COURT FILE NO.: P51/04
DATE: 20071001

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:	)	
	)	
HER MAJESTY THE QUEEN	)	Michael Bernstein, Robert Gatrell, Peter Napier, Stacey D. Young, Chris Dwornikievicz, Elizabeth Pereira and Peter Fraser for Her Majesty the Queen
	)	
	)	
- and -	)	
	)	
	)	
ARMOUR PHARMACEUTICAL COMPANY, MICHAEL RODELL, ROGER PERRAULT, DONALD WARK BOUCHER, and JOHN FURESZ	)	Brian H. Greenspan and Sharon E. Lavine for Armour Pharmaceutical Company Earl Levy Q.C. and Robin McKechney for Michael Rodell Edward L. Greenspan, Q.C., Julianna Greenspan and David N. Tice for Roger Perrault Michael J. Neville and William F. Murray for Donald Wark Boucher David W. Scott, Q.C., Peter K. Doody and Isabella Mentina for John Furesz
	)	

BENOTTO J.

REASONS FOR JUDGMENT

TABLE OF CONTENTS

Introduction

[1] The evidence in this trial sought to reconstruct the unfolding course of events of the mid-1980s relating to the processing of a blood coagulation product used to treat haemophilia. It was commercially known as HT Factorate.

[2] Charges of criminal negligence and common nuisance were brought against the corporate manufacturer of the product, one of its senior officers, the Director of the Bureau of Biologics in Canada, the Chief of the Blood Products Division and the National Director of the Blood Products Services of the Canadian Red Cross. The corporation is also charged with failing to report a deficiency under the *Food and Drug Act*. These accused were involved in the manufacture, licensing, and distribution of HT Factorate.

[3] The events considered here were part of a disaster that gained national and international attention. It was often labelled "tainted blood." It gave rise to civil law suits, an inquiry and much publicity. Strong emotions still abound.

[4] But here, in the process of judging the conduct of these four men and one corporation, discipline is required to ensure that subsequently acquired knowledge is not imported into the analysis. Sir Winston Churchill, in other circumstances, said:

> It is not given to human beings... to foresee or to predict to any large extent the unfolding course of events. In one phase men seem to have been right, in another they seem to have been wrong. Then again, a few years later, when the perspective of time has lengthened, all stands in a different setting. There is a new proportion. There is another scale of values. History with its flickering lamp stumbles along the trail of the past, trying to reconstruct its scenes...[1]

[5] So we embark upon the trail of the past, following the controversies, the developments and the knowledge in the medical and scientific world of over twenty years ago for this will establish the context in which the accused are to be judged.

Haemophilia

[6] Haemophilia is a disease, primarily affecting males, where certain clotting factors called AHF[2] are absent from the blood. The most common clotting factors are factor VIII and factor IX. Factor VIII deficiency is called haemophilia A.

[7] There was a time when haemophilia was fatal. A person with the disease would be unable to stop bleeding internally or externally. Often, he would bleed into joints causing severe crippling. Transfusions, initially life saving, would later lead to heart damage and early death. There was no effective treatment. His life expectancy was short.

---

[1] House of Commons, November 12, 1940
[2] Anti hemophilic factors

[8] In the 1960s it was discovered that by freezing ("lyophilizing") plasma, factor VIII could be separated from other blood components. A blood product known as cryoprecipitate was developed and used extensively to treat haemophiliacs. Life was still difficult however. Everyday activities could cause a cut which could cause a bleed. The patient would regularly have to go to a hospital or clinic for infusions.

[9] In the 1970s new biological concentrates were developed. Through a process known as fractionation, the constituent factors of plasma are separated and a clotting factor is produced. Whereas cryoprecipitate was derived from a single donor, concentrates were derived from the pooling of plasma from thousands of donors.

[10] This was a huge change, described as a miracle for haemophiliacs. It made possible home infusion instead of hospital-based treatment. The person could travel, have a normal life and a normal life expectancy. Concentrates could also be used prophylactically to prevent bleeds. However, as would become evident later, the fact that concentrates were derived from many donors also increased the risk of transmission of blood-borne diseases.

Licensing Blood Products

[11] In order to legally market a drug in Canada, the manufacturer must be licensed. In the case of a biological drug (such as factor VIII concentrates), the product must be licensed as well. The regulation of these biologics was governed by the Bureau of Biologics ("BoB"), a division of Health Canada. Dr. John Furesz was, during the 1980s, the Director of the BoB. Dr. Donald Wark Boucher became the Chief of the Blood Products Division in 1983. Dr. Boucher reported to Dr. Furesz.

[12] Before a biological product can be licensed, the manufacturer is required to submit complete information on the safety and efficacy of the drug along with chemistry and manufacturing data to the BoB. This is contained in a new drug submission. Daryl Krepps was a screening officer at the BoB. She received and reviewed new drug submissions before forwarding them for scientific review and gave evidence at trial about this process. The Blood Products Division of Health Canada was the scientific review body with respect to new drug submissions. As part of the review process the Bureau of Biologics would independently test samples of the product to confirm consistency with the manufacturers' statements. If the information was satisfactory, Dr. Boucher would make a recommendation to Dr. Furesz. If acceptable, the manufacturer would receive a Notice of Compliance ("NOC"). Typically, there would be discussions between the Director (Dr. Furesz) and the Division Chief (Dr. Boucher) before a NOC was issued. It was not a unilateral decision on any one's part. Once the NOC was approved, it was forwarded to the Assistant Deputy Minister for signature and stamp.

[13] Inspections of the manufacturing facilities were a condition of licensing. The authority to inspect was contained in the regulations to the *Food and Drug Act*. Generally, inspections were conducted yearly for facilities in Canada, biannually for those in the United States and every three years for those abroad.

The Canadian Red Cross ("CRC")

[14] The Canadian Red Cross Society's Blood Transfusion Service ("CRC-BTS") was the distributor of blood products in Canada. In the 1980s it was comprised of 17 regional centers across Canada responsible for collecting and distributing blood products. Each regional center was led by a medical director. The medical directors were described as representing most of the knowledge and expertise in transfusion medicine in Canada. They reported to the National Director. The national head office was originally in Toronto but moved to Ottawa in 1987. The centers placed orders to the head office and distributed the products to hospitals, which in turn dispensed them to patients.

[15] In the 1980s the BTS included the Blood Product Services, or fractionation department. It also included nursing, laboratory services, and the national reference laboratory. The Blood Products Services was responsible for the purchase and distribution of fractionated blood products including factor VIII concentrates. The CRC-BTS was advised by a medical advisory committee, comprised of a wide sampling of people involved in the blood system. This committee included physicians who treated haemophiliacs. Their role was to advise the National Director on the needs of the treating community and the needs of, and impact on, the patients.

[16] Dr. Roger Perrault was the National Director of the CRC-BTS from 1974 to 1986. Essentially, he was in charge of the Blood Transfusion Service. In 1986 he became the Deputy Secretary General of Operations at the CRC. At the relevant time, Dr. Thomas Walker was the deputy director of Blood Products Services. He was joined by Stephen Vick in 1986. Both Mr. Vick and Dr. Walker testified. Others at the BTS were Craig Anhorn, a senior manager, Dr. Derek Naylor, a biochemist specializing in plasma proteins, Dr. Martin Davey, a clinical haematologist and serologist described as having impeccable knowledge of blood products and Dr. John Derrick, a specialist in protein chemistry and plasma proteins.

[17] The Blood Products Services Department was responsible for maintaining supplies of plasma products and coagulation factors (including factor VIII). This included managing the accumulation and transport of Canadian plasma to fractionation plants in the United States and Canada, the return of products from those plants, and the eventual distribution throughout Canada to hospitals. The department was also responsible for negotiating contracts with commercial suppliers of blood products. Canadian plasma could only make up about 50 percent of the Canadian demand for factor VIII, leaving the remaining 50 percent to be purchased from other manufacturers as commercial product.

[18] Barbara Dickson was responsible for the purchasing of fractionated products at the CRC BTS from 1983 to 1989. Her responsibilities included issuing tenders and purchase orders once a product was selected. Information would be provided to Ms. Dickson's department by the fractionation department, which would be assembled and issued to suppliers. This final document was known as a Request for Proposal or "RFP". Suppliers would respond with a tender that would be presented to the vendor selection committee.

[19] Dr. Walker holds Ph.D. in biochemical engineering. He began working at the CRC-BTS in May of 1983 as the Deputy Director of Blood Products Services, reporting to Dr. Naylor. In 1985, he accepted the position of Director of Quality Assurance, and his responsibility was to ensure that all of the CRC's operations met regulatory requirements.

[20] Mr. Vick began his career with the CRC-BTS at the Medical Center in Hamilton, Ontario in 1973 and worked for the CRC for 26 years. Mr. Vick was hired by Dr. Perrault as a full-time administrator at the center. He was then assigned by Dr. Perrault to manage the administrative set-up of a new center in Sudbury. Mr. Vick moved to the CRC-BTS National head office in Toronto in mid-1986 and became Deputy Director of the Blood Products Department. Upon the departure of Dr. Naylor in 1986, Mr. Vick became the acting director of blood products and reported to Dr. Davey. Mr. Vick's responsibility at head office was to ensure that adequate supplies of fractionated products were available for Canadian hospitals.

[21] The Canadian Blood Committee was formed in 1981 to oversee and fund the Canadian Blood Programme. In 1983 the Secretariat to the Committee was formed. Dr. Denise Leclerc-Chevalier was the executive director.

Armour Pharmaceutical Company

[22] Armour Pharmaceutical Company ("Armour") is an American drug manufacturing company with offices in Pennsylvania and Illinois. It manufactured HT Factorate, a factor VIII concentrate at its plant in Kankakee, Illinois, using plasma collected by Plasma Alliance. The plasma was collected from donors, who were paid for their donation, at licensed plasmaphersis centres. Plasmapheresis involves the removal of plasma from donors and the return of red blood cells and other blood components to the donor.

[23] Plasma collected by Plasma Alliance was shipped to Knoxville, Tennessee and then on to Armour's manufacturing plant in Kankakee for pooling, concentration, manufacturing and labelling. HT Factorate was licensed by the Bureau of Biologics at Health Canada and distributed in Canada exclusively by the Canadian Red Cross Society Blood Transfusion Service.

[24] HT Factorate came in two levels of purity: intermediate purity which was called Generation I, and high purity which was called Generation II. Only Generation I was distributed in Canada.

[25] Armour sold factor concentrate around the world: in the United States, Germany, Italy, the United Kingdom, Canada, Spain, Japan, France, Australia, Chile, Puerto Rico, Singapore and in countries in Scandinavia.

AIDS

[26] Almost everyone who lived through the early 1980s was acutely aware of the stigma, fear and misinformation that arrived along with the horrid disease which became known as AIDS.[3] As scientists were struggling to determine the cause of this ravaging illness, politicians were reducing their budgets and people were dying painful deaths.

[27] Unlike other infectious diseases, AIDS presented not with direct effects of the disease, but rather with secondary symptoms derived from a destroyed immune system. Typically those who contracted the disease would go through one horrible infection after another, be in hospital again and again, waste away and become so weak they could not get out of bed. In the early years, no one survived AIDS.

[28] There was and is no issue in this trial with respect to the bodily harm inflicted by AIDS.

[29] Today, with the advent of antiretroviral drugs, AIDS is no longer necessarily fatal. But during the long, arduous path to identifying the cause of AIDS so that treatment could be developed, many died.

Identifying the Cause of AIDS

[30] There are three major agencies in the United States that deal with diseases such as AIDS: the Centre for Disease Control (CDC); the National Institute of Health; and the Food and Drug Administration (FDA). They work well together, sharing information and research.

[31] The CDC is an arm of the United States government that deals with the issues of preventative medicine for the United States and around the world. It started exclusively with infectious disease outbreaks and then moved into the prevention of some chronic diseases. Its activities include surveillance and design of ways to prevent the disease from occurring. It employs epidemiologists, who are its backbone, to determine the extent, cause and methods of prevention of particular diseases. People all over the world look to the CDC for its expertise and the data it produces. It is a highly regarded agency charged with protecting the nation's health. It was referred to as the "gold standard."[4] Its scientists are recognized experts in their fields. Not surprisingly, the CDC became involved with AIDS very early on.

[32] The technology we live with today has made us accustomed to the instantaneous availability of information. It was not so in 1981. At that time, the CDC issued weekly reports called the Morbidity and Mortality Weekly Report ("MMWR") so that information could be quickly disseminated.

---

[3] It was not until the Washington meeting (referred to below) in July 1982 that the medical and scientific community agreed on the acronym AIDS for Acquired Immune Deficiency Syndrome. It is used here for simplicity and consistency.

[4] Anita Bessler: April 10, 2007, at 17045-17046

[33] The June 5, 1981, MMWR reported five cases of a very unusual and highly fatal disease in gay men. This was the first description of what would become known as AIDS. A task force was set up at the CDC.

[34] Dr. Donald Francis, a highly respected virologist joined the CDC in 1971. He had previously worked with cholera, Ebola, and small pox. He holds a Doctorate from Harvard University in microbiology/virology. In 1981 he was working in the hepatitis division of the CDC in Phoenix, Arizona. Dr. Francis was appointed to the AIDS task force. The following month, on July 3, 1981, the MMWR reported that Kaposi's sarcoma, hitherto a relatively benign cancer, was killing gay men in New York and California. Dr. Francis stopped the work he had been doing with respect to hepatitis. He began working on AIDS full time, within a few months had moved to Atlanta and has been working on AIDS ever since.

[35] On June 11, 1982 the MMWR reported that this new disease had spread to the heterosexual community and was doubling every six months. To Dr. Francis, it was like Ebola or cholera. It was a huge epidemic. They could not find the cause. To make matters worse, the United States had made budget cuts which affected his work. In these early days, research was terribly under funded. Dr. Francis testified about this period:

> For us at CDC, I would characterize it probably as hell. This was a huge epidemic ... someone, myself who had unfortunately or fortunately specialized in high mortality infectious agents, like plague and Ebola and the like, and cholera, this was one that ranked way up at the top and was one that was very frustrating in terms of finding the cause of it. As we got more and more laboratory work and from the political side of the United States, very unfortunate time to have a public health problem at a time when this was anti-government politics, and, therefore, getting the budgets necessary to deal with this disease was extremely hard. And so huge numbers of people like myself and others spend hours – early morning, late hours – working full-time on this, probably several hundred people at CDC at this time and the same in local health departments. Anyone who saw this disease knew it was bad and knew that it was terribly important to find the cause and to understand it fully.[5]

Dr. Francis testified that by June 1982, he and other members of the CDC task force believed that the infectious agent was being transmitted by blood and sex.

[36] On July 16, 1982 the MMWR reported that the disease was seen in haemophiliacs who had received factor VIII concentrates.[6] This also pointed to the infectious agent being blood borne.

[37] As of July 1982, there still was no universally used name to describe this new disease. Dr. Francis organized a meeting of the factor VIII and blood products component groups. It was held in Washington D.C. in July 1982. From that time on, the disease was referred to as AIDS.

---

[5] Dr. Francis: February 27, 2006 at 468, 469
[6] Exhibit 15

Those in the scientific community continued their search for the infectious agent of the disease. They were quite sure it was transmitted through sexual activity, bodily fluids, blood and blood products. They were also concerned about the haemophilia community. Dr. Francis told the participants at the conference that the consequences to the haemophilia population could be disastrous. There was no reliable test for the causative agent.

