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Blood Money: Bayer's Inventory of HIV-Contaminated Blood Products and Third World Hemophiliacs

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This article presents an overlooked case of research misconduct and violations of basic principles of medical and business ethics. When Bayer's Cutter Laboratories realized that their blood products, Factor VIII and IX or antihemophiliac factor (AHF), were contaminated with human immunodeficiency virus (HIV), the financial investment in the product was considered too high to destroy the inventory. Cutter misrepresented the results of its own research and sold the contaminated AHF to overseas markets in Asia and Latin America without the precaution of heat treating the product recommended for eliminating the risk. As a consequence, hemophiliacs who infused the HIV-contaminated Factor VIII and IX tested positive for HIV and developed AIDS.

Keywords: AIDS, antihemophiliac factor (AHF), Bayer, Cutter Laboratories, hemophilia, hepatitis, human immunodeficiency virus (HIV), Third World

INTRODUCTION

Pharmaceutical companies uniformly claim to embrace moral values as one of their highest obligations to patients. Bayer, for example, claims "to help patients around the world by preventing, alleviating and curing disease" as part of their mission: "Science for a Better Life" (Bayer, 2013). Marketing strategies that are concealed from the public contrast sharply, however, with the image provided by public relations campaigns. Given the importance of what is known in relatively small legal circles as "the hemo case," we believe that a fuller account merits exposure in the biomedical literature. Although there were several media reports, the two most important that came to the

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public's attention included an article in *The New York Times* (Bogdanovich and Koli, 2003) and a German documentary called *Tödlicher Ausverkauf: Wie BAYER AIDS nach Asien importierte* (*Deadly Sale: How Bayer Imported AIDS into Asia*) (Koch, 2004).

Other cases on record reveal that companies use people outside of the United States and Europe to market a product that is potentially deadly. For example, in the 1970s and 1980s, the Swiss-based Nestlé Corporation aggressively marketed breast milk substitutes, particularly in less economically developed countries, which contributed to the unnecessary suffering and deaths of babies largely among the poor in Africa (Ferriman, 1999). Moreover, the World Health Organization (WHO) has long been concerned with the complaint that the Third World is the dumping ground by pharmaceutical companies for unwanted, obsolete, and poor quality drugs rather than supplying essential medicines for the world's most pressing health problems (D'Arcy, 1985, p. 983; Charev, 2012, p. 93). While the hemo case involved human immunodeficiency virus (HIV)–infected hemophiliacs in the United States and abroad, our account below focuses attention on the marketing and distribution of contaminated blood products in Asia, the so-called "dumping" aspect of the larger body of cases litigated.

Whereas the vast majority of incriminating documents from litigation disappear as a result of settlement agreements or defense attorneys' successful arguments for maintaining the confidentiality designation of the documents, the documents cited below are part of the public record as attachments to motions that were made public. Many others became public when used as exhibits in court cases such as *Chang, Y. et al. vs. Bayer Corporation and Baxter Healthcare Corporation*, Civil Action No. 3:04–CV–01925 and *In re Factor VIII or IX Concentrate Blood Products, Product Liability Litigation,* MDL No. 986. The following report is based upon a selection of those documents produced and made public in litigation against Bayer that were posted in May 2013 on the Drug Industry Document Archive (DIDA) at the University of California, San Francisco. Many more documents that were produced in discovery remain sealed by the courts and, therefore, have not been released to the public.

HEMOPHILIA AND FACTOR CONCENTRATE BLOOD PRODUCTS

Hemophiliacs either produce inadequate concentrations or no concentrations of various pro-coagulation proteins that are present in normal human blood. A normal, healthy individual who gets a cut will bleed for a short time and then the blood will clot, thereby stopping any further bleeding. In the case of hemophiliacs, once they get a cut, they will continue to bleed for a long period of time. Many bleeding episodes involve spontaneous bleeding into leg and arm joints, causing severe crippling, or life-threatening bleeding in the brain. In situations where a severe cut or internal bleeding occurs, death may

follow from significant blood loss. Before antihemophiliac factor (AHF) was discovered, hemophiliacs had to be hospitalized and infused with blood products such as fresh frozen plasma and whole blood to control severe bleeding. AHF was a life-changing discovery that allowed hemophiliacs to live fairly normal lives. It is a composition of various pro-coagulation proteins (Factors II, IV, VIII, IX, X, etc.) derived from the blood of so-called normal, healthy donors. AHF is produced by pooling plasma to create a "lot" comprised of 1,000 to 50,000 individual donations. Once the frozen blood product or cryoprecipitate from these combined plasma pools is chemically treated to produce the freeze-dried AHF product, the powder from each lot is placed into handy vials that are reconstituted with saline and injected intravenously by the hemophiliac.

