted an abstract about his test to be presented at the 1983 annual meeting of the AABB, the organization rejected it.

Engleman's action and the controversy that surrounded it epitomized America's second year of dealing with blood-related AIDS. The Public Health Service announcement of March 1983 had marked the end of the first stage of the drama, in which widespread denial held sway. Now the nation entered a second period, characterized by confusion and half-steps. The AIDS virus had still not been identified. With insufficient science to go on, people were forced to make "decisions without data," as health-policy analyst Dr. Suzanne Gaynor has written, making educated guesses in a highly charged atmosphere of heightening market pressures and public concern. Everyone wrestled over what to tell the public, who might panic depending on the information. Unfortunately it turned out that just as in wartime, truth was an early casualty in the battle against AIDS.

Nowhere did this issue surface more painfully than in the National Hemophilia Foundation. Torn between their concern for hemophiliacs and their loyalty to the drug industry, the foundation's leaders stumbled through a series of missteps and miscommunication. On the one hand, they continued to press for safer clotting factors; now, for example, in addition to demanding the exclusion of gay donors, they insisted that the drug firms use the core antibody test, a costly proposition that the companies resisted. On the other hand, they urged hemophiliacs to keep using the clotting factors, despite growing evidence that the products were dangerous.

As the months went by, these assurances became irresponsible. In May 1983, for example, after discovering that a plasma donor came down with AIDS, Hyland recalled a lot of nearly two hundred vials of clotting factor. The foundation announced the withdrawal in its bulletin, but minimized the problem, saying, "*a recall action should not cause anxiety or changes in treatment programs*" (emphasis in original). The next month, Aledort stated his philosophy about Factor VIII use, when he spoke at an awards ceremony at Alpha: "My position is business as usual. There is no reason not to treat. There is no evidence that treatment *per se* is the cause of AIDS." A few months later, when Hyland and the Red Cross both announced product recalls, the foundation again urged its members to keep taking their medicine. Indeed, even after the Cutter company issued a massive recall in November, the foundation told its members to keep taking their clotting factors just as before.

Yet business as usual was becoming a perilous direction, as a massive contamination incident had already shown. In the fall of 1983, a transient gay man named Christopher Whitfield died of AIDS in Austin, Texas. The story made news as the city's first AIDS fatality. The name sounded familiar to the manager of a local plasma center who, looking through her records, found that her organization had purchased plasma from Whitfield forty-eight times in the previous year. He had no visible symptoms of AIDS when they examined him, and lied when asked if he belonged to a high-risk group.

Immediately she called Cutter Laboratories, which had a long-standing contract to buy plasma from the center. Cutter realized that most of the products had already been used, but recalled whatever they could right away. In the end, Cutter destroyed sixty-four thousand vials of factor—about 2 to 3 percent of the nation's entire annual supply. In a press announcement, Cutter spokesman Bud Modersbach said that, even though the company had taken this emergency action, "there is no evidence that AIDS is transmitted this way." Meanwhile, the NHF

continued to assure the nation's twenty thousand hemophiliacs that clotting factors were basically safe.

It seemed that no one was telling hemophiliacs the truth—neither their mother organization nor the pharmaceutical firms with which they had traditionally enjoyed close relations. At one point Cutter issued a press release reassuring them that there were "no Cutter centers in New York, San Francisco, Los Angeles or Miami, where the vast majority of AIDS cases to date have been reported." Yet the company operated a center in Berkeley, just across the bay from San Francisco, no less popular among drug users and gays. They also ran plasma centers along the Mexican border and in a prison. Alpha Therapeutic, having touted their tough questionnaire policy, also advertised that they no longer collected plasma in high-risk areas. What they did not say was that when they shut down their San Francisco collection center, for example, they did not destroy the inventory of plasma. They shipped at least some to their laboratories to be made into Factor VIII.

The deception extended to the voluntary sector, whose Joint Task Force of the major blood-banking organizations had begun to issue authoritative advisories. In June 1983, the Joint Task Force addressed the question of directed donations. More and more members of the public, concerned about AIDS in the community blood supply, had been asking before surgery if their friends and family could give blood for them. The blood bankers opposed this, reasoning that being put in such a position might tempt a donor to bend the truth about his risk status, especially if the patient did not know his friend's sexual orientation. (Their motivation was not entirely selfless—keeping track of these separate donations would create a bookkeeping nightmare.) As part of this argument, the blood bankers issued a reassuring statement about the safety of the nation's blood supply, asserting that the AIDS risk from transfusion was something on the order of "one in a million." This number became a mantra for the blood bankers, who used it whenever the question of safety came up. They based it on a back-of-the-envelope calculation comparing the number of suspected transfusion-AIDS cases at the time—fewer than twenty—to the more than thirty million units of blood collected and distributed since the epidemic began.