[38] About ten days after the July 16, 1982 MMWR, a patient was admitted to hospital in Montreal. As chance would have it, he was the president of the World Federation of Haemophilia. He was admitted because he had high fever and suspected infection. Partly in response to this patient, Dr. Christopher Tsoukas, an immunologist at the Montreal General Hospital designed and organized a study to look at the immune system of people with haemophilia. His plan was to determine if the infection was acquired through blood products. At this point, there was no transmissible agent known so the study was directed to the immune system of people with haemophilia. One theory studied was whether people with haemophilia who had a lot of foreign proteins through the injection of factor VIII concentrates would have abnormalities.

[39] The study began in the fall of 1982 with 32 patients who were all examined by Dr. Tsoukas. All of them were receiving lyophilized factor VIII concentrate. He concluded that the immune systems of otherwise healthy haemophiliacs with no symptoms were abnormal. Dr. Tsoukas also compared the immune systems of people that had received factor VIII concentrate with those who had received cryoprecipitate. The latter turned out to be closer to normal.

[40] On December 10, 1982, the MMWR reported on two haemophiliac children who had contracted AIDS. To Dr. Francis, this meant that factor VIII concentrates could cause the infection. The same day another article also in the MMWR reported AIDS in a 20-month-old baby in California. The disease was contracted after blood transfusions which included donations from a healthy gay male who was subsequently found to have AIDS.

[41] By the end of 1982, the doctors at the CDC believed (as earlier suspected) that the infection was in fact blood borne. Health Canada published an article in December 1982 recommending how to deal with AIDS patients. The recommendations were consistent with the disease being blood borne.

[42] In the December 11, 1982 edition of the "Canadian Disease Weekly Report,"[7] Dr. Tsoukas reported on his study of the 32 asymptomatic haemophiliacs. His data showed that a substantial proportion of asymptomatic hemophiliacs show abnormal cellular immunity.

[43] In January 1983 another meeting was held in Atlanta. The CDC was recommending donor screening of the established risk groups, including homosexuals and intravenous drug users. Dr. Francis wanted something to happen at the blood collection sites. He asked how many people had to die before action was taken. Dr. Tsoukas was there and presented his findings.

---

[7] Exhibit 1

[44] Dr. Francis was frustrated that there were no universally accepted recommendations arising from the meeting. It was agreed that factor VIII was associated with transmission of the virus but Dr. Francis wanted the CDC to go farther. In a memo on January 6, 1983, he wrote that "post factor VIII receipt AIDS will occur in this country in the coming two years." He urged the CDC to make its own recommendations. He said that for haemophiliacs, "I fear it might be too late."[8] In the end, recommendations came out in MMWR and it was essentially agreed that factor VIII-associated virus was transmissible by blood products.

[45] Meanwhile, on both sides of the Atlantic work, was ongoing toward isolating the virus so vaccines and therapeutic interventions could be developed. There was Dr. Francis working as head of the CDC–HIV lab; Dr. Robert Gallo at the National Institute of Health in the United States; Dr. Jay Levy at the University of California in San Francisco; and Dr. Luc Montaigner at the Pasteur Institute in France. Politics and competition among some of the labs made this a "very ugly" time[9]. Co-operation between the Americans and the French was strained.

[46] In May 1984 Dr. Gallo published what came to be seen as a seminal article in *Science* magazine describing the causative agent of AIDS. The scientific community knew that a new retrovirus variously known as HIV or HTLV-III or HRI or LAV was linked with AIDS. From this point on, there was a general awareness that a retrovirus was most likely associated with this disease.

[47] In July 1984 an oft-referred to article in *Science* magazine described the causative agent of AIDS and gave it the name HIV. [10]

Multi-Centered Study in Canada

[48] The Laboratory Centre for Disease Control ("LCDC") in Ottawa is responsible for tracking epidemics. In 1984 it was heavily involved with AIDS research. Dr. Michael O'Shaughnessy of the LCDC had been to Dr. Gallo's laboratory at the National Cancer Institute in Bethesda Maryland. Through his colleague Dr. Peter Gill, he asked Dr. Tsoukas for serum samples taken from individuals who were at high risk for developing AIDS or those who did have AIDS. This was in order to test the new assays[11] that were being developed in Washington.

[49] The World Federation of Haemophilia met in Rio de Janeiro in August 1984. Dr. Tsoukas spoke about the immune system of persons with haemophilia. He also presented data which showed that a high percentage of persons who had been treated with factor VIII developed antibodies to HIV. Dr. Tsoukas told the conference that over 90% of the patients that had received non-heat treated factor VIII had become antibody positive or had "seroconverted".[12] This came as a shock to those present. Dr. Tsoukas thought the reaction was a sign of denial.

---

[8] Exhibit 19
[9] Dr. Francis: February 28, 2006 at 624
[10] At various times the virus was called HIV, HTLV III, LAV and HRI. For ease of reference, I will only use the initials HIV.
[11] Method used to measure how much HIV is present.
[12] To "seroconvert" means to go from a negative to a positive status with respect to the antibody

[50] In the fall of 1984, Dr. Tsoukas started a multi-centre study. The study was to determine what changes occurred in haemophiliacs with the use of blood products and to associate some of the changes with any infectious agents they would have come across, including HIV. The multi-centered study started in January 1985. Patients were added to the study over time. The results were eventually presented in May 1987. What surprised Dr. Tsoukas was the shocking difference between those who used cryoprecipitate and those who used concentrates: 9% of the former were positive; 50% of the latter were positive. The percentage for the latter was higher if the concentrates from Canada were mixed with those from the United States. To Dr. Tsoukas it meant that there was a higher risk if the patient received American concentrates. At this point, however, he was only concerned with non heat-treated factor VIII concentrates.

Heat Treatment of Blood Products

[51] By 1983, the major drug manufacturers were already heat-treating their products for hepatitis B. Armour treated its HT Factorate at 60°C for 30 hours. This temperature/time combination was known as 60/30.

[52] All manufacturers were also working on methods of inactivating the AIDS virus. There was some controversy and concern that the heat activation would actually cause other problems, which would inhibit the effectiveness of the concentrate. Indeed, early on, the haemophilia community refused to consider heat-treating.

[53] During 1984 and 1985 there was a great deal of research conducted to determine the effectiveness of heat treatment on the virus. As is customary in the scientific world, results are published to "get the word out."[13] It is important to understand what the state of knowledge was in the scientific and medical community during this time.

[54] Dr. Bruce Evatt was the Director of the Division of Immunologic Oncologic and Haematologic Diseases at the CDC. In early 1984, he and Dr. Steven McDougal of the CDC began HIV viral inactivation experiments with factor concentrates. These studies were started by the CDC and then further experiments were conducted on commercial products from the drug companies called Cutter and Alpha.

[55] The CDC did not know whether those products would be completely safe. The scientists assumed that the level of safety would increase and the risk of transmission would decrease with heat treatment, but by the end of 1984 they "had no idea."[14] They just knew that non-heat-treated factor VIII would be extremely dangerous for patients with haemophilia. The preliminary results from the studies demonstrated that HIV had an extreme sensitivity to heat. The CDC wanted to get this message out. To do so, Dr. Evatt met with representatives of the National Haemophilia Foundation's Medical and Scientific Advisory Council ("MASAC"). The meeting was in early October 1984 and MASAC immediately recommended the use of heat-treated factor concentrates.

[13] Dr. Tsoukas: February 22, 2006 at 160
[14] Dr. Evatt: June 28, 2006 at 6641

[56] On October 13, 1984 MASAC released a publication that suggested that HIV was sensitive to heat treatment and recommended that haemophiliacs switch to heat-treated concentrate. These recommendations were published in the MMWR. This was the first time that data was published on inactivation of HIV in factor concentrates. The publication confirmed that virally spiked samples of factor concentrate that had been lyophilized and heated at 60° C. contained no detectable virus after 24 hours of heating.

[57] The message from Dr. Evatt and the CDC was heard loud and clear by the haemophilia treaters. By the spring of 1985 most haemophilia treaters had switched to heat-treated concentrates. This switch actually halted an epidemic. According to Dr. Evatt, "it stopped it cold."[15]

[58] Dr. Evatt continued the studies. Representatives of Armour were most interested in his experiments. Dr. Fred Feldman from Armour had inquired about them. On November 29, 1984 Dr. Evatt wrote to Dr. Feldman. In that letter he described the process used in the experiment and outlined his preliminary results. The letter indicated that there was no detectable virus with a heat treatment at 60°C for 24 hours. Dr. Evatt's letter concluded:

> Because LAV appeared to be extremely heat labile, we believe that the procedures presently used by the manufacturers for heat treatment of hepatitis virus would adequately inactivate the LAV virus.

[59] This letter was significant to Armour since its heat treatment of 60/30 exceeded the 60/24 process referred to in the studies. Dr. Evatt confirmed at trial that these results were the best available at the time.

[60] In August 1985, Drs. Evatt, McDougal and others formally published the results of these studies in the prestigious *Journal of Clinical Investigation* ("JCP").[16] The article included the results of preliminary heat inactivation studies conducted by the CDC in the spring of 1984 and the collaborative heat inactivation studies conducted by the CDC, Cutter and Alpha later the same year. The authors concluded that the HIV virus appeared to be heat labile and that by heating factor concentrates, the transmission of the virus should be substantially reduced or eliminated.

[61] The data contained in the article showed that there was a margin of safety in Armour's heat treatment process. It showed that HIV is inactivated at a rate of one log[17] every 32 minutes in lyophilized factor VIII when heated to 60° C. The results of the experiments on the commercial product showed that no detectable virus was found after heat treatment at 68°C for 24 hours and at 60°C for 20 hours. This led to the conclusion that there would be a 37-log reduction with 60/20 heat treatment. The article stated: "This should provide a large, if not absolute, margin of safety."

---

[15] Dr. Evatt: July 6, 2006 at 7337
[16] Exhibit 49
[17] A logarithmic measurement

[62] To arrive at this conclusion, the authors extrapolated from the measured data, assuming a constant rate of inactivation. The Crown has argued that this was in error. Dr. Alfred Prince, who testified for the Crown, said that Dr. McDougal is a very fine scientist but "he goofed"[18] here. Dr. Prince said it was not justified to extrapolate because projections always "flatten out." The Crown alleges that in Dr. McDougal's article a year later, on August 11, 1986,[19] he agreed that he was in error. Actually, neither Dr. McDougal's article nor his testimony at trial supports this assertion. Dr. McDougal said that the factor IX product that was the subject of the second article, demonstrated a curved line of inactivation and it was difficult to extrapolate from a curve. He explained that if measured data is "not linear, it will not obey linear kinetics through extrapolated point forms".[20] He did not acknowledge an error.

[63] In any event, even if the extrapolation was not justified, it does not follow that those who relied on it were at fault. The highly respected authors from one of the leading agencies in the world were discussing results in a relatively new and evolving area of science. This was the highest state of knowledge at the time. To attack their conclusions twenty years later is to wrongly apply hindsight. Even Dr. Prince did not make this critique at the time. Although Dr. Prince now claims to have come to a different conclusion, two months after the publication of the *JCI* article, he wrote: "it is difficult to explain the difference between the results reported by McDougal *et al* and (my) findings."[21] He did not say the results differed because Dr. McDougal wrongly extrapolated. I believe that Dr. Prince revised his opinion with the benefit of hindsight. He practically admitted this in cross-examination:

> I cannot tell you what I was thinking in regards to the linear extrapolation at that time. This is twenty years ago or more.[22]

[64] Also, the reference to extrapolation was in the "discussion" part of the article. The raw data confirmed no detectible virus after heat treatment at 68/24 and 60/20, parameters that bracketed Armour's process.

[65] Later that same year, on October 19, 1985, Drs. J. Petricciani of the FDA, Evatt and McDougal published a letter in *The Lancet* promoting the use of heat-treated product. The letter used existing data on the seropositivity rate of donors and the behaviour of HIV during fractionation and viral inactivation. An extrapolation was then made about the expected viral titre of a plasma pool and the required level of heat inactivation to obtain a safe product. Dr. Petricciani calculated how much virus may be in a pool, how much reduction was necessary and the amount of concentrate a patient is given. The authors calculated that the infectivity of a plasma pool would be five logs. They applied the CDC data and calculated that the minimum reduction of virus due to the lowest heat treatment method of 60/20 would be 20 logs. The studies were done with unscreened plasma (that is, it had not been tested for HIV). The authors concluded:

---

[18] Dr. Prince: September 20, 2006 at 8652
[19] *Exhibit 392*
[20] Dr. McDougal: October 10, 2006 at 9514
[21] Exhibit 368
[22] Dr. Prince: September 26, 2006 at 8941

> There seems to be enough of a safety factor afforded by AHF heat treatment to permit the conclusion that LAV/HTLVIII is unlikely to be present in the currently licensed heat treated AHF, and that the use of such products should not result in additional cases of AIDS in persons with haemophilia.[23]

[66] This article gave great comfort and confidence to Armour as it confirmed once again that its process of 60/30 was safe. As will be seen below, it also provided assurances to the regulators and distributors of blood products. The November 1984 letter of Dr. Evatt and the CDC data were used by Armour as part of its successful license applications around the world.

[67] Nonetheless, the Crown contends that the defendants who relied on these articles were wanton and reckless. As with the earlier article, the Crown took issue with the CDC findings, alleging that the many assumptions made were erroneous and that Drs. Evatt and McDougal did not have direct knowledge of the processes used by the commercial manufacturers. The Crown argues that the data was not used in the US for licensing because the product was already licensed there and that the CDC does not establish industry standards. Once again, it was Dr. Prince who testified in support of the Crown's position.

[68] It is suggested by the Crown that the calculations were done on the basis of limited data and that Dr. Evatt did not know about the unfavourable heat inactivation data obtained by Armour including the studies by Dr. Prince. I discuss in detail below my views of the studies of Dr. Prince and his evidence. As I conclude later, his studies were unreliable and I do not accept his evidence. The "second guessing" about the correctness of the CDC conclusions are inextricably wound up with hindsight. More importantly, all who had to make decisions about blood products cannot be faulted for relying on the CDC particularly as endorsed by the FDA. The article of October 19, 1985 was confirming that, based upon the state of knowledge at the time, all of the licensed manufacturers were using processes that bettered the results in the experiments. That was the belief of the CDC and the FDA.[24]

Dr. Levy's Studies

[69] While the CDC studies were going on, Dr. Levy, another well-respected expert in HIV in San Francisco, was also doing experiments using mouse retrovirus as a model virus. He worked with Cutter which heat-treated the virus for this study. Dr. Levy published an article in *The Lancet* in September 1984 wherein he concluded that the retrovirus was able to withstand heat and that substantial inactivation was found only after samples of factor VIII had been heated for several hours at 68°C. Dr. Levy was surprised that the virus was so resistant to heat.

[70] The Crown says this should have been a warning sign, especially to Armour. However, the article was effectively ignored by the scientific and haemophiliac communities as having no bearing on the sensitivity of human HIV. Dr. Levy then studied human HIV, again with Cutter's process. He wrote a letter to *The Lancet* that was published on June 22, 1985. He concluded that HIV was resistant to heat and that after treatment at 68°C for 30 hours the virus continued to

[23] Exhibit 46
[24] Dr. Evatt: June 29, 2006 at 7077

exist. It took, in his view, 48 hours of treatment at 68 degrees to reach a point where the HIV virus was not detectable.