It is well known that individuals with a history of IV drug use, prisoners, and promiscuous gay males are at high risk for prevalence of viral diseases, such as hepatitis B, hepatitis C, and HIV, that are transferred through exposure to human blood. As early as 1975, Szmuness et al. specifically identified the connection between promiscuous gay males' sexual behavior and the spread of hepatitis B infection. They recommended that such individuals "refrain from blood donations" (Szmuness et al, 1975, p. 494). Due to the risk of transmitting and thereby spreading deadly and debilitating diseases, the United States federal government passed a law between the late 1970s and early 1980s that required companies to obtain blood for manufacturing their blood products strictly from normal, healthy individuals. At that time the main companies that produced AHF included as follows: Cutter Laboratories (purchased by Bayer in 1974), Baxter Healthcare, Alpha Therapeutic Corporation, Armour Pharmaceutical Company, Aventi Behring, L.L.C., and Sventis, Inc.

HIV-CONTAMINATED AHF

In the 1980s, Cutter and other companies targeted categories of plasma donors—IV drug users, prison inmates, skid row residents, and promiscuous, gay males—to manufacturer AHF because the donors were readily available and willing to sell blood for cheap and demand was high for AHF. But the companies also wanted this plasma from these high-risk donors to manufacture other lucrative blood-based products (e.g., a general immune globulin, and antigen specific immune globulins, particularly hepatitis B immune globulin [HBIG]), which had to be manufactured from blood with high levels of antibodies. The blood donors Cutter targeted were at high risk for transmitting blood-borne diseases (Cutter, 1982b,c).

Immune globulins are injectable medications used to increase the recipient's antibody levels. This product was particularly useful for healthcare professionals exposed to needle sticks and infectious diseases as well as tourists visiting areas of the world with high levels of hepatitis B. If exposed to a disease like hepatitis B, it was useful to have a boost of antibodies promptly to

defend against illness. These were expensive and very profitable products at the time. In order to sell such products as efficacious medications, the products had to have a high level of antibodies and in order to harvest high levels of the antibodies, the manufacturers purchased plasma from donors who would likely have been exposed to the targeted diseases (e.g., hepatitis). In the late 1970s and early 1980s, promiscuous gay males and prisoners were widely exposed to hepatitis B, so acquiring plasma from those populations would likely harvest sufficient levels of antibodies to warrant selling it as HBIG or a general immune globulin.

One of Cutter's strategies to acquire blood with the high levels of antibodies was to purchase plasma from advertisers in gay men's magazines in which blood donations were solicited for the betterment of hepatitis research and the creation of a vaccine. One such advertisement typical of those in 1981 reads as follows: "Have you ever had hepatitis? Have you ever been in contact with hepatitis? Now you can make it pay, as much as $650 extra each month. And, at the same time, you'll be helping to contribute to the health and welfare of other Gay men" (Cutter, 1981a). Cutter laboratories was inspected in 1981 to determine whether it was in compliance with the law regarding use of high-risk donors and found to be "in compliance in all areas except for the practice of accepting donors into the program who have a past history of illegal IV drug use"(Cutter, 1981b).

By 1982, the Centers for Disease Control's (CDC) *Morbidity and Mortality Weekly Report* included the alarming discovery that hemophiliacs treated with AHF (heterosexuals without a history of IV drug abuse) had contracted a rare form of pneumonia, *pneumocystis carinii* pneumonia, frequently diagnosed in AIDS patients. The CDC noted that "*pneumocystis carinii* pneumonia has not been previously reported among hemophilia patients who have had no other underlying diseases and have not had therapy commonly associated with immunosuppression" (CDC, 1982, p. 14). Also in 1982, based on studies in which chimpanzees injected with AHF developed "AIDS-like symptoms" that included *pneumocystis carinii* pneumonia, it appears that Cutter, in particular, had strong evidence that AHF could transmit HIV (Cutter, 1982a).

Once a person is infected with HIV, the virus incorporates itself into the DNA and targets the CD_4+ T cells (the white blood cells that are necessary in the production of acquired and adaptive immunity within the body). AIDS (acquired immunodeficiency syndrome) develops as the HIV virus spreads and destroys more and more CD_4+ T cells with the result that there is greater susceptibility to common infection. At that stage, defined clinically when the cell count is below 200 CD_4+ T cells, individuals require a great deal of medical intervention to survive infections that healthy individuals could fight off effortlessly.