Engleman, for one, felt the estimate misled. As he later explained to author Randy Shilts, the Joint Task Force only counted transfusion recipients with full-blown cases of the disease, not those with emerging infections. Nor did they account for the fact that the average recipient receives not one but three units of blood. Finally, they averaged the risk for the entire country. The more honest approach would be to provide

regional estimates, especially for the nation's hot spots. In such a calculation, Engleman said, the risk in San Francisco would be closer to one in ten thousand, or even one in five thousand. (Some years later a study showed that in 1983, at the peak of contamination, the rate in San Francisco had risen to one in a hundred.)

Meanwhile, Engleman's surrogate testing had proved its usefulness. In one incident, he rejected a man who showed no apparent symptoms but who eight months later was hospitalized with AIDS. He later learned that the man had donated thirteen times to other blood banks in the region, none of which had successfully screened him.

In the summer of 1983, just as Engleman was beginning his program, Dr. Herbert Perkins of the Irwin Blood Bank conducted a trial with surrogate testing. Over a three-month period, he tested more than eight thousand donors with the hepatitis B core antibody test. Then he tabulated his results according to the ZIP code of the donors. He found the strongest correlation not with ZIP codes representing the Castro, the city's gay area, but with Chinatown. This made sense, since hepatitis B is endemic to Asia. It led him to conclude that the test was a useless screen against AIDS, since it correlated more closely with ethnic group than sexual orientation.

CDC scientists scorned Perkins's experiment as amateurish and vague. He had not asked the donors whether they were gay, but simply tabulated the lab tests by ZIP code, a crude procedure at best. The epidemiologists continued to press for surrogate testing as the best available barrier against AIDS. They raised the issue at a meeting of the FDA's Blood Products Advisory Committee in December, during which a government representative suggested that the industry begin using the tests. But the drug companies, having previously met to coordinate a strategy, proposed an interim task force instead. "The general thrust of the task force is to provide a delaying tactic . . . ," wrote Steven J. Ojala, Cutter's representative, in a company memo. "This proposal was one that had been agreed upon by all the fractionators the previous evening. . . . It was generally agreed that core testing would eventually become a requirement." Three months later, in an interim report, the task force concluded that hepatitis B core testing was "not appropriate" for screening high-risk individuals.

The pressure for surrogate testing continued, especially in California, where people had heard about Engleman's testing and demanded that their own blood banks take action as well. "We now had patients . . . who were getting totally hysterical that we weren't doing everything possible to make the blood supply safe," Perkins later testified. The head of the Veterans Administration Hospital in Palo Alto

wrote that he was no longer interested in buying blood from the Red Cross San Jose chapter, which traditionally had supplied him, since they did not use a surrogate test. Soon after that, the San Jose chapter, convinced that gay donors were slipping through the net, began using the hepatitis B core test, contrary to the Red Cross's national policy. At Irwin, Perkins had put the hepatitis B core test in place, even though he believed it to be ineffective. Soon the entire Bay Area, five blood banks in all, was screening its blood with surrogate tests. With the exception of two others, in Louisiana and Oklahoma, none of the nation's other blood banks had done so. Meanwhile, the Cutter and Alpha companies experimented with core tests, only to be told by the FDA that the companies could not print the claim on their labels that the testing made their products safer. The companies stopped testing.

Later, after the AIDS test became available, Engleman went back and re-evaluated samples he had saved of the nearly six hundred units his test had rejected. He found that only about 5 percent of the donors he rejected would have tested positive with the AIDS test. On the other hand, considering the volume of blood his center was handling, he had prevented thirty-three transfusion recipients from becoming infected.

The Factor VIII molecule is a big, ungainly entity, a sprawling glycoprotein so prone to clotting that with the slightest manipulation "it turns to glue," according to the technicians who isolated it. That tendency to congeal, of course, makes the medicine effective. It also explains why chemists did not even consider heat-treating the material when they began producing it, even though they had done so with albumin a generation before.

Dr. Edward Shanbrom led the team who developed Factor VIII at Hyland. Soon after they began producing the substance, he noticed that the lab workers developed jaundice after breathing the plasma mist in the cold rooms. Suspecting hepatitis, he conducted tests on the liver enzymes of experimental patients, which showed pathological changes. "It was obvious there was some kind of virus there," he said later. He did not consider withdrawing the product; like everyone who had seen its miraculous effects on hemophiliacs, he had no doubt that the benefits exceeded the risk. Yet he felt that, given that the product could spread a chronic disease, the company should try to minimize the risk. He notified his superiors to take preventive measures, such as closing its collection centers in hepatitis hot spots. They ignored his suggestion, and eventually he left Hyland.