[71] On July 3, 1985, Christopher Bishop from Armour UK sent an interoffice memo to Dr. Michael Rodell and others attaching the June 22, 1985 letter from Dr. Levy. Mr. Bishop's letter said:

> It would appear from Table 2 of this article that a heat-treating process of 60°C for 30 hours would be ineffective in eliminating the ARV.[25]

[72] Mr. Bishop testified that he was simply referring the matter on to the scientists as he was not qualified to assess the information from Dr. Levy. At Armour, it was viewed as a study done for Cutter, a competitor, and not a comment on Armour's product. Anita Bessler was Vice-President of Marketing for Armour and later Vice-President of Licensing and Acquisitions for Revlon Health Care which included Armour. She considered the Cutter study "marketing data."[26] It is not clear how much time Armour spent considering this information. The standard of review, however, is not perfection viewed with the benefit of 20/20 hindsight vision. There is no evidence that Dr. Levy's second study caused anyone in the medical, scientific or regulatory communities to question Armour's process or to reconsider the views of the CDC. Also, there was evidence to support Armour's process.

Armour's Tuckahoe Meeting

[73] On October 15, 1985 Armour's Recombinant DNA Steering Committee met in Tuckahoe, New York. This committee's purpose was, in part, the development of factor VIII products. It was made up of employees and officers of Armour and an affiliated company, Meloy Laboratories. Dr. Rodell was present as were many of those who testified at trial. Most of the meeting was taken up with the topic of the heat treatment of Armour's product. Dr. Joseph Perpich, a lawyer and a physician, was the Vice-President of Planning and Development for Armour. He was the note taker at the meeting. He said there was a good deal of anxiety about the heat inactivation results and that detectible virus was found in the final heated product. The minutes of the meeting disclose that the changes in the heat treatment would cost millions of dollars. Dr. William Terry chaired the meeting. Dr. Terry was an immunologist from the National Cancer Institute. He joined Meloy Laboratories and was its President. Meloy did research and development for Armour.

[74] By the time of this October 15, 1985 meeting, Armour had preliminary results from Dr. Prince. Dr. Terry is recorded as asking whether the FDA should be approached with the preliminary results from Dr. Prince. Dr. Rodell was recorded as saying it would be "unwise to go to the FDA without completing our own work first."[27]

---

[25] Exhibit 519
[26] Anita Bessler: April 10, 2007 at 17098
[27] Exhibit 483

[75] The statement of Dr. Terry (who was not called as a witness) and the response of Dr. Rodell and ultimately Armour are relied on by the Crown in its allegation of wrongdoing.

[76] The Crown alleges that Armour and Dr. Rodell knew at this point that their product was unsafe and chose to wait for more favourable results before informing consumers, treatment providers and regulatory bodies. To a large extent, the Crown relies on the studies and testimony of Dr. Prince.

[77] Dr. Prince was an important witness for the Crown. The Crown alleged that his studies conducted in 1984 and 1985 showed that Armour's process was unsafe. Armour, instead of disclosing this or changing its process, is alleged to have buried the findings. In addition, as outlined above, his testimony at trial was relied upon to discredit Drs. Evatt, McDougal and Petricciani. It is therefore important to consider his testimony in some detail.

Dr. Prince: His Studies, His Testimony

[78] The New York Blood Centre is a major voluntary blood donor center. It also fractionates plasma to make derivatives such as factor VIII. It distributes factor VIII to the haemophiliac community in New York area, a region which includes about 20-25 million people. It is the largest distributor in the U.S. after the American Red Cross.

[79] Dr. Alfred Prince was, for 42 years from 1965 to 2006, the head of virology at the New York Blood Centre. During this time he worked on eliminating, inactivating and preventing the transmission of blood borne virus.

[80] In 1983 he approached Dr. Gallo's lab to obtain HIV to experiment on viral inactivation. In the fall of 1984 he was asked by Armour to evaluate the efficacy of its 60/30 heat treatment of HT Factorate. Dr. Prince's approach was to get both Generation I and Generation II factorate from Armour in a freeze dried form, liquefy it, spike it with the virus, lyophilize it then send it back to Armour for heat treatment. It would then be returned to him to see what the viral kill was. A few weeks before Dr. Evatt's letter to Dr. Feldman, on November 19, 1984, Armour had retained Dr. Alfred Prince of the New York Blood Centre to conduct these studies. Armour hoped to establish that its 60/30 heat treatment process would kill 4-5 logs of virus. This was not including the inactivation that would result from the lyophilizing process.

[81] Dr. Prince performed five studies. They were plagued with difficulties. After a longer than expected delay, he reported to Armour. The first report was in January 1985. He had evaluated both Generation I and Generation II samples. In both samples, the virus was not detected after lyophilization and heating. The virus stock used was unexpectedly low. The study was repeated. The second study was conducted in two parts: 2(a) dealt with Armour's factor VIII Generation II; 2(b) dealt with Armour's factor VIII Generation I. The first part was reported to Armour in April 1985. There, the amount of the HIV inactivation due to lyophilization alone was 0.5 log. Heat treatment at 60/30 inactivated an additional 1.5 logs leaving a total inactivation of 2 logs. The study showed that heating for 72 hours at the same temperature killed much more virus, more than one hundred times more than heating for 30 hours. The second part of the second study was also reported in April 1985, two days after the

first part. Dr. Prince concluded that the total inactivation of HIV in Generation I after lyophilization and heating was either 1.5 or 2.5 logs. Armour had expected a 5-log kill from heat alone.

[82] Studies 3 and 4 did not produce measurable results.

[83] Study 5 evaluated the effect of heating at 60 degrees in the dry state of infectivity of HIV in Armours Generation II AHF and Factor IX. The results revealed that HIV remained in Armour's product and that the heating alone was responsible for less than 1.0 logs of inactivation. When the heating was combined with lyophilization, the total effect was reduction of 3.7 to 3.9 logs.

[84] The only experiment completed by Dr. Prince on Generation I was 2(b), the report of which was sent on April 5, 1985. At trial, Dr. Prince had great difficulty interpreting his results. There were several arithmetic errors which made his testimony confusing and difficult, if not impossible to follow. If it was difficult to follow at trial, with all the benefits of hindsight, I find it must have been equally difficult for Armour and Dr. Rodell to follow at the time.

[85] Eventually, Dr. Prince concluded that the efficacy of dry heat by Armour was somewhat limited. He wanted to publish an article and sent his manuscript to Armour. It appears to have been received by Dr. Rodell on November 12, 1985. Dr. Prince said that Armour took the position he could not publish it because it violated their agreement. In fact, it was most likely not publishable since one of the hallmarks of valid scientific research is the ability to reproduce results. Dr. Prince was unable to adequately reproduce the results of his experiments.

[86] Dr. Prince claimed to be annoyed with Armour and set out to repeat the experiments on behalf of the New York Blood Center using factor VIII manufactured there. Dr. Prince reported his findings with respect to this experiment in a letter to *The Lancet* published on May 31, 1986. In that letter he did not say the Armour product was unsafe, he did not provide data for the 60/30 method and did not mention any manufacturers. He did not call for any action, but suggested long term surveillance.

[87] There is no evidence that the publication of this letter impacted the medical or scientific community. In fact, it appears not to have impacted Dr. Prince. His own organization, the New York Blood Centre continued to purchase and distribute Armour HT Factorate.

[88] Dr. Prince testified that the Armour method had "relatively low effectiveness."[28] The Crown's alleges that Armour and Dr. Rodell had a duty to disclose this information from Dr. Prince. In my view, this was not what Dr. Prince communicated to Armour, or to anyone, for that matter. In actual fact:

- His letter of May 31, 1985 did not say that the Armour product was unsafe because he did not want to create fear in the haemophiliac community.

[28]Dr. Prince: September 20, 2006 at 8696

- He did not say that Armour was manufacturing an unsafe product. Instead, he said his "*private* feeling was this was not enough to make a safe product."[29] (Emphasis added)

- He had "no idea" whether or not the New York Blood Centre continued to buy Armour 60/30 factorate after his *Lancet* letter and did nothing to bring the matter to the attention of the purchasing department. He said that, as chief of virology, he had "no role in any decision making on distribution of factor VIII."[30]

[89] In short, the Crown would have Armour put more value on Dr. Prince's studies than Dr. Prince did himself.

[90] This was a time of great uncertainty. In the face of this, and in light of the clearly articulated studies of the CDC, supported by the FDA, it would have been unreasonable, if not irresponsible, for Armour to have thrust such confusing, incomplete and inconclusive information into the community.

[91] Dr. Prince's views articulated at trial were not only tainted by hindsight, they were substantially revised from his earlier views and opinions. In 1995, ten years after the experiments done for Armour, Dr. Prince issued a press release dated October 6, 1995. It was published in the Philadelphia Inquirer on October 23, 1995. It was a public statement with respect to the Armour studies. It said:

> Although some newspaper reports imply that Armour was negligent in continuing to distribute the original 60/30 treated product through 1987, I do not share this conclusion.[31]

[92] I believe that this is an accurate representation of Dr. Prince's views both in 1985 and 1995. His statement goes on to say:

> It must be remembered that our knowledge of HIV was very limited at the time. Actions taken then cannot be judged in light of our knowledge today.

[93] Inadvertently, Dr. Prince has summarized the position of the defence. If Dr. Prince felt Armour's product was not safe, he did not tell anyone. In cross-examination he was asked about the public statement and the following exchange took place:

> A. I think this statement, as I've said many times before, does not really reflect what I was thinking at all respects. This statement, I think, reflects a desire not to harm a given production facility, company. Uhm, but I think many other statements that I've made indicate that I was quite concerned that the product might not be safe when given in large amounts to large numbers of people.

---

[29] Dr. Prince: September 20, 2006 at 8697
[30] Dr. Prince: September 27, 2006 at 8959
[31] Dr. Prince: September 27, 2006 at 8973

> Q. And you kept that to yourself; you kept that as your private thoughts and you permitted the New York Blood Center to distribute this as your public position and the position that you were prepared not only to distribute to the American public but to the scientific community as well? That's what you permitted the New York Blood Center to provide to the public; isn't that right?
>
> A. Evidently.[32]

[94] Dr. Prince produced studies that were unreliable, confusing and inconclusive. He could not possibly have thought that Armour's product was unsafe or he would not have allowed his own organization to continue to distribute it. Nor would he have clarified his position in a press release 10 years later.

[95] Armour and Dr. Rodell had a reasonable response to Dr. Prince's studies. It would have been wrong for them to rely on or to disseminate those studies in any way.

[96] For the reasons set out above, I find that Dr. Rodell's comments at the Tuckahoe meeting were reasonable. (I will come back to Dr. Terry's comments later.)

The Meloy and Ehrlich Studies

[97] It was clear throughout the trial that studies and/or experiments had been done by Meloy Laboratories and by the Paul Ehrlich Institute. Regrettably, no one who had knowledge of either set of experiments was called as a witness.

[98] Towards the end of 1985, Meloy Laboratories conducted heat inactivation studies for Armour. In monthly reports, Dr. Alain Schreiber provided updates as to the studies. The updates from 1985 to 1986 referred to the ineffectiveness of the 60/30 process and the benefits of a 68/72 process. No one was called from Meloy to explain the results of those studies. Thus, they are not before me. Dr. Terry of Meloy had certain comments attributed to him in the minutes of meetings.

[99] Dr. Walker testified that the Paul Ehrlich Institute was a world-renowned research facility. He said: "in the area of virology, I would say that there are two recognized...authorities in the world: CDC in Atlanta and the Paul Ehrlich Institute in Germany."[33] There was peripheral evidence at trial indicating that the Paul Ehrlich Institute reported favourable findings about Armour's product. There was also peripheral evidence that Dr. Terry criticized those findings as well.

[100] Dr. Terry was not called to testify. The Crown nonetheless sought to excise portions of his comments recorded at meetings to support its case. Those comments included:

---

[32] Dr. Prince: September 27, 2006 at 8973-8974
[33] Dr. Walker: May 24, 2007 at 18127

- His query at the Tuckahoe meeting as to whether the FDA should be notified about Dr. Prince's preliminary results; and

- His statement (referred to below) at the PEC[34] meeting in February about proceeding with the exchange of screened for unscreened product immediately.

[101] The Crown does not mention the fact that Dr. Terry also criticized the Paul Ehrlich Institute results which were actually favourable to Armour. The Crown has made inferences from Dr. Terry's statements that support the allegation that Armour and Dr. Rodell did not discharge their duties. The Crown relies on Dr. Terry's statements as somewhat of a warning which was ignored. There is an equally plausible inference that can be drawn from his statements when considered in context.

[102] In the dynamics of a meeting involving scientific data it would be expected, if not demanded, by responsible people that those present would be encouraged to express and discuss divergent views. One reasonable inference from Dr. Terry's recorded comments is that he played the role of "devil's advocate": always questioning, always testing. This is part of responsible decision making. However, decisions taken were done by consensus and it is obvious that Dr. Terry concurred in those decisions.

[103] The Crown's position with respect to Dr. Terry's comments highlights the dangers of hearsay evidence, particularly taken out of the entire context.

[104] Throughout the trial the Crown sought to have information about the Meloy Studies introduced indirectly. Reference was also made in submissions. It is ironic that the Crown would aggressively attack the findings of the CDC when those involved in the studies were called, yet assert that the Meloy studies could be introduced without explanation. The manner in which the Crown attacked the findings of Drs. Evatt, McDougal and others, underscored the need to have at least one participant in the study testify.

Request for Proposals by the Canadian Red Cross and the BoB Requirements

[105] The CDC studies and related articles did not go unnoticed in Canada. On November 16, 1984, Drs. Boucher and Furesz on behalf of the BoB issued a telex to all fractionators indicating that all AHF products needed to be heat-treated. A month later, the BoB issued what has been referred to as a "position paper." It included the Cutter collaborative experiments with the CDC, confirmed that Cutter was the only company to have so far demonstrated that their product eliminated HIV and went on to assure the haemophiliac community that all manufacturers would be required to provide evidence that HIV was inactivated by their procedures. The paper said:

> ...we have informed the Canadian Red Cross that further reliance on AHF products that have not been heat-treated cannot be justified and that such products should be replaced with heat-treated AHF as soon as feasible...The Bureau is

[34] Plasma Executive Committee

> requiring all other manufacturers to provide evidence that HTLV III is inactivated by their procedure.[35]

[106] The Crown sought to elevate this position paper into a requirement that data verified by the manufacturer be provided on its own product. The paper actually requires evidence of inactivation. The studies by Drs. Evatt and McDougal are such evidence. The BoB had received evidence establishing a 6 log kill for product following Armour's methods. The paper was meant to explain why the November 16 directive was made and was one of several presented at the conference.

[107] In late 1984, the CRC circulated a RFP to fractionators for the purchase of 40 million units of factor VIII. All manufacturers were required to submit heat inactivation data. The vendor selection committee of the CRC included people from the fractionation department, the national reference lab, the finance department and purchasing. Representatives of the CRC considered the manufacturers Cutter, Travenol, Alpha and Armour. They met with Armour on December 19, 1984. Memoranda of the meetings were prepared by Dr. Naylor. At both the Cutter and Armour meetings, scientists presented data on the inactivation procedures. Anita Bessler from Armour said that the company would not provide precise data as to its temperature and time parameters due to patent issues and patient confidentiality concerns. Instead, Dr. Feldman provided a general overview of the Armour process. Dr. Rodell and Armour then provided Dr. Feldman's chart documenting the CDC's collaborative studies with Cutter and Alpha. Dr. Walker assumed that the results applied to Armour's product.