According to Cutter documents from 1982, the FDA asked Cutter "to voluntarily exclude plasma collected from known homosexuals from pools" used in

the production of AHF specifically from areas such as New York, San Francisco and Hollywood (Cutter, 1982b,c). In response, Cutter suggested to educate the high-risk populations in an attempt to have individuals voluntarily exclude themselves from donating centers (1982c). While it was reported that "there had been no cases of AIDS reported in prisons," Cutter scientists knew that it took several years for HIV to develop into AIDS. The "etiology of the syndrome and the insufficient time" suggested that such a judgment was premature (Cutter, 1982c). Even though there was a risk of transferring HIV via the AHF product, Cutter made the decision not to exclude such high-risk donors.

By 1983 Baxter Healthcare had developed a heat-treat process to deactivate virally AHF products and was granted a FDA license for the new product (Leveton et al., 1995, p. 92). The very idea of heat treating AHF to reduce the risk of blood borne disease was counterintuitive since the process involved using plasma that had been immediately frozen to prevent the coagulating proteins from denaturing at room temperature and thereby eliminating the effectiveness of the product for stopping bleeding episodes. Cutter's competitor, Baxter, nonetheless pioneered this successful process and thereby threatened Cutter's market share. As Cutter began to develop the heat-treated AHF following their own experiments with chimpanzees in 1983, they concluded that, "At this point, the data clearly support that our pasteurization procedure has inactivated non-A non-B hepatitis" (Cutter, 1983a). In fact, Cutter's own medical adviser cautioned that "once this product is licensed, it would be unethical to place a patient on other therapy" (Cutter, 1982d). Cutter's filing for an FDA license would depend on "satisfactory clinical results and successful introduction of the process into manufacturing." Cutter concluded as follows:

> The recent concern about AIDS and its possible transmission by an infective agent should encourage a rapid review and approval of the submission. Even without hard data, it is certainly logical that a heated product, with no sacrifice of clinical efficacy, should be potentially safer than one not heated. Such a product should be made available to those whose life depends on it in as rapid a time frame as possible even without the final unequivocal demonstration of its freedom from hepatitis and/or AIDs. (Cutter, 1983a)

Instead of following this advice, Cutter continued to market the non-heat treated AHF manufactured from the pooled plasma of thousands of donors who were screened using only voluntary, self-reporting methods. The Biological Bulletin from Cutter's Marketing Services affirmed that Cutter believed that screening procedures had reduced "the possibility that AIDS may potentially be transmitted through certain blood products" so the company "reinforced its existing program of donor screening to assure that the raw material for its quality plasma products continue[d] to be of high quality" (Cutter, 1983b). At the same time Cutter denigrated the use of the heat-treated AHF on the alleged basis that it had not been shown to be effective for complete viral deactivation

(Cutter, 1983c). By May of 1984, however, Cutter had tested its own non-heat treated AHF and determined that HIV survived the manufacturing process, but that HIV did not survive the heat-treated AHF viral-deactivation process (Cutter, 1982a,d, 1984a). The inconsistency in their position, we believe, is explained by the fact that Cutter wanted to protect its market share through sale of its inventory non-heat treated AHF.

CUTTER'S MARKETING PLAN

By 1984, Cutter's inventory included both heat-treated and non-heat treated AHF. The company began the process of reviewing its international markets to determine if excess inventories of non-heat treated AHF could be sold (Cutter, 1984b, 1985a). It found these willing markets in countries where it predicted, according to the 1985 Far East Region Preliminary Marketing Plan, that "AIDS will not become a major issue amongst Asian hematologists during 1985" (Cutter, 1985a). AIDS hysteria had not reached these countries, according to Cutter,

> because the region has so many other health hazards of greater, more common concern . . . In Taiwan, for instance, where 16% of the population are carriers of Hepatitis B, a hemophiliac is apt to suffer as much risk routinely using cryoprecipitate or blood as with American-made concentrates. With these considerations in mind, we have no immediate plans to introduce Koate-HT or Konyne-HT [Heat Treated Factors VIII and IX AHF]. (Cutter, 1985a)