Meanwhile, other methods were developed to control hepatitis. In the mid-1970s, as we have seen, the FDA mandated a series of increas-

ingly sensitive hepatitis blood tests. The disease rates dropped for a while, as the tests screened out dangerous donors, but climbed again as a new form of the virus emerged. Called non-A, non-B hepatitis (and later renamed hepatitis C), it eluded their most rigorous laboratory screening. At this point several companies gave heat treatment another look, with little urgency. After all, even those hemophiliacs who developed the disease seemed to live long, active lives. Some doctors thought that once patients contracted the virus they developed an immunity or tolerance.

It was just about then that Shanbrom came back on the scene. An independent scientist now, he had developed a way to kill hepatitis by introducing a detergent to the fractionation. The detergent would break down the virus's lipid, or fat-based, outer shell, without which the virus cannot survive. As he proposed his formula from one company to another, "no one expressed interest, not a soul," he recalled. It later turned out that the AIDS virus also has a lipid outer shell. Indeed, years later a detergent-based treatment similar to his own became the preferred method of viral deactivation. If people had listened to Shanbrom at the time, the hemophilia-AIDS scourge might never have occurred.

Meanwhile, the fractionators moved forward with their own work on heat-treating Factor VIII to kill off pathogens. The secret eluded them until the Behringwerke Company of Germany developed a way to stabilize the Factor VIII protein with certain sugar-based chemicals before heating. The process was impractical, since it diminished the yield by as much as 90 percent, but the mere fact of its existence inspired the competitors to redouble their efforts. In March 1983, Baxter's Hyland Division received the first American patent to heat-treat Factor VIII. By early 1984, all the major fractionators had received FDA approval and began pasteurizing at least a portion of their Factor VIII for the removal of hepatitis. They had no proof that the process killed AIDS, since the causative agent had not been identified. Yet they thought, wrote Dr. Milton Mozen of Cutter Laboratories, "that *if* AIDS were caused by a virus and *if* this virus were heat labile, then heating the product *might* possibly prove beneficial in reducing the risk of infection."

The National Hemophilia Foundation hesitated to recommend the heat-treated products. After all, no one had conducted clinical trials, so the products' effectiveness remained unproved. Moreover, heating might alter the proteins, causing dangerous allergic reactions. It was not until October 1984, after the AIDS virus was identified and a team of scientists from the CDC and Cutter proved that heat treatment

killed it, that the foundation urged that doctors "strongly consider" switching to the new products. Yet even then the old contaminated products remained. Rather than issuing an across-the-board recall, the FDA allowed the companies to phase in the new factor according to their individual schedules. The old tainted products circulated in the marketplace well into the following year.

If heating promised to solve the problem for hemophiliacs, it could do nothing for recipients of whole blood, since heating red cells would destroy them. The only defense was to screen out the pathogen *before* it reached the blood supply. Blood banks were doing that with increasingly stringent questionnaires, yet they were deadlocked, as we have seen, on the issue of surrogate testing.

It was science, finally, that ended the indecision. On April 23, 1984, at a highly publicized Washington press conference, Dr. Robert Gallo of the National Institutes of Health announced that he had discovered the virus that caused AIDS. It belonged to a family of pathogens called "retroviruses." He explained that, rather than kill their host cells directly, these furtive micro-organisms insert their own genetic code into the host's so that it reproduces more of the agent that infected it. The AIDS virus selectively invaded a critical component of the immune system called the CD4 helper cells. In time the viruses overwhelmed them, disabling the immune system. That mechanism explained both the lag time and the opportunistic nature of the disease. Standing with Gallo, Health and Human Services Secretary Margaret Heckler used the occasion to counter those who had criticized the Reagan administration's inaction. "Today we add another miracle to the long honor role of American medicine and science . . . ," she proclaimed. "Those who have disparaged this scientific search—those who have said we weren't doing enough—have not understood how sound, scientific research proceeds." She then predicted that a test to screen the blood supply with "one hundred percent certainty" would become widely available within six months.

By this time forty-nine Americans had been infected with AIDS through blood transfusions, and another forty-nine through clotting factors. Heckler's announcement mooted the arguments for surrogate testing, since a specific AIDS test was supposedly on the way. Contrary to Heckler's prediction, the test would not become available for nearly another year.