[108] The vendor selection committee of the CRC decided to choose Cutter for 30 million units and Armour for 10 million units. Alpha and Travenol were rejected on the basis of price. It was decided to purchase from two suppliers to guarantee adequate supply as this was always a critical issue. Dr. Perrault approved the recommendation. Dr. Walker said that during the selection process, the meetings were open and everyone was able to voice an opinion. They always tried to reach a consensus. Once the committee decided, a recommendation was sent to Dr. Perrault who had "a keen eye for detail" and was not "just a rubber stamp."[36]

[109] On April 12, 1985 the BoB approved the package insert/monograph and issued a NOC for Armour HT Factorate. The product monograph for HT Factorate that had been submitted on October 30, 1984 by Armour contained the following words under the heading "Warning:"

> The possibility exists that Acquired Immune Deficiency Syndrome (AIDS), an immunologic disorder with extremely severe consequences, may be transmitted by blood, blood products, and blood derivatives including clotting factors. However, the causative agent has neither been identified nor isolated.[37]

[110] The Crown argued that this label was deficient and misleading because, by this time, U.S. scientists had announced the discovery of the virus thought to be the causative agent of

---

[35] Exhibit 151
[36] Dr. Walker: May 24, 2007 at 18271-2
[37] Exhibit 189

AIDS.[38] This, it is argued, was known to Drs. Furesz, Boucher and Perrault as well as Dr. Rodell and Armour when HT Factorate was licensed and distributed with this product label.

[111] On November 27, 1985, the CRC sent out another RFP for the upcoming contract period and Armour submitted a proposal. This was the first RFP factor VIII concentrate that required that the plasma be screened for HIV antibody. The wording of the technical requirement for heat-treating changed from the previous RFP to now only include a process under conditions "acceptable to the Bureau of Biologics." Dr. Walker testified that the viral inactivity data was seen as "academic" because they did not intend to compare the processes but to accept the standards set by the BoB.[39] Armour was awarded a contract for 12 million units. An additional 12 million units was awarded to the American Red Cross.

[112] On November 20, 1986, the CRC issued another RFP. This time, Armour was eliminated.

The Seroconversions

[113] On May 1, 1985, Dr. Rodell advised the FDA that a donor from one of the Plasma Alliance locations had developed AIDS. This donor had contributed 20 times and his donations had been traced to 17 different batches of concentrate, some heat treated, some not. Armour planned, as a result, to withdraw all non-heat treated product, taking the view that there was no need to withdraw the heat-treated lots.

[114] The American authorities were notified. Dr. Elaine Esber of the Office of Biologics Research and Review in the US agreed that there was no need to withdraw the heat-treated lots. Of the 17 contaminated lots, some had been distributed in Europe, including lots X57610 and Y60402.

UK Seroconversion

[115] Dr. David Whitmore was a haematologist at the Lewisham Hospital and Director of the Haemophilia Unit. On May 10, 1985 he was advised by Armour that lot Y69402 had been distributed at Lewisham. On June 28, 1985 Dr. Whitmore wrote to Robert Christie, the Director of Clinical Sciences at Armour in the United Kingdom. He advised that one of his seven patients who had received the product had seroconverted. This patient had tested negative on January 17, 1985, received the product on February 5, 1985, and tested positive thereafter. Dr. Whitmore was not too concerned about the seroconversion at the time. He assumed that the virus was killed by the heat treatment and the positive test was the result of a reaction to dead virus. Dr. Whitmore testified at trial that the implicated lot of Armour was the cause of the patient's seroconversion.

[38] Dr. Gallo's article was published in May 1984; the article in Science magazine was in July 1984
[39] Dr. Walker: May 24, 2007 at 18162

Dutch Seroconversion

[116] Dr. J.W. TenCate was the head of the Department of Haematology at the Academic Medical Center in Amsterdam. Dr. Cees Breederveld was another haematologist at the hospital who primarily treated children. In the spring of 1983, they commenced a study to determine if there was any difference in terms of safety between the use of paid and unpaid donor products and on the use of heat-treated products. There were 157 haemophiliacs in the study. All were HIV negative. Between 1983 and 1986, 20 patients seroconverted. All but one was related to the use of non heat-treated product. The remaining seroconversion was a haemophiliac who had received one of the contaminated Armour batches distributed in the Netherlands.

[117] Drs. TenCate and Breederveld exchanged information with representatives of Armour. Dr. Breederveld withdrew the product from their hospital. On September 6, 1985, Dr. Rodell was informed by way of memorandum that Dr. TenCate's patient had seroconverted. Mr. Bishop from Armour U.K. was dispatched to speak to Dr. TenCate and to investigate. Mr. Bishop reported the results of his investigation to Dr. Rodell on October 30, 1985.

[118] Dr. TenCate requested vials of the product to test on chimpanzees. Armour was not prepared to provide them without the approval of Meloy Laboratories. In any event, Armour believed their product safe because it had been tested and no virus had been isolated or cultured.

[119] On April 5, 1986, *The Lancet* published a letter from Drs. TenCate, Breederveld and others about this seroconversion. The letter stated:

> Thus, seroconversion to anti-HTLV III positivity occurred in a patient using exclusively heat-treated intermediate and high purity FVIII concentrate of American origin. According to the manufacturers, one of the donors whose plasma was included in on of the transfused batches which was of intermediate purity, has developed AIDS. All other possible routes of infection were excluded.[40]

[120] Dr. Evatt had a vague recollection of learning about this seroconversion in the Netherlands in 1986.

The Chapel Hill Seroconversion

[121] Dr. Gilbert White was a haematologist specializing in blood coagulations in charge of the Haemophilia Treatment Center at the University of North Carolina at Chapel Hill.

[122] In December 1985 he telephoned Armour and Dr. Evatt because he identified a patient thought to have seroconverted after receiving heat treated factorate product. The patient had been treated with cryoprecipitate in his youth but had not had plasma, cryoprecipitate or other blood factors since 1975. He was admitted to the hospital on June 30, 1985 and at that time tested

[40] Exhibit 335

negative. After this test, he received Armour HT Factorate. He tested negative again in late July. During a follow up at the haemophilia clinic in August, he tested positive.

[123] Dr. Rodell investigated the heat treatment of the implicated lot and was in contact with the CDC. The lot had been made with a combination of screened and unscreened donations. Dr. Rodell also advised the FDA.

[124] On March 15, 1986 *The* Lancet published a letter from Dr. White about this. He stated:

> ...the *possibility* remains that in this case, heat treatment failed to inactivate virus and immunity was in response to infectious virus...Another *possibility* is that inactive virus or viral fragments provoked the immune response. If viral material is present in concentrates, heat treatment might inactivate virus, but viral antigen might still be present in amounts sufficient to elicit an immune response. Seroconversion in this case would not signify exposure to active virus. Another *possibility* is passive transfer of HTLV-III antibody...Another final *possibility* is that the patient acquired HTLV-III through intravenous drug use...This case illustrates the need for further studies...*(Italics added)*[41]

[125] Dr. White was exploring various possibilities. His letter highlights the immunization versus infection debate that was still an issue in March 1986. He does not suggest Armour's process was unsafe.

[126] This particular patient did have other risk factors, primarily drug abuse. Dr. Evatt spoke to Dr. Rodell of Armour about this. Their discussion was typically direct and candid. They shared information. Dr. Evatt told Dr. Rodell that this patient was possibly involved in a fraud and that he may also have taken a blood product from Cutter, a competitor of Armour. Dr. Evatt said he had some problems with this case because there were other risk factors.

[127] In the spring of 1986, Dr. Evatt then got a call, he thinks it may have been from Dr. Rodell, advising him of seroconversions in the United Kingdom also associated with the Armour heat treated factor. This was Dr. Whitmore's patient. However, there were other patients who took product from the same Armour lot who were seronegative.

[128] All three seroconversions were investigated by the CDC. The CDC reported them to the FDA. All relevant information was disclosed to the National Haemophilia Foundation. Dr. Evatt had several discussions with Dr. Rodell. There was nothing kept secret.

[129] The seroconversions were known to the CDC, The FDA, MASAC and the United Kingdom's Department of Health and Social Services ("DHSS"). Dr. Evatt testified that he consulted with Dr. Zuck of the FDA, Dr. Levine of MASAC and Dr. Rodell of Armour. Documents show he was also in contact with Dr. Peter Jones in the UK.

---

[41] Exhibit 334

The Newcastle AIDS Conference

[130] Dr. Peter Jones was the Director of the Regional Haemophilia Comprehensive Care Centre for North of England in the mid-1980s. He had heard rumours of the seroconversions associated with heat-treated factor concentrates and organized an AIDS conference in Newcastle in February 1986. During the conference he voiced concerned about the possibility that heat-treated products were transmitting HIV. He did not name Armour publicly although he was concerned about its heat treatment. He had read Dr. Levy's publication, had spoken to other physicians and was aware of the seroconversions in the UK, Netherlands and Chapel Hill. As a result of his remarks, a number of organizations began their own investigations.

[131] Shortly after the conference, Dr. Jones wrote to the DHSS Committee on Safety of Medicines about his concerns. This time he named Armour. Dr. Francis Rotblat was a haematologist and the senior medical officer responsible for reviewing pharmaceutical company submissions for DHSS. After receiving Dr. Jones letter, she contacted Mr. Christie at Armour. Mr. Christie promised to provide everything available.

[132] Mr. Christie then went to see Dr. TenCate who admitted that it was possible the positive test was a response to dead virus. Mr. Christie also investigated the Lewisham seroconversion. He reported to Armour that the positive test might be the immune response to dead virus.

[133] The Crown alleges that Drs Perrault, Furesz and Boucher were negligent in their conduct after the Newcastle conference. It is argued that they made no meaningful inquiries in early 1986. Had they done so, the Crown alleges they would have learned the following:

- Two patients who received HT Factorate batches containing donations from a known AIDS donor had seroconverted;
- One of the patients who received a contaminated lot was a patient in Lewisham who was HIV negative before receiving treatment, received two vials of the implicated lot, and had seroconverted approximately four months later. He had no other risk factors, and had not received any other products for a substantial amount of time before the last negative test;
- Dr Whitmore was the patient's treating physician and he believed that Armour HT Factorate Y69402, a contaminated lot, was the cause of the seroconversion;
- Another patient who received a contaminated lot was treated by Drs. TenCate and Breederveld. The patient had tested HTLV-III negative on numerous occasions previously, but had seroconverted by January 1985. The patient had received only Armour's HT Factorate for a year prior to that and had no other risk factors;

- Physicians treating this patient had contacted the company because they believed that Armour had caused the seroconversion and the product was unsafe;

- Upon learning of the seroconversion, the physicians requested that Armour remove the product from their hospital. Armour did so;

- Dr TenCate had requested vials of the implicated lot to inject into chimpanzees to see if an infection would result, but Armour refused to provide the material; and

- The last seroconversion occurred in a patient in Chapel Hill and was publicly reported by Dr White. The patient was hospitalized following a car accident. The patient was negative during his hospitalization, but tested positive a couple of months later. During his treatment he had received a substantial amount of HT Factorate. Although the patient admitted to past IV drug use, there were no clinical or physical signs of recent use. The medical staff at the hospital did not believe the patient was currently using drugs, or was in any other risk group. Dr White believed that Armour HT Factorate was the cause of the patient's seroconversion.

[134] These allegations ignore the facts that the Chapel Hill and Dutch seroconversions were reported in *The Lancet*. They ignore the fact that the medical community, including Dr. White, was unsure and calling for more investigation. They ignore the fact that Armour was fully open and cooperating with all the authorities, including the CDC and the FDA. Drs. Perrault, Furesz and Boucher did not have a duty to speak to every single person involved in the Newcastle Conference. As set out in more detail below, their investigations were careful and complete.

Armour's Internal Investigation: the PEC Meetings

[135] On February 20, 1986 the Plasma Executive Committee ("PEC") of Armour met at Fort Washington. Dr. Rodell and other executives of Armour and Meloy were there. The minutes of the meeting show that a review of the viral inactivation data was necessary because of doubts in the plasma community concerning the efficacy of heat treatment. Dr. Jone's comments at Newcastle were referred to.

[136] Dr. Terry presented the results of Meloy's HIV inactivation studies on Armour products and apparently told those present that "it appears that dry heat treating plasma may not be totally effective."[42] As a result, although the data was not absolutely conclusive, and comparisons of the methods were not yet completed, a decision was made to upgrade the heating cycle to 68 degrees for 72 hours. It was also decided that no product should be used if the plasma donors were not screened. The timing of the switch from unscreened to screened was discussed. The minutes of the meeting show that it was agreed to postpone the exchange:

[42] Exhibit 522

> Since this may be an industry wide problem, pending BoB response, centers where unscreened product may have been delivered will not be contacted until the situation is clear.[43]

[137] These centres included Canada. It was also agreed that Dr. Rodell would review the Meloy data, which had been presented by Dr. Terry, with the FDA. Five days later, Dr. Rodell met with Dr. David Aronson of the FDA. The Meloy data and the seroconversions in UK, Amsterdam and Chapel Hill were discussed. Dr. Aronson stated that Armour's current heat treatment process was adequate relative to HIV and that the product need not be withdrawn from distribution.

[138] Two days after Dr. Rodell's meeting with Dr. Aronson, the PEC met again, on February 27, 1986. The purpose was to decide what action to take regarding the unscreened HT factorate, namely whether or not to withdraw it. In a four page memo reporting on the meeting, Dr. Rodell states:

> The consensus attained at that meeting was to initiate the following steps, in order to provide the haemophilia community with product reflecting as much added margin of safety as possible:
>
> 1. The distribution of product derived from plasma not tested for Anti-HTLV III would be stopped, unless absolutely no adequate supplies of material produced from tested plasma were available.
>
> 2. When adequate supplies of new product are in inventory, an exchange program will be undertaken. At that time, customers will be advised to exchange their existing supplies for product derived from tested plasma.[44]

[139] The Crown alleged[45] that the failure of Armour and Rodell to withdraw the product immediately represented a marked departure from the conduct of a reasonable person and of sufficient magnitude to give rise to a conviction of common nuisance. They were, it is argued, under a duty not to distribute unsafe product and at this point there was evidence that the product was unsafe.

[140] Since the exchange of screened for unscreened was made a few months later, in June, the Crown's submissions are that Armour should have immediately withdrawn the product in February 1986. The submission is based on Dr. Terry's comments as recorded in the minutes that unscreened product should not be used. Once again, the Crown seeks to excise Dr. Terry's statement in support of its position. He was not called as a witness. Others who were at those meetings were. It is clear that, at the end of the day, there was a consensus reached, which must

[43] Exhibit 522
[44] Exhibit 762
[45] This allegation was made for the first time in the Crown's written submissions.

have included Dr. Terry. His isolated comments in minutes, unexplained by him cannot amount to a basis to criticize the ultimate decision taken. (I refer as well to my comments about Dr. Terry above.)

[141] It is clear from Armour's PEC meetings that Armour and its employees were acting in a responsible manner. Adequate supplies were necessary to effect the exchange. In fact, Armour was an industry leader in connections with the screening of blood products.

Follow up to Seroconversions

[142] Armour UK initiated a follow up to the patients who had received product from lot Y69402. Mr. Christie reported that 12 patients had received this lot. Five of the 12 had been seropositive before receiving it and one died of unrelated causes. Of the remaining six only Dr. Whitmore's Lewisham patient had seroconverted. In addition that patient appeared to be physically healthy.

[143] In early March, 1986, Dr. Rodell and others from Armour flew to the UK to meet with representatives of the DHSS including Dr. Rotblat. The purpose of the meeting was to discuss the safety of Armour's product. While the seroconversion of Dr. Whitmore's patient remained a concern, the DHSS was not completely certain it was caused by Armour's product.

[144] Dr. Rotblat issued a report on March 4, 1986 which mentioned discussions with Dr. Ten Cate as well as the BoB in the United States. Based on this information, the DHSS came to the same conclusion as the FDA that no action on Armour products was necessary.

[145] The Crown alleges that Armour did not provide all of the information to Dr. Rotblat, namely all the information about the Chapel Hill patient or the Prince conclusions. As outlined above, the FDA was aware of the Chapel Hill patient and that there were serious issues with the case. I have already explained why Armour was justified in not discussing Dr. Prince.