The 1985 Marketing Plan states as follows: "If we see a need for a heat-treated product in the Far East, we will react to the demand swiftly. Otherwise, we will try to continue to dominate the markets with low-cost standard Koate and Konyne [Factors VIII and IX AHF]" (Cutter, 1985a). Instead of destroying the high-risk non-heat treated AHF in their inventories, Cutter determined that they would need to "sell as much of it as possible, even at marginal prices" (Cutter, 1985a). The marketing plan lamented the fact that Cutter was forced to terminate its business in New Zealand in 1982 when AIDS became an "issue" there, but optimistically identified India, Philippines, Indonesia, Thailand, Hong Kong, Taiwan, Singapore, Malaysia, Brunei, Korea, Pakistan, Sri Lanka, Burma, and Nepal as possible markets for the non-heat treated AHF (Cutter, 1985a). Throughout Latin America, Argentina, Venezuela, Columbia and Costa Rica were the main markets to which non-heat treated AHF was exported (Cutter, 1983d).

Heat-treated AHF would be introduced in Asia only "if necessary to defend against the fear of AIDS" (Cutter, 1985a). A Cutter memo of 1984 unequivocally asserted that the supply of regular AHF would need to be exhausted before the heat-treated product could be introduced in the Far East. Since, however, the production costs of the heat-treated AHF would be more expensive, the

company was faced with the problem of having to sell the new, more expensive product at the same price as contaminated AHF under the existing contract (Cutter, 1984c). In a 1985 memo to a Hong Kong consignee, Cutter expressed regret for its failure to supply heat-treated AHF "due to a shortage of human plasma in the U.S. and rapid increase in demand for [heat-treated AHF]," but assured the consignee that the regular AHF is not "hazardous" and is the "same fine product we have supplied for years" (Cutter, 1985b).

Cutter discussed a plan internally to deal with the growing controversy. When Asian physicians practicing in the United States relocated in Hong Kong, they knew that the heat-treated product had become the standard of care in the United States and surmised that Cutter was probably selling off excess stocks of non-heat treated AHF to less developed countries. In Hong Kong, 40% of pediatric hemophiliacs had tested positive for HIV, and so there was a demand for the heat-treated AHF. In the mean time, Cutter's competitors were "stirring up trouble by pushing their heat treated products" (Cutter, 1985c). Cutter's response was to obtain 350 vials of heat-treated AHF to satisfy the most vocal patients and concluded that, "It appears there are no longer any markets in the Far East where we can expect to sell substantial quantities of non heat treated [AHF]" (Cutter, 1985c).

Meanwhile in the United States, Cutter and the other manufacturers of AHF were faced with the threat that the FDA could revoke their licenses for the non-heat treated AHF if the manufacturers continued selling the product. In spite of large AHF inventories held by the manufacturers and the potential expense of heat treating the inventory, the head of the FDA, Dr. Harry Meyer, proclaimed "he did not want any attention paid to the fact that the FDA had allowed this situation to continue for so long, and he would like the issue quietly solved without alerting the Congress, the medical community and the public" (Cutter, 1985d). In 1985, Cutter discontinued the manufacture and distribution of all non-heat treated AHF (Cutter, 1985e). In our opinion, however, by this time the damage was done.

TAIWANESE HEMOPHILIA-AIDS CASES

While a 1984 marketing memo states categorically that there would be no major recalls since it "could deprive Cutter of up to $2 million worth of sales in the Far East Region during 1984,"(Cutter, 1984d) late in 1983, Cutter did recall voluntarily 16 lots of AHF because plasma regularly donated from an AIDS victim had contaminated their supply. Vials of tainted AHF were distributed to 304 domestic and 14 international consignees (Cutter, 1983d). In Taiwan, however, the consignee was told that only two lots were being recalled (Cutter, 1983e). This did not mean the other lots of non-heat treated AHF were safe for hemophiliac use. This evidence appears to support the conclusion that Cutter knew certain lots were contaminated with HIV and, even amongst those lots,

there was an inconsistency, at least in Taiwan as to how the recall was treated. Cutter assured the consignee that the withdrawal was "a precautionary measure as there [was] no evidence that these products will transmit the disease. There have been no reports of adverse reactions involving the lots containing the plasma from the donor" (Cutter, 1983e).

In Taiwan alone, as alleged in the complaint filed in *Chang, Y. et al. vs. Bayer Corporation and Baxter Healthcare Corporation*, thirty-four Taiwanese hemophiliacs or partners of hemophiliacs developed AIDS as a result of infusing HIV-contaminated AHF. Many of those individuals died from AIDS complications.