The Exchange

[146] On June 23, 1986 Armour announced the exchange of screened for unscreened product. This is the exchange which had been agreed upon on February 27, 1986. Armour's Canadian agent distributed the information to the Bureau of Biologics and the Canadian Red Cross. Dr. Rodell's letter included the following statements:

> Armour Pharmaceutical Company has an ongoing policy to openly discuss issues associated with the care and treatment of the haemophiliac. One such issue is the potential for Anti-HTLV III seroconversion subsequent to administration of heat-treated clotting factor concentrates produced from units of plasma collected prior to implementation of Anti-HTLV-III testing.
>
> We have been made aware of three instances in which hemophiliacs have tested positive for Anti-HTLVIII subsequent to

> the administration of H.T. FACTORATE ...however the circumstances surrounding each case prevent a definite conclusion regarding association of the use of the product with seroconversion.[46]

Dr. Rodell discusses the cases in UK, in Chapel Hill and in Amsterdam. He states:

> [with respect to Chapel Hill patient] ...received two units of packed red blood cells...questions have also been raised concerning the patient's personal history with regard to other risk factors...
>
> [with respect to the Amsterdam patient] ...reportedly received only H.T. FACTORATE....
>
> [with respect to the UK patient] ...the initial determination of seronegativity for Anti-HILV-III was made using unlicensed reagents and purported seropositive ELISA results using these unlicensed reagents.

Dr. Rodell then requests that product from unscreened plasma be exchanged for screened.

[147] The National Haemophilia foundation (NHF) in the US was supportive of the exchange and endorsed the safety provided by heat treatment.

[148] The Crown alleges that Dr. Rodell's letter was "skewed and selective" and did not accurately set out the known facts. In particular:

- The reference to "two units of packed red blood" in connection with the Chapel Hill patient was designed to suggest that this could be the cause of the seroconversion;
- The reference to "questions" about the patient's history was misleading as there was only one question, namely the possible IV drug use;
- In discussing Dr. TenCate's patient, he used the word "reportedly" before the information that he received HT Factorate;
- The wording with respect to Dr. Whitmore's patient refers to "unlicensed" reagents and "purported" seropositive results; and
- The letter omitted:

[46] Exhibit 508

- the fact that both Dr. TenCate's and Dr. Whitmore's patients seroconverted after using HT Factorate made with plasma from a known AIDS donor;
- the results of the Prince studies;
- the results of the Meloy studies which indicated residual virus;
- the decision to upgrade to 68/72;
- the concern expressed at an Armour meeting in February 1986 that plasma from multiple hot (i.e. positive) donors could surpass the ability of dry heat treating to eliminate sufficient virus;
- that he and others had been required to attend in the UK before the DHSS; and
- that they were waiting to exchange until they had sufficient replacement product.

[149] In addition, it is argued that the exchange was far too late in that it was eight months after the Prince results, six months after the Chapel Hill information, nine months after the Dutch notification and almost one year after notification of Dr. Whitmore's patient.

[150] I do not agree that the letter was misleading. Armour was one of the first to make the switch to screened product. The UK and Dutch seroconversions had been reported in the literature. There was no need to include in house discussions that led to a corporate decision that was reasonably and responsibly arrived at.

Canadian Response to the Exchange

[151] The CRC received Dr. Rodell's letter and immediately called a meeting of the recall/withdrawal committee. The withdrawal was carried out by Dr. Anhorn and staff in the BTS centres. Dr. Walker monitored the progress. Once the plan was in place, Dr. Davey would have informed Dr. Perrault since they worked as a team.

[152] Dr. Davey circulated a memo to the medical directors of the CRC-BTC centres explaining the withdrawal, and attaching the letter from Armour, a list of all the lot numbers involved, an itemized inventory of each lot number issued to the centres and a draft letter to be forwarded from the centers to the hospitals explaining the situation. Dr. Davey apparently felt there was no need to withdraw the product. Dr. Walker agreed that the screening was an added level of protection and that Armour was justified to rely on this distinction between screened and unscreened product.

[153] On July 22, 1986, Dr. Robert Card, the MASAC Chair in Canada wrote to Dr. Davey of the CRC about the withdrawal. In the memo he expressed concern that "the methods used in Armour factor VIII by implication might not be effective."[47]

[154] Dr. Davey replied saying that Dr. Card had already received all the information available to the CRC and concluded: "the data I have seen suggest that their heat treatment is as effective as the other manufacturers for inactivation of retroviruses although the heating period is shorter".[48]

Donor Screening/Lookbacks

[155] The Crown alleges that in the absence of an effective heat inactivation procedure or proof that heat treatment was killing sufficient virus, the defendants ought not to have relied on donor screening as a safety net to eliminate HIV from Armour's factor concentrates derived from pooled plasma. The time between infection and the detection of the antibody by laboratory tests is called the window period. Donor screening did not detect individuals with a high viral load when they were in the window period. This window period could last as long as six months. All of the defendants, it is argued, knew this. In addition, the tests during the 1980s were fallible and the defendants are alleged to have known this too.

[156] Armour had developed a system of "lookbacks" to test donors who tested positive to see if they had previously donated. If so, the donations that had not yet been pooled were removed from the manufacturing process. The Plasma Alliance centres maintained records that enabled them to search back and trace prior donations of positive donors and send a lookback notice to Armour at Kankakee. The units would be identified and removed if they had not already gone into production. The Crown argues that many units thus identified were not in fact retrieved. Also, the Crown contends that Armour developed a self-serving policy of determining when a product was "in production" and thus not retrievable. Armour's policy was to retrieve only plasma units packed in shipping boxes. Once the units were removed from these boxes, they were considered in process.

[157] Armour's lookback policy complied with FDA standards and was known to the FDA. The Crown's criticism regarding the designation of "in process" plasma is difficult to assess in the absence of any evidence as to the industry standards. There was no evidence about other manufacturers' plants, or from the FDA or the BoB in the United States. There was evidence about the "time sensitive" nature of the process and the need to move quickly or lose the coagulation effectiveness of the plasma. In any event, it seems as though the FDA was aware of this process. There is no evidence that the practice regarding the lookback deviated from the reasonable practices at the time.

---

[47] Exhibit 820
[48] Exhibit 820

The UK Withdrawal

[158] During the summer of 1986, Dr. Rotblat became aware that the Chapel Hill case was associated with Armour HT Factorate. In September 1986 she was advised by Dr. Frank Hill of Birmingham Children's Hospital that two boys had seroconverted after receiving unscreened Armour product. She reported this to her superior, Dr. David Jeffreys. He was the Principal Medical Officer in charge of new drug licensing.

[159] On October 1, 1986 Armour representatives were called to an emergency meeting in London. On October 3, 1986 Armour's UK representatives met with officials from the DHSS who were considering suspending the product if Armour did not voluntarily withdraw it. By this time, Dr. TenCate's patient had developed full-blown AIDS.

[160] Two more meetings took place on October 6, 1986 when Dr. Rodell and others met in London with five members of the DHSS. Armour's data, presented at the meeting, indicated that the product was now donor-screened. They also advised that the new 68/72 heat treatment could be ready for the market in a few weeks.

[161] Despite these assurances, the DHSS decided to require a withdrawal of the product and it was agreed that Armour would formally surrender their product licenses. Armour issued a press release announcing the withdrawal from the UK market. It included the following:

> On September 29th ARMOUR received a telephoned report that two haemophiliac patients in the U.K. had sero-converted.... Both patients had, for some months, been treated with Armour's heat-treated Factorate, which was manufactured from plasma collected before the general availability of...screening...[49]

[162] Armour sent copies of this press release to Dr. Walker of the CRC and to the BoB on October 7. (Details of the response of the CRC and the BoB are set out below.)

[163] The Crown alleges that Armour and Dr. Rodell should have provided the CRC and the BoB with more information including:

- that Armour was forced to withdraw its heat treated product to avoid having a license suspension;
- the DHSS knew of five cases of seroconversions, not just the two on Mr. Christie's memo;
- the medical director of Armour UK was concerned when told about the need for withdrawal and expressed no antagonism toward the DHSS;
- test results for 3 others patients of Dr. Hill's were imminent;

[49] Exhibit 710

- the Dutch patient now had full blown AIDS;
- the DHSS officials knew that the current product was screened and still wanted a withdrawal;
- other manufacturers had no reported seroconversions; and
- Armour offered to provide 68/72 to the UK.

[164] On October 14, 1986, Mr.Christie went to the Birmingham Children's Hospital to investigate. His trip report included comprehensive details about the two patients involved. His report said that one of the two patients was probably product related, the other not. This memorandum was provided immediately to the regulatory authorities in Canada and the US.

[165] By October 20, 1986, Dr. Rodell had been advised of a seroconversion of another of Dr. Hill's patients. It was a young boy with no other risk factors. The tests indicated that the seroconversion occurred by April 1986. Mr. Christie immediately advised the DHSS. Later, Dr. Hill advised of a forth patient who seroconverted. It is alleged that Dr. Rodell and Armour did not contact the BoB or the CRC with respect to these other seroconversions.

[166] On January 13, 1987, the results of the HIV tests on two of Dr. Hill's patients were received by Mr. Christie and immediately disclosed to the DHSS.

[167] Despite submissions to the contrary, I find that Armour's response was quick, concerned and professional throughout. The alleged omissions did not amount to matters that Armour had a duty to disclose. The events were happening quickly and Armour was responding appropriately and not hiding any information.

The Response in Canada to the UK Withdrawal

[168] Dr. Walker received the press release about the UK withdrawal on October 7 or 8, 1986. He sent a copy to Dr. Perrault and others at the CRC. People immediately burst into action. The next two weeks involved a constant stream of conference calls, meetings and activity. The issue was treated as a priority. Employees at the CRC began to check inventory to determine if they had enough AHF products to fill demand in the event of a withdrawal in Canada. The actions at the CRC upon receipt of the press release were summarized by Dr. Walker as follows:

> From memory, it is very difficult to place events exactly -- place them exactly in time, ... 20 years ago. I recall that Dr. Davey, Mr. Vick and I held several meetings. We contacted -- Dr. Davey contacted colleagues from the U.K. We contacted the representatives of the Canadian Haemophilia Society or the Haemophilia Treaters Society. We contacted the BoB.... We tried to put together a full picture of what had led to Armour's action in the U.K., what it meant for Canadian patients, ... what the impact would be, both on, ... - in terms of direct safety and also on availability of product, mindful that non-availability of the product, of Factor VIII in particular, is itself a safety hazard, and we tried to, and

> we worked with BoB to come to a consensus as to what action should be taken in Canada.[50]

The evidence of Dr. Walker, Mr. Vick and others confirms this response.

[169] The following day, Dr. Walker called Dr. Boucher to see if he had any information on the situation. Dr. Boucher did not. Dr. Boucher requested information from the CRC about existing inventory. Employees of the CRC went on a search for possible replacement product.

[170] At approximately 5:15 pm on October 8, 1986, Dr. Perrault learned for the first time about the UK withdrawal when he was briefed by Mr. Vick. Dr. Perrault instructed him to keep trying to find replacement product.

[171] On October 9, 1986 at 10:30 am Mr. Vick called Dr. Boucher to provide him with the requested information. Dr. Boucher requested more data from the CRC about the status of the Armour product received since April 1985. Dr. Boucher called Mr. McDade the President of Armour on October 9, 1986. According to the notes of the conversation, Mr. McDade said that Armour was developing a product which would be heated for a longer period. Dr. Boucher's notes of the conversation indicate that Mr. McDade did not have information as to when the patients seroconverted on the non-heated material.

[172] On October 9, 1986 at 2:30 pm, Mr. Vick spoke to Dr. Boucher and provided him with information that had been requested. Dr. Boucher indicated that Armour was in discussions with the FDA and they anticipated having a new heat-treated product licensed within a few weeks. At that point, it was suggested that Armour replace the product. Dr. Boucher apparently wanted to wait to speak to Dr. Furesz who was not available until the following day.

[173] The same day, Dr. Boucher called Dr. Leclerc-Chevalier at the Canadian Blood Committee to update her on the situation. He told her that there had been seroconversions in the UK but that the product had been heat treated, not screened.

[174] On October 10, 1986 at 9:45 am, Dr. Perrault met with Dr. Walker and Mr. Vick. Dr. Walker testified that Dr. Perrault was strongly in favour of a withdrawal of the Armour product. Later that morning, they participated in a conference call with Drs. Furesz and Boucher. Mr. Vick indicated that replacement product could be shipped by October 14 and they hoped the BoB could fast-track the approval process. Dr. Furesz wanted more information. He advised that the FDA was not going to withdraw the product because of concerns about the impact on the US market. Dr. Furesz indicated that the information from Britain was inconclusive because the transfusion history of the patients was unclear so it could not be tied directly to the Armour product. Dr. Perrault pressed the BoB for more information. Dr. Walker testified that the position put forward by Dr. Perrault was that there should be a withdrawal. The position put forward by Dr. Furesz was that such action could destabilize the world market and thus he opposed full withdrawal. Dr. Perrault requested this position in writing from Dr. Furesz. Dr.

---

[50] Dr. Walker: May 22, 2007 at 17892

Perrault gave instructions to Mr. Vick to buy 10 million units of the Cutter product in case the withdrawal went ahead.

[175] Another conference call took place at 2:15 p.m.. Dr. Card of the Canadian Haemophilia Society was asked to participate. Dr. Furesz indicated a concern of the FDA that a Canadian withdrawal would force the US to follow and a significant shortage would ensue. The FDA was going to meet in October 14, 1986, and it was decided to have another conference call after that meeting.

[176] Dr. Rodell called Dr. Walker of the CRC on October 10, 1986. Dr. Walker was filling in that day for Dr. Perrault. He testified as follows:

> Dr. Rodell, indicated that Armour was aware -- ...that the Red Cross, ... was proposing to withdraw the Armour product from the Canadian market; that Armour considered that unnecessary and inappropriate; that if the Red Cross persisted, it would be seen as a defamatory action and would be -- and the company would take the appropriate legal action. I wrote a speedy memo recording that call, left a copy for Dr. Perrault to receive on his return, and filed the retention copy, and I'm not sure in which file. [51]

[177] I pause here to note that Dr. Rodell's words to Dr. Walker were relied on by the Crown to suggest an aggressive stance or a lack of cooperation. This comment stands in isolation and complete contrast to all of the other evidence about Dr. Rodell's words and actions. The evidence discloses patience, and thoughtful, well-reasoned responses. The comment was four days after the withdrawal which resulted from what must have been a difficult meeting overseas. It is understandable that one intemperate remark was made at this pressure-packed time. It does not establish lack of cooperation or lack of concern.

[178] On October 14, 1986 during yet another conference call, Dr. Walker spoke to Dr. Furesz who said he had received additional but inconclusive information from the UK according to which it appeared that the Armour product was all unscreened and that one patient may have received other product. Dr. Furesz spoke to Dr. Thomas in the UK who worked for the National Institute for Biological Standards and Control and received the information from him.

[179] During all this time, the CRC was working on buying more replacement product. The efforts resulted in a sense that they had enough product to last for six months. Later in the day, Dr. Furesz indicated that he was now leaning towards a recall or withdrawal.

[180] On October 15, 1986 Mr. McDade sent Dr. Boucher a copy of Mr. Christie's report about his visit to Dr. Hill and relating the details of the two boys who seroconverted. That information provided details about two patients: patient no. 1 was 11 years old, sexually immature and had no risk factors; patient no. 2 was 15 years old, believed sexually inactive. He

[51] Dr. Walker: May 22, 2007 at 17940

did have a history of treatment with cryoprecipitate. He received the non-screened Armour product.[52]

[181] On October 16, 1986 after the FDA meeting, another conference call took place with Drs. Perrault, Davey, Walker, Furesz and Boucher and Mr. Vick. Dr. Furesz indicated that the FDA looked at the product's safety data and concluded it was adequate. The FDA was not going to require a withdrawal. In Dr. Furesz view, this fact, plus the inconclusive nature of the UK seroconversions meant that a withdrawal was not warranted. Mr. Vick recalled that Dr. Furesz had told him that the FDA undertook its own review of the viral inactivation data presented by Armour for its license and upon doing so concluded that it was safe. Also, Mr. Vick stated that Dr. Davey had been in contact with those involved in the UK cases and he was also of the view that a withdrawal was not necessary. Dr. Perrault supported a withdrawal until the very last meeting. Mr. Vick stated that, at the end of this meeting, Dr. Perrault passed him a note reminding him to ask for the BoB position in writing. In response, Dr. Furesz sent a written direction advising the CRC to re-issue the suspended Armour product. That letter reads:

> Following our review of the available scientific data, we concluded that the product, when prepared from plasma screened for HIV antibodies, is considered non-hazardous with respect to HIV infection in hemophilia patients. Consequently, we advise you to continue with the distribution of this product.[53]

[182] On October 22, 1986, Dr. Davey on behalf of the CRC sent a memo to the Medical Directors at the Blood Services Centers in Canada advising of the BoB's position and indicating that the CRC would continue to distribute the current Armour product.

[183] In response to concerns raised by members of the Haemophilia Society, Dr. Card who held positions with both the Haemophilia Society and the CRC responded to Bill Mindell of the Ontario Chapter of the Canadian Haemophilia Society. Dr. Card stated that the patients in question had received non heat-treated product from non-screened donors. The Crown argues that this statement was not reflective of the evidence to that date. Also, the Crown argues that the information received about Dr. Hill's patient the day before was not inconclusive and should have led to a withdrawal.

[184] I find that the consultation and communication that was ongoing was extensive. The CRC was in constant discussion with the BoB which in turn was in consultation with the FDA. Also, there is also evidence that:

- Dr. Davey had consulted Dr. Forbes, the Chair of the UK Haemophilia Directors;
- Dr. Forbes had heard the presentation by Dr. Hill on October 9, 1986;
- Dr. Davey had contacted Dr. Bloom who knew the basis of the DHSS decision, who visited the FDA and who had spoken to the CDC;

[52] Exhibit 825
[53] Exhibit 805

- The FDA had the UK data; and
- Dr. Furesz had a close collaborative relationship with the FDA, with Drs Esber, Mayer, Parkman and Petricciani and they kept each other informed of scientific and regulatory matters.

[185] The information about Armour was available to all regulators. The UK was the only jurisdiction to require a recall.

Armour's Move to 68/72

[186] At the end of 1986, the manufacturing facility at Kankakee converted its heat treatment process from 60/30 to 68/72. Dr. Rodell indicated in the New Drug Submission[54] that all steps in the manufacturing process, with the exception of the heating of the final lyophilized finished product are the same as those provided for in the HT Factorate licence.

[187] Dr. Rodell sent Dr. Boucher a copy of the application filed with the FDA to support the application to distribute 68/72. He included studies done by Meloy on both 68/72 and the previous 60/30. These results indicated less inactivation in the Generation I product and failed to reflect the 6-log kill Dr. Boucher had referenced in his original recommendation of HT Factorate in March 1985.

[188] The Crown alleges that this information should have caused Dr. Furesz and Dr. Boucher to withdraw the product. Although licensed in the US, 68/72 was never licensed in Canada. Armour withdrew the application in favour of "Monoclate" another product that had been tendered several months earlier. This submission is therefore not relevant.

The BC/Alberta Seroconversions

[189] In early to mid October, 1987, Dr. Walker and Mr. Vick learned of seroconversions in Western Canada. They immediately looked into the patient records and began withdrawing all products that the patients had received. On November 7, 1987, Dr. Walker wrote to the BoB announcing the withdrawal.

[190] Both the CRC and the BoB worked together to share information, track down implicated lots and withdraw them. They were in daily contact. At the time, the seroconversions were not tied to one company and there was a concern about supply as the product was withdrawn.

[191] In the fall of 1987, the BoB retained Dr. Robert Remis, an epidemiologist and public health specialist. Dr. Remis was told about the cluster of HIV infections among haemophiliac patients in British Columbia. He was asked to carry out an outbreak investigation or field investigation to determine the cause. In connection with this, he travelled to the Kankakee plant with Dr. Boucher. He learned that lots B71308, B71408 and B71508 had all come from the

[54] Exhibit 581

same donor. Dr. Remis testified that this was very important in arriving at an explanation. Soon after, on December 10, 1987 a formal recall of three lots of Armour HT Factorate was announced by the BoB. They were lots B71308, B71408 and B71508.

The Charges

[192] Armour, Dr. Rodell, Dr. Perrault, Dr. Boucher and Dr. Furesz have been charged with four counts of criminal negligence, and one count of nuisance. Each count of criminal negligence is identical in its wording except for the time period covered (from 7 to 18 years) and the initials of the alleged victim. The nuisance charge covers a time span of over three years. The corporate defendant is also charged with a sixth count: that if failed to notify the Minister of a deficiency or alleged deficiency as required by the *Food and Drugs Act*.

Criminal Negligence

[193] Counts numbered 1-4 have similar wording. The following is typical:

> Armour Pharmaceutical Company, Michael RODELL, Roger PERRAULT, Donald Wark BOUCHER, and John FURESZ, between October 1, 1984 and February 29, 1992, at the City of Toronto and elsewhere in the Province of Ontario, and in the Province of Alberta and elsewhere in Canada, and in the State of New York, and in the Commonwealth of Pennsylvania, and in the State of Illinois, and elsewhere in the United States of America, did, by criminal negligence, permit or cause to be distributed Armour H.T. Factorate infected with Human Immunodeficiency Virus (H.I.V.), which was infused into MM causing him bodily harm, contrary to Section 221 of the Criminal Code, R.S.C., 1985, c. C-46

The *Criminal Code* defines criminal negligence as follows:

> 219. (1) Everyone is criminal negligent who
>
> (a) in doing anything, or
>
> (b) in omitting to do anything that it is his duty to do,
>
> shows wanton or reckless disregard for the lives or safety of other persons.
>
> (2) For the purposes of this section, "duty" means a duty imposed by law.

[194] The penalty for criminal negligence causing body harm is set out in section 221 which provides that:

> Everyone who by criminal negligence causes bodily harm to another person is guilty of an indictable offence and liable for imprisonment for a term not exceeding ten years.

[195] Where criminal negligence arises from an omission, the defendant must be under a duty to do the omitted act. This is not the case where the criminal negligence involves the commission of an act.

[196] The conduct of the accused must demonstrate wanton and reckless disregard for the lives or safety of others. This has been described as a marked and substantial departure from the standard of a reasonably prudent person in the circumstances. It involves an element of moral blameworthiness.[55]

"Wanton" has been described as:

- "heedlessly";[56]
- "ungoverned" and "undisciplined";[57]
- "unrestrained disregard for consequences";[58]

Reckless has been described as "heedless of consequences, headlong, irresponsible."[59]

Common Nuisance

[197] Count 5 reads:

> Armour Pharmaceutical Company, Michael RODELL, Roger PERRAULT, Donald Wark BOUCHER, and John FURESZ, between October 1, 1984 and December 31, 1987 at the City of Toronto and elsewhere in the Province of Ontario, and in the Province British Columbia, and in the Province of Alberta, and in the Province of Manitoba, and elsewhere in Canada, and in the State of New York, and in the Commonwealth of Pennsylvania, and in the State of Illinois, and elsewhere in the United States of

---

[55] *Leblanc v. R.* (1975), 29 C.C.C. (2d) 97 (S.C.C.); R. v. J(.L.) (2006), 204 C.C.C. (3d) 324 (Ont. C.A.). *R. v. Waite,* [1989] 1 S.C.R. 1436

[56] *Regina v. Waite* (1996), 28 C.C.C. (3d) 326 (Ont. C.A.) at 341 per Cory J.A. (as he then was)

[57] *Regina v. Sharpe* (1984), 12 C.C.C. (3d) 428 (Ont. C.A.) at 430 per Morden J.A.

[58] *Regina v. Pinske* (1988), 6 M.V.R. (2d) 19 (B.C.C.A.) at 33 per Craig J.A. (affirmed on a different basis, [1989] 2 S.C.R. 979 at 979 per Lamer J. (as he then was)

[59] *Regina v. Sharpe*

> America, did commit a common nuisance by distributing or failing to take sufficient measures to prevent the distribution or infusion of Armour H.T. Factorate, and did thereby endanger, through exposure to the risk of Human Immunodeficiency Virus (H.I.V.) infection, the lives, safety or health of the public, contrary to Section 180 of the *Criminal Code*, R.S.C., 1985, c. C-46.

[198] Common nuisance is defined, and the offence created, by s.180 of the *Criminal Code*. It is as follows:

> 180(1) Everyone who commits a common nuisance and thereby
>
> (a) endangers the lives, safety or health of the public, or
>
> (b) causes physical injury to any person, is guilty of an indictable offence and liable to imprisonment for a term not exceeding two years.
>
> (2) For the purposes of this section, everyone commits a common nuisance who does an unlawful act or fails to discharge a legal duty and thereby
>
> (a) endangers the lives, safety, health, property or comfort of the public; or
>
> (b) obstructs the public in the exercise or enjoyment of any right that is common to all the subjects of her Majesty in Canada.

[199] Whereas the criminal negligence counts relate to specific individuals, the common nuisance count relates to "endangerment" of the public. It does not require proof of actual injury or damage[60]. The defence has acknowledged that if HIV was distributed to the public, it placed the public at risk.[61]

[200] While common nuisance may be satisfied by less egregious conduct than criminal negligence, the offence still requires conduct that discloses a marked departure from an objectively reasonable standard of care. The objective test was somewhat modified by Justice Cory for the majority in *Regina v. Hundal*[62] to ensure that, "...the objective test should not be applied in a vacuum but rather in the context of the events surrounding the incident". Justice Cory elaborated by adopting the same standard as that of criminal negligence as described by Justice McIntyre in *Regina v. Tutton*:[63]

---

[60] *R. v. Thornton* (1991), 82 CCC(3d) 530 (CA)
[61] Transcript May 7, 2007 at 17444
[62] (1993) 79 C.C.C. (3d) 97 (S.C.C.)
[63] (1989) 48 C.C.C. (3d) 129 (S.C.C.)

> The application of an objective test...however, may not be made in a vacuum. Events occur within the framework of other events and actions and when deciding on the nature of the questioned conduct, surrounding circumstances must be considered. The decision must be made on a consideration of the facts existing at the time and in relation to the accused's perception of those facts. Since the test is objective, the accused's perception of the facts is not to be considered for the purpose of assessing malice or intention on the accused's part but only to form a basis for a conclusion as to whether or not the accused's conduct, in view of his perception of the facts, was reasonable...if an accused under s. 202 has an honest and reasonably held belief in the existence of certain facts, it may be a relevant consideration in assessing the reasonableness of his conduct...

[201] The fault requirement for conduct in criminal law is mandated by the principles of fundamental justice as guaranteed by s.7 of the *Charter of Rights and Freedoms.*[64]

Count 6

[202] Armour Pharmaceutical is charged alone with one additional offence. It is alleged pursuant to the particulars, that, under the direction and authority of Michael Rodell, it failed to notify the Minister of Health of a deficiency in its product. The indictment is:

> **ARMOUR PHARMACEUTICAL COMPANY** further stands charged that between August 1, 1985 and December 15, 1987, at the City of Toronto and elsewhere in the Province of Ontario, and elsewhere in Canada, and in the State of New York, and in the Commonwealth of Pennsylvania, and in the State of Illinois, and elsewhere in the United States of America, failed to notify the Minister immediately of a deficiency or an alleged deficiency, in the viral inactivation process as described in the studies of Dr. Alfred Prince, concerning the safety of Amour [sic] H.T. Factorate, a licensed Schedule D drug manufactured by Armour Pharmaceutical Company and distributed to the Canadian Red Cross Society, as required by Section C.04.010 (b) of the *Food and Drug Regulations*, contrary to Section 26 of the *Food and Drugs Act*, R.S.C. 1970, c.F-27.

[203] The Crown alleges that once Dr. Prince questioned the efficacy of the heat treatment process, the company was under an obligation to report this to the Minister.

---

[64] *(R. v. Naglik,* [1993] 3 S.C.R. 122 at para.36; *R. v. Hundal,* [1993] 1 S.C.R. 867 at paras. 42 and 43; *R. v. Gosset,* [1993] 3 S.C.R. 76 at paras. 31, 35-37)

The Victims

[204] There is a publication ban with respect to the identities of the persons named in the indictment and others who received Armour product. The order is for the benefit of those persons, it is not meant to preclude them from self-identifying. Here, initials will be used.

The negligence victims

[205] "MM" is named in count 1 of the indictment. He was born in December 1950 lived in Edmonton and seroconverted in 1987 at the age of 36. He died of AIDS related causes in 1992 at the age of 41.

[206] His wife testified at trial and described the horrible course of his disease and the debilitating symptoms which caused him to develop blisters and sores and drop in weight from 150 to 90 -100 pounds.

[207] While he was not part of Dr. Remis' initial investigation. Dr. Remis learned, in the course of his investigation about MM and believed that he had seroconverted as a result of the Armour product. In his opinion, the critical exposure period was from November 2, 1986 to October 13, 1987. During this period he received two types of factor concentrates, Cutter Factor IX and Armour concentrates from a paid donor. Dr. Remis was of the opinion that most likely explanation for his seroconversion was the product B71508 that he was infused with on January 30 and January 31, 1987. During his visit to the Armour plant in Kankakee on December 2, 1987, he learned that B71308, B71408 and B71508 were all made from the same pool. Since it appeared that 71308 and 71408 were contaminated, and given that they all came from the same pool, then B71508 was also likely contaminated.

[208] "CL" is named in count 2 of the indictment. He was 15 years old when he seroconverted, having tested positive for the first time on September 22, 1987. He was not sexually active and not an intravenous drug user.

[209] His sister and his father provided heart-wrenching testimony about the early stages of his life, his hemophilia, the development of AIDS and the resulting loss of his dreams.

[210] CL was part of Dr. Tsoukas study. His medical records reveal that the exposure period for him was between December 9, 1986 and September 8, 1987. During this period he underwent a programme of immune tolerance induction which required large doses of factor VIII concentrates including 191 vials of Armour HT Factorate lot B71408. Based on his medical records, he likely became infected with HIV between December 9, 1986 and September 8, 1987. Within two weeks of the first dose of this lot he developed fever, a rash, fatigue and febrile illness. Dr. Remis testified that he was very certain that he was infected by the Armour lot. CL died in October 1995 at the age of 23.

[211] "DH" is named in count 3 of the indictment. He was born in 1943. He tested positive for HIV in May 1983 but remained asymptomatic until 1987 when he became ill with a high

fever and flu-like symptoms. He was hospitalized in September 1994 and steadily declined in health until his death in February 1996 at the age of 43.

[212] DH was part of Dr. Tsoukas' study. Unlike the other patients in British Columbia who seroconverted, he was an adult. He was married, denied any high-risk activity and did not use intravenous drugs. He received treatment for his haemophilia as an outpatient in the emergency room at Vancouver General Hospital. His first positive test was May 25, 1987, although it was thought that this was a mistake caused by a mix up of the samples. He developed an acute seroconversion illness on July 10, 1987 and it is argued that this is consistent with having seroconverted in June after the infusion of Armour lot B71408. Dr. Remis testified that he was very certain that DH was infected by Armour B71408 which he received in June 1987.