CONCLUSION

In our view, the main issue of research misconduct concerns the manner in which Cutter represented the results of its own research by withholding data on the safety of the non-heat treated AHF to patients in Asia and Latin America. This appears to have occurred at the critical point in 1984 when Cutter's research revealed that HIV survived the non-heat treated AHF but not the heat-treated AHF. Cutter then had to decide what to do with the contaminated inventory. The documents produced by Cutter unambiguously describe a strategic business plan to sell off its inventory of HIV-contaminated AHF blood products in what were considered Third World countries at the time. Since these plans were proposed by top-level management in the company, they cannot be dismissed as the behavior of a few individuals who failed to follow corporate policies. In fact, John Hink, a former Cutter employee who was interviewed for his role in overseas marketing of HIV-contaminated AHF said as follows:

> When we changed to the new, heated product, and the boss asked for a decision what to do with the stock of the old product, it was decided, instead of throwing it into the trash, we would rather sell it to other countries. And that led to the loss of human life and damages to human health. I think that I have made mistakes. I think I could have done things better. (Koch, 2004)

Seldom, if ever, are such plans made with respect for the dignity of human life; few in marketing departments seem to be even vaguely aware of the importance of basic principles of medical and business ethics. Their partnership with medicine commits them to the same principles governing medical practice such as non-malfeasance, beneficence and informed consent. As individuals engaged in business, they are morally obligated to follow basic precepts of honesty, integrity, fairness and accountability. Many of these principles overlap with their legal obligations. If Cutter executives were aware of any such principles, they were not understood to be universal principles of morality since they were apparently not applied to persons at a great distance or to those outside of

a severely limited moral community. In short, we think the evidence reveals that Cutter treated persons in terms of abstract categories of markets to be manipulated merely as a means toward the company's financial end, not as ends in themselves deserving of health and life itself. Apparently, many died as a result.

It should not be overlooked that Cutter infected chimpanzees with viruses for the sake of experiments that were meant to benefit humans. Even if one were to accept speciesism as a defensible moral position justifying such a practice, in this case the results of animal testing were not communicated to patients who infused the non-heat treated AHF or their physicians and thus the chimpanzees' lives were of no utility to this population.

When Bayer acquired Cutter, it took ownership of assets and liabilities, including the legal liabilities that resulted from the thousands of HIV/AIDS cases. Bayer has paid over $600 million in settlements for what they have called in Taiwan "humanitarian aid" rather than compensation for wrongful death (Cutter, 1998). In spite of over 2,700 cases worldwide litigated on the basis of dumping, the company maintained that Cutter had "behaved responsibly, ethically and humanely" (Bogdanovich and Koli, 2003).

CHRONOLOGY

1975: Szmuness et al. identify the connection between promiscuous gay males' sexual behavior and the spread of hepatitis B infection and recommend that promiscuous gay males not be used as plasma donors due to the risk of transmitting blood borne diseases.

1980s: Cutter and other companies target categories of plasma donors–-IV drug users, prison inmates, skid row residents, and promiscuous gay males.

January 1982: Cutter scientists learn of competitors' development of "hepatitis–free" AHF.

July 1982: The Centers for Disease Control reported that hemophiliacs treated with AHF had contracted a rare form of pneumonia, *pneumocystis carinii*, frequently diagnosed in AIDS patients.

August 1982: FDA meets with AHF manufacturers and recommends that they stop using plasma from centers catering to gay males due to the AIDS scare amongst the hemophilia community.

December 1982: Cutter scientists find that chimpanzees given non-heat treated AHF develop AIDS-like symptoms.

January 1983: Cutter scientists send internal memo stating that heat-treated AHF would most likely be safer and decrease risk of HIV and hepatitis transmission to patients.

July 1983: Cutter denounces the safety of competitors' heat-treated AHF.

November 1983: Cutter recalls 16 lots of AHF after discovering that a blood donor had died of AIDS.

November 1983: Cutter informs Taiwan businesses that the recalled lots of AHF were due to a patient who was "suspected" of having AIDS.

May 1984: Cutter's heat-treated AHF is approved.

November 1984: Internal Cutter memo discusses the need to sell excess non-heat treated AHF to Third World countries in order to limit loss of profits.

November 1984: Cutter responds to inquiries from Taiwan AHF businesses as to why heat-treated AHF is not being supplied.

1984–January 1985: Cutter marketing plan for 3rd World countries discusses need to sell non-heat treated AHF to prevent loss of potential 2 million dollars.

May 1985: FDA requests that Cutter cease production of non-heat treated AHF.

June 1985: Cutter stopped making and distributing non-heat treated AHF.

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