[213] "JA" is named in count 4 of the indictment. He was born in 1974. He was 13 years old when he was infused with Armour product. He had no risk factors and had never received non-heat treated concentrates. He tested positive for the first time on July 21, 1987 at the age of 13. He received a diagnosis of HIV positive after using factor VIII products. Based on his medical charts, it appears he was infected between June 16, 1986 and July 7, 1987. During this period he received Cutter and Armour heat-treated concentrate. Within the Armour product he received lots B71308 and B71408. Dr. Remis testified that he was infected by one of the two Armour lots. He is the only named victim in the indictment who has not died.

[214] JA testified by video link from British Columbia where he lives with his mother. He learned when he was a small child that he suffered from haemophilia. He initially had to go to the hospital to receive treatment with cryoprecipitate. Later, he was taught by Lois Lidner, the nurse at the haemophilia clinic in Vancouver, how to infuse concentrates at home. Currently he is at stage two of the AIDS progression and feels his health is pretty good.

The common nuisance victims

[215] The Crown alleges that there were victims of the common nuisance in Ontario, British Columbia, Manitoba and Alberta. They were individuals who, in various ways were put at risk by the Armour product. With respect to the Ontario patients it is alleged that Armour distributed the unscreened product for six months after the decision to replace it. As such, the public was put at risk by Armour and Dr. Rodell. With respect to the B.C., Manitoba and Alberta patients, all parties agree that a long list of persons received Armour HT Factorate lot B71308, B71408 or B71508.

Causation

[216] The Crown alleges that lots B71308, B71408 and B71508 were contaminated and that product from these lots caused the seroconversions of MM, CL, DH and JA.

[217] Dr. Remis testified that his investigations in Kankakee and in Canada led him to this conclusion. In his analysis of the seroconversions in Canada, Dr. Remis created a "critical period of exposure" for each patient analyzed. That period was from three months before the last negative HIV test to two weeks before the first positive test. Dr. Milton Mozen gave expert

testimony that the latency period of the virus can be up to 27 months. If this is the case, then the infection period would date back to the non-heated era, prior to July 1, 1985. In addition, Dr. Remis acknowledged his previous statements that other drug manufacturers could be implicated in the seroconversions.

[218] The Crown also relies on the evidence of Richard Pilon. After a long and scientifically complex *voir dire,* the results of the so-called "RNA" and phylogenetic testing were admitted into evidence. Mr. Pilon, under the direction of Dr. Sharon Cassol and at her lab conducted sequencing. Dr. Cassol designed the test but then relocated to South Africa, so did not actually take part in the hands on work.

[219] The tests compared samples of the serum from Dr. Tsoukas' lab relating to patients who had seroconverted with vials of the implicated factor VIII lots. Both the serum and the vials were seized by the RCMP in 1999. The virus from these lots was sequenced and compared to the positive serum samples. Two samples from CL were sequenced. Mr. Pilon found that all of the serum samples were more closely related to each other than to any other HIV specimens and were likely derived from the same source virus. It is argued that this demonstrated that the HIV found in the Armour lots received by CL was in fact the HIV that infected him.

[220] Additional testing performed by Mr. Pilon in 2004 in relation to another section of the HIV genome has confirmed these results. The samples (from CL and Armour) showed closely related sequences suggesting again that they originated from a common source.

[221] The Crown argues that Mr. Pilon's evidence supports the study done by Dr. Remis and his conclusion that the infusions of lots B71308 and B71508 were responsible for the seroconversions of the patients. It provides direct evidence with respect to CL and circumstantial evidence with respect to the others.

[222] The Crown submits that there is overwhelming evidence of causation based on the following:

- Before receiving Armour HT Factorate, lots B71308, B71408 and/or B71508, each of the patients tested HIV negative;
- After using the implicated Armour lots, the patients tested HIV positive;
- Other than the use of blood products, the victims had no risk factors. Most were young and sexually inactive and there is no evidence of IV drug use;
- Lot B71308, B71408 and B71508 were made from the same plasma pool;
- Eleven donations entered Armour's plasma pool 713 during the six-month period before the donors who gave them began to test antibody-positive;

- There is a "window period" for HIV which precedes the emergence of detectable levels of antibodies. At this stage, the donor is highly viremic, but continues to test negative;
- Armour used the least rigorous heat-inactivation method;
- Lot B71308, B71408 and B71508 contained HIV;
- None of the tested products produced by Armour's competitors contained HIV;
- CL and DH experienced febrile illness consistent with acute seroconversion within two weeks of using the implicated lots; and
- The HIV from CL's serum is closely related to the HIV found in Armour's product.

[223] The Crown alleges that Armour HT Factorate caused the seroconversions which caused the bodily harm in the criminal negligence counts and put the public at risk in the nuisance count. I have a doubt about that assertion for the implicated lots were distributed elsewhere apparently without incident. I also have doubts about the efficacy of the phylogenetic testing. The samples were highly degraded. There were flaws in the study which rendered it inappropriate for forensic purposes.

[224] The issue is, however, academic. The law requires that the bodily harm or risk to the public be caused by the actions or inactions of the accused. There were no actions or inactions by the accused which showed wanton or reckless disregard for the lives and safety of others that in turn in caused the seroconversions. Likewise, there were no unlawful acts or failure to discharge legal duties which endangered the public. I have found that the conduct of the accused was reasonable throughout.

[225] If the imputed lots did cause the seroconversions (which I do not find as fact) then nothing that the accused did or did not do (within the meaning of the criminal negligence and common nuisance sections of the *Criminal Code*) caused those lots to be infected, licensed or distributed.

The Accused

Dr. Roger Perrault

[226] Dr. Perrault was the National Director of the Blood Transfusion Service of the Canadian Red Cross. The particulars alleged against Dr. Perrault with respect to counts 1-4 (negligence) are that he:

- Between November 21, 1986 and December 1, 1987 participated in the distribution of HT Factorate despite unfavourable laboratory results;

- Between November 21, 1986 and December 1, 1987 participated in the distribution of an inaccurate product insert;
- Between November 27, 1985 and December 1, 1987 failed to obtain information from Armour and from the BoB about Armour's processes; and
- Failed to inform others and failed to inquire into the safety of blood products being distributed.

[227] The Crown relied on his job description to establish a duty to the public, a duty he allegedly breached. The job description includes:

- To ensure the highest possible medical and managerial standards are maintained in the operation of the BTS centres;
- To secure all accessible information to contribute standards, policies and long range plans; and
- To ensure that contracts with major suppliers meet quality and technical delivery requirements.

[228] With respect to count 5 (nuisance), it is alleged that, between April 12, 1985 to December 17, 1987, he placed the public at risk of HIV infection by:

- Participating in the distribution of HT Factorate that potentially contained HIV;
- Failing to remedy the inaccurate label;
- Failing to obtain relevant information from Armour and the BoB; and
- Distributing unsafe blood products and failing to inform medical personnel and consumers about the safety of blood products.

[229] The Crown alleges that Dr. Perrault's conduct showed a marked departure from the standard of care of the reasonable person and thus contributed to bodily harm and put the public at risk. The Crown alleges that Dr. Perrault was under a duty not to distribute unsafe blood products, to inform medical personnel and consumers of blood products about their safety and to inquire into the safety of blood products.

[230] I reject the Crown's interpretation of the evidence and find, on the contrary, that the evidence taken as a whole establishes a thoughtful, careful and considered course of conduct by Dr. Perrault that has no element of blameworthiness.

[231] Dr. Perault was considered a workaholic. His dedication to his work was often at the expense of his family and even his own health. He is an internationally respected scientist and an expert in transfusion medicine and science. He made decisions only after consultation with his

experienced top staff, in the context of a thorough analysis of the available information and only after careful deliberation. The medical information available at the time confirmed that screening plasma for HIV was an additional level of security. Dr. Davey was of the view that the Chapel Hill and Dutch seroconversions showed only a tenuous link to Armour and a withdrawal was unnecessary.

[232] The Crown alleges that Dr. Perrault himself had doubts about screening, relying on statements he made that there were frailties in the screening tests. These comments on their own are equally consistent with a level of detailed analysis which questioned all the commonly held views. The evidence disclosed that screening issues were thoroughly studied by Dr. Perrault and the CRC and then implemented nation wide in September 1985. He would not have done this if he thought it was not to further enhance safety. This is an opinion that was widely held by the many experts who testified, including Drs. Tsoukas, Evatt, Jones and Breederveld. There is also evidence that the FDA held this view. As late as March 1987, it was reported in the MMWR that there were no reported factor concentrate-related seroconversions from donor screened plasma.

[233] The Crown called no expert evidence on the standard of care. The Court is asked to infer that Canada should have followed the UK lead. However, Armour's screened Factorate continued to be distributed throughout the world. Moreover, the conduct of Dr. Perrault was careful and cautious throughout.

[234] Intense consultation, careful consideration and a weighing of various factors related to public health marked the two-week period in October 1986 following the UK withdrawal. While Dr. Perrault was of the opinion that a withdrawal was necessary, he acted in consultation with the BoB whose scientists and administrators were considering the view of the FDA, the CDC and others on a worldwide basis. Dr. Perrault took the precautionary step of arranging for a contingency plan if a withdrawal or recall was ordered. Dr. Perrault instructed his staff to find alternative supplies in case of withdrawal. Only after the information from the FDA that the product was safe did he arrange to continue to distribute it.

[235] There is no evidence that Dr. Perrault was under any duty to review labels, product inserts or monographs. This was the sole authority of the BoB. Even if he had been, my decision with respect to Dr. Furesz and Boucher below would apply to Dr. Perrault.

[236] Dr. Perrault, through Dr. Davey, kept the hemophiliac community informed with respect to the relative risks of contracting HIV from HT Factorate. Dr. Davey followed the literature and kept the community advised of the events in 1986.

[237] Far from establishing the requirements of either negligence or nuisance, the Crown has persuaded me that Dr. Perrault acted carefully and reasonably in regard to the health and safety of the hemophiliacs in Canada. He worked diligently in the interests of the hemophiliac community. He hired leading experts to work with him at the National Office and in the regional centres. He relied on the regulatory authorities and was in consultation with them on all the important decisions. They were forced to choose between distributing a product that was not risk free and leaving hemophiliacs without a life-saving treatment. Dr. Walker discussed the

balancing between risks and "non-availability of the product, factor VIII in particular is itself a safety hazard."[65] Although product had been obtained to replace Armour in the short term, it would have been irresponsible to de-stabilize the world market. A worldwide shortage would have been a potentially greater risk to Canada. Dr. Perrault analyzed, in painstaking detail, the various options, balanced the pros and cons and made a decision in conjunction with the regulators. He was put in a position of immense public trust. In that capacity he was thrust into a series of difficult events to which he responded with care, thoughtfulness and utmost professionalism.

[238] The scientists at the CRC were confronted with a devastating disease which threatened to ravage the blood supply worldwide. It was a time of uncertainty with the medical and scientific knowledge constantly evolving. The causative agent of AIDS was discovered only a few years before many of the decisions herein were taken. By the time of the discovery, many hemophiliacs had already been infected.

[239] Dr. Perrault's conduct has none of the elements that would lead to a finding of negligence or nuisance. Dr. Perrault acted properly and professionally throughout. The Crown has argued, somewhat ironically, that there was a foreseeable risk of harm. Of course there was. That is why Dr. Perrault took such care.

[240] The Crown urges a cumulative look at the conduct of Dr. Perrault to establish a "continuum of liability." I have done so despite the defence submission that this is an inappropriate attempt to alter the standard of objective criminal liability. Having done so, I remain convinced that Dr. Perrault exercised care and diligence throughout such that would be expected from a person in a position of public trust.

[241] Throughout the Crown's submissions, are lists of "meaningful inquiries" that Dr. Perrault failed to make. Had they been made, the Crown implies that the decisions made might have been different. While omissions can be the foundation for reckless conduct, it is unreasonable to suggest that Dr. Perrault and his staff had a duty to contact every single person who may have had information about the seroconversions. The scientists at the CRC were making inquiries on an ongoing basis throughout the time period in question. The hemophiliac community was represented by Dr. Card. Dr. Furesz consulted with his counterpart in the UK. Viewed in the context of what was and what was not done, Dr. Perrault's conduct was reasonable.

[242] The Crown made improper references to the Krever Inquiry during submissions. Even if I took them into account, my decision would not be different.

[243] Dr. Perrault is acquitted of all the charges against him.

---

[65] Dr. Walker: May 22, 1986 at 17892

Dr. John Furesz

[244] Dr. Furesz was the Director of the Bureau of Biologics of the Department of Health of the Government of Canada.

[245] The allegations against him, as particularized are as follows.

> Counts 1-4 (criminal negligence):
>
> (a) On or about October 30, 1984 to April 12, 1985, John Furesz and Wark Boucher, in Ottawa, Ontario, approved of the licensing of HT Factorate on the basis of inadequate documentation concerning the inactivation of HIV and the safety of Armour Pharmaceutical Company's manufacturing processes;
>
> (b) On or about April 12, 1985 to December 1, 1987, John Furesz and Wark Boucher in Ottawa, Ontario, participated in the failure to withdraw HT Factorate's licensing in light of unfavourable laboratory results relating to HIV, HIV seroconversions associated with HT Factorate and the availability of alternative products, thereby allowing HT Factorate to be distributed in Alberta and British Columbia;
>
> (c) On or about April 12, 1985 to December 1, 1987, John Furesz and Wark Boucher in Ottawa, Ontario, approved of the continued use of an inaccurate product insert/monograph respecting the safety of HT Factorate in relation to the risks posed by HIV and failed to remedy this with accurate information in a revised insert/monograph or other means of communication such as a label, communiqué, or press release;
>
> (d) On or about April 12, 1985 to December 1, 1987, John Furesz and Wark Boucher in Ottawa, Ontario, failed to inspect Armour's manufacturing plant and to request of Armour and foreign regulatory agencies information concerning the inactivation of HIV and the safety of Armour Pharmaceutical Company's manufacturing process relevant to the withdrawal of HT Factorate and which could have been shared with medical personnel, haemophiliacs and their families in Alberta and British Columbia;
>
> Duty for Omissions
>
> (f) John Furesz and Wark Boucher had a duty to withhold or cancel licenses for unsafe blood products; to conduct adequate inquiries into the safety of blood products; impose conditions on

licenses to ensure safe blood products; and to enforce the regulatory scheme applicable to blood products.

Count 5 (nuisance):

(g) On or about April 12, 1985 to December 1, 1987, John Furesz and Wark Boucher put the public at risk of HIV infection by approving the licensing of HT Factorate on the basis of inadequate documentation concerning the inactivation of HIV and the safety of Armour Pharmaceutical Company's manufacturing process;

and by participating in the failure to withdraw HT Factorate's licensing in light of unfavourable laboratory results relating to HIV, HIV seroconversions associated with HT Factorate and the availability of alternative product allowing HT Factorate to be distributed in Ontario, Manitoba, Alberta and British Columbia;

and by approving the use the an inaccurate product insert/monograph respecting the safety of HT Factorate in relation to the risk posed by HIV and failing to remedy this with accurate information in a revised insert/monograph or other means of communication such as a label, communiqué, or press release;

and by failing to inspect Armour's manufacturing plant and to request of Armour and foreign regulatory agencies information concerning the inactivation of HIV and the safety of Armour Pharmaceutical Company's manufacturing process relevant to the withdrawal of HT Factorate or which could have been shared with medical personnel, haemophiliacs and their families in Ontario, Manitoba, Alberta and British Columbia;

Duty for Omissions

(h) John Furesz and Wark Boucher had a duty to withhold or cancel licenses for unsafe blood products; to conduct adequate inquiries into the safety of blood products; impose conditions on licenses to ensure safe blood products; and to enforce the regulatory scheme applicable to blood products pursuant to food and drug regulations, Part C, section 216, section 217 of the *Criminal Code*, *Public Service Employment Act*, section 23, Schedule III and the common law.

Licensing

[246] On March 26, 1985 Dr. Boucher wrote to Dr. Furesz:

> The heat treatment procedure employed by Armour (60°C for 30 hours) differs from that of Hyland (60°C for 72 hours) and Cutter (68°C for 72 hours). The Armour heat treatment procedure has been shown to inactivate at least 6.0 logs of the human retrovirus, LAV. The procedure therefore meets the requirements for heat inactivation.
>
> ...
>
> I see no objection to the issuance of a notice of compliance for this drug.[66]

[247] This was a reasonable conclusion for Dr. Boucher, since it was based on the study done by the Centres for Disease Control. The state of the art of scientific opinion at the time was that the Armour heat-treating process was effective to kill the maximum amount of virus which was expected to be present in any plasma pool.

[248] This represented the state of knowledge in the medical and scientific community at the time. Dr. Evatt testified that:

a) His letter of November 29, 1984 to Dr. Feldman was widely disseminated because the CDC felt an obligation to get the information out as fast as possible because they wanted people to switch to heat treatment;

b) The paragraph that included the words: "procedures presently used by manufacturers for heat treatment of hepatitis virus would adequately inactivate LAV virus" was put in the letter because the CDC believed it at the time;

c) The results set out in the letter were the best available results at the time;

d) The letter was the basis for the article in the *Journal of Clinical Investigation* in August 1985. That article included the following:

> Certainly, a procedure that reduces titre only 1 to 2 logs is insufficient to decontaminate Antihemophilic Factor because this reduction is obtained with lyophilization alone and lyophilized products transmit AIDS. However, the first-order kinetics of thermal decay and the long heating times, which are based on considerations for hepatitis virus inactivation (7) indicate an expected reduction of 37 logs at 60°C in 20 h (and even greater for higher temperatures and times). <u>This should provide a large, if not absolute, margin of safety.</u> [emphasis added]

[66] Exhibit 180

e) in his article in *The Lancet*, of October 1985 it was confirmed that there was currently enough of a safety factor afforded by heat treatment in the currently licensed heat-treated AHF.

[249] Dr. Tsoukas testified that he shared this opinion at the time. He also testified that it was generally understood that the FDA which licensed HT Factorate in the US on the basis of the CDC studies of Dr. Evatt and Dr. McDougal had high requirements and if they were met, it was an acknowledgment of achievement in terms of a product. The CDC was relied upon by agencies throughout the world. Dr. Levy's letter in *The Lancet* did not establish the state of scientific knowledge. In fact, it was largely ignored.

[250] Dr. Furesz was perfectly justified in relying on the CDC information to license the drug.

Failure to Withdraw

[251] The Crown alleges that HT Factorate should have been withdrawn from the Canadian market in 1986. The decision not to withdraw was taken after consultation with other regulators, with the CRC and its medical and scientific advisors, the FDA, and the haemophiliac community and its medical advisors both in Canada and elsewhere. His decision not to withdraw was one which was made by regulators around the world, except in the UK. He acted responsibly and reasonably throughout and there is no evidence of wanton or reckless conduct. While subsequent events may have shown that the decision could have been different, at the time, it was entirely reasonable.

[252] In particular, Dr. Furesz had the following information:

- The patient in Chapel Hill had a history of previous drug abuse and had been treated with various non heat treated product;
- All three of the patients who seroconverted had been treated with unscreened product;
- Even Dr. Prince's letter to *The Lancet* stated that his finding does not mean that dry heat treated products are unsafe with respect to AIDS transmission; and
- The haemophilia community's advisors believed that screening was safer and provided an added level of security. This was supported by the clinical evidence at the time.

[253] Dr. Furesz conduct in October 1986 after receiving the press release about the UK withdrawal was described in detail by Dr. Walker and Mr. Vick. That evidence discloses a careful, considered approach to a very difficult problem. Dr. Furesz was clearly balancing the potential risks of the product with the greater risks of a worldwide shortage. Dr. Walker best

described this analysis when he said that, although the position of the BoB was scientifically sound, some at the CRC had a "sixth sense" that it was the wrong decision. Eventually, however, the CRC came to the point of agreeing with the BoB. Dr. Walker said:

> The manufacturer said a recall is not necessary. The BoB said a recall is not necessary. We heard the FDA was not intending to do a withdrawal. We still felt there was a risk, but it would leave us in a position where we would have to replace the withdrawn product, and the purchase has a price. We would be spending Canadian health care dollars to address a feeling in the pits of our stomach.[67]

[254] The Crown alleges that Dr. Furesz' concern about a worldwide shortage put the interests of US haemophiliacs before those in Canada, because at the time the replacement product obtained by the CRC was "safe and sound" in Canada. No expert evidence was lead with respect to regulation of drugs, yet the evidence discloses that the replacement product was for an interim period only Dr. Furesz was reasonably considering the long term affects of his decision. I infer that a worldwide shortage would ultimately impact Canada. This factor, however, was only one of many being considered by Dr. Furesz. He believed the product was safe. His belief was reasonable and shared by others.

[255] Dr. Furesz had a difficult job to do, one that no one would have envied at the time. Whether he was right or wrong is not the point. The point is that he made a careful, reasoned analysis of the information available and did what his job required him to do: make a decision. That decision made on the basis of the facts before him was entirely reasonable.

Product Labelling

[256] Dr. Furesz was advised by Dr. Boucher that the labels and product monograph for HT Factorate were satisfactory. They had FDA approval. They warned that patients might contract AIDS. They made no claim that the 60/30 method of heat-treating could totally eliminate the virus.

[257] The labels accurately describe the significant risk of exposure to AIDS by using the product. There was no evidence that the label caused any patient to use the product who would not otherwise have done so.

Inspections

[258] The Crown alleges that it was unreasonable for Dr. Furesz not to order inspections of the Armour manufacturing plant between April 12, 1985 and December 1 1987. There is no evidence to support this allegation. The inspections were not mandatory. Many inspections were not done due to cutbacks on funds and shortages of staff and a hiring freeze. Dr. Furesz could not hire his own staff or spend money or conduct inspections without authorization.

---

[67] Dr. Walker: May 24, 2007 at 18176

[259] There was no evidence that any information uncovered during a routine inspection would have led to a different result. The visit to the Amour plant in December 1987 was an investigation specific to the seroconversions. It was not routine and did not mirror what would have occurred in a routine inspection.

Failure to Request Information

[260] Dr. Furesz made extensive inquiries of Armour, the UK authorities, the FDA and medical and scientific advisors to the CRC and the haemophiliac community. There is no evidence that, had Dr. Furesz made more extensive inquiries, he would have obtained any more information that would have affected his decision.

[261] Dr. Furesz is an internationally recognized scientist. He is a leading expert in fractionation. He is respected and has an excellent reputation for dedication to science and commitment to public health. He is held in high regard both personally and professionally. He called on all of those qualities during the difficult times surrounding these events. His conduct was thoughtful, careful and considered throughout. As such, his conduct did not fall within the meaning either charge of negligence or nuisance.

[262] Dr. Furesz' counsel submitted that a criminal trial is an inappropriate forum to review the decisions of a public health regulator. Since I have found Dr. Furesz' conduct beyond reproach, I do not need to address this.

[263] Dr. Furesz is acquitted of all the charges against him.

Dr. Donald Wark Boucher

[264] The particulars set out above with respect to Dr. Furesz apply to Dr. Boucher. He was the Chief of the Blood Product Division of the Bureau of Biologics. He reported to Dr. Furesz.

Approval of HT Factorate

[265] For the reasons set out above, with respect to Dr. Furesz, I conclude that Dr. Boucher's conduct in recommending the approval of HT Factorate was reasonable at the time. The Armour product was licensed around the world. There is no evidence to suggest that Dr. Boucher behaved differently from any other regulator in the world. There was thus no departure (marked or substantial) from the applicable standard of care. It is indeed ironic, as counsel point out, that the UK regulators, used by the Crown as a standard for the events of October 1986 licensed Armour's HT Factorate on the basis of the same studies and documents. Those studies and documents which I have extensively referred to represented the state of the scientific and medical knowledge at the time.

[266] It was Dr. Boucher who requested that Armour's Canadian representative provide data from the studies. Olga Yacoub, who worked for Armour's Canadian representative, wrote to Dr.

Boucher. Her letter[68] both attaches Dr. Evatt's memorandum and copies his words exactly stating:

> Based on these findings it appears the LAV is extremely heat labile; therefore our treating cycle of 60 degrees C for 30 hours developed initially against the hepatitis virus would adequately inactivate the LAV.

[267] Although this data was said to be preliminary at the time of the correspondence, it was published very shortly thereafter in the prestigious *Journal of Clinical Investigation*. Dr. Boucher's personal stamp and initial appear on this document.

[268] There is no basis to find that the conduct of Dr. Boucher in recommending a license for HT Factorate was a marked or substantial departure from that of a reasonable person in the same circumstances.

Failing to Withdraw

[269] The information available to Dr. Furesz was also available to Dr. Boucher. For the same reasons I find his conduct reasonable.

Labelling

[270] For the reasons set out with respect to Dr. Furesz, I reject the Crown's position.

Failure to Inspect

[271] For the reasons set out with respect to Dr. Furesz, I reject the Crown's position.

Failure to obtain Information

[272] The Crown has not satisfied me that Dr. Boucher failed to obtain any information that could be causally connected to the allegations in counts 1-5.

[273] The Crown asserts that Dr. Boucher had a legal duty in relation to the safety of blood products. In the opening statement, it was asserted that "he was to ensure the protection of the Canadian public from health hazards arising form the use of these types of drugs."[69] This was apparently a paraphrase of an unsigned job description for "Chief, Blood Products Division." The Crown's position would require a public servant to virtually guarantee the safety of blood products. This defies the evidence, which established that no biological drug can ever be perfectly safe.

[274] Dr. Boucher is acquitted of all the charges against him.

---

[68] Exhibit 442
[69] February 21, 2006 at 36

Armour Pharmaceutical Company and Dr. Michael Rodell

[275] Armour and Dr. Rodell are also charged in counts 1-4 with criminal negligence for permitting or causing Armour HT Factorate infected with HIV and that was infused into four identified individuals causing each bodily harm.

[276] Throughout the narrative of events numerous findings have been made with respect to Armour and Dr. Rodell directly in reference to the allegations against them. In each case, the allegations were rejected and there is a finding that they acted responsibly and reasonably.

[277] The circumstances in the medical and scientific communities in the early 1980's were such that the conduct of Armour and Dr. Rodell was reasonable throughout. During the entire period of the particularized indictment, the following circumstances describe the context of Armour's manufacture and distribution of its 60/30 product:

- The medical and scientific literature supported the efficacy of viral inactivation through lyophilization and heat treatment utilized by all licensed manufacturers;
- The FDA, the primary regulator under whose scrutiny Armour's manufacturing facility and process was licensed, supported Armour's process and its responses to any concern raised;
- The accepted literature which affirmed that viral loads would not exceed five logs remained the standard against which the effectiveness of viral inactivation was measured;
- The dialogue between the haemophiliac community and Armour, particularly as represented by MASAC, evidenced the responsiveness of Armour and its complete compliance with all regulatory efforts;
- The disparate seroconversions associated with Armour were comprehensively investigated and reported to the appropriate regulatory agencies and led to action plans fully accepted and adopted by Armour;
- Plasma Alliance had been at the forefront of HIV testing so as to reduce even the theoretical possibility of significant viral loads;
- Action plans developed by regulatory agencies were fully accepted and adopted by Armour;
- Armour had initiated an exchange of all unscreened product for screened by the end of June 1986; and

- Counts 1 to 4 of the particularized indictment relate exclusively to fully screened product in relation to the three lots derived from a single pool of plasma.

[278] The particulars in relation to Armour and Dr. Rodell alleges as follows (emphasis added, in order to relate to the headings below):

1. That from July 16, 1986 to December 19, 1986 Armour, under the sole authority of Dr. Rodell, **used HIV infected plasma** received from Plasma Alliance in the manufacture of HT Factorate and failed to address the use of HIV infected plasma through particularized measures.

The significance of July 16, 1986 is that it marked the commencement of the collection of the blood donations by Plasma Alliance implicated in the Canadian seroconversions. The draw dates recorded on the laboratory reports indicate that these donations were received between July 16 and July 29, 1986. The significance of December 19, 1986 was that it was the date upon which the Canadian Red Cross received the third and final lot implicated in the Canadian seroconversions.

2. That from August 8, 1986 to September 3, 1986 Armour, again under the sole direction of Dr. Rodell, used **heat treatment** in the manufacturing of HT Factorate that was **of insufficient duration and temperature** to prevent HIV infection.

The commencement date of this particular, August 8, 1986, represents the date on which the plasma previously particularized was pooled at the Kankakee facility and received the designation Pool #713. September 3, 1986 represents the date that the manufacturing process for lots B71308, B71408 and B71508 derived from Pool #713 was completed.

3. That between September 3, 1986, (the date on which the manufacturing process for the three implicated lots was completed) and December 1, 1987, (the date on which Armour commenced the recall of all AHF treated by the 60/30 protocol) Armour, under the sole direction of Dr. Rodell, **distributed HIV** infected HT Factorate to its Canadian affiliates and to the Canadian Red Cross for distribution in Alberta and British Columbia.

4. That between the same dates, September 3, 1986 to December 1, 1987 Armour, under the sole direction of Dr. Rodell, **failed to withdraw** or recall its product in light of unfavourable inactivation studies and seroconversions associated with its product.

5. That between the completion of the manufacturing process on September 3, 1986 of the three implicated lots and the recall of 60/30 which commenced on December 1, 1987, Armour, under the sole authority of Dr. Rodell, used an

inaccurate product **insert/monograph** respecting the risk posed by HIV and failed to provide accurate information.

6. That between the date of the manufacture of the three implicated lots and the withdrawal of 60/30 Armour, under the sole direction of Dr. Rodell, **failed to notify** the Bureau of Biologics, the Canadian Red Cross, medical personnel, haemophiliacs and their families in Alberta and British Columbia of the risk of HIV infection posed by HT Factorate.The Crown further particularized that this alleged misconduct occurred while Armour and Dr. Rodell were under a duty not to distribute unsafe blood products and a duty to inform the various stakeholders with respect to the safety of HT Factorate.

Used HIV infected plasma

[279] The plasma received from Plasma Alliance on July 16, 1986 and thereafter had been fully screened and tested in accordance with the highest standards and advanced technology available and employed at that time. Armour had addressed the risk of HIV in all aspects of its process. In particular, Plasma Alliance collected plasma in low-risk centres and was at the forefront of advances in testing procedures. There is no evidence of any conduct on the part of either Dr. Rodell or Armour that would constitute wanton or reckless behaviour or a marked or substantial departure from that which is reasonable.

Heat treatment of insufficient duration and temperature

[280] It was almost universally accepted that HIV was extremely heat labile and that heat treatments of substantially shorter duration than 30 hours at 60°C would effectively inactivate any anticipated viral load. As set out above, in August and September 1986 the state of knowledge with respect to heat treatment had been established by Drs Evatt, McDougal and Petricciani. The UK withdrawal had not taken place. The exchange of screened for unscreened had taken place. Armour and Dr. Rodell were acting reasonably.

Distribution of HIV

[281] The distribution of Armour 60/30 HT Factorate continued unabated in all marketplaces globally with the exception of the United Kingdom after October 6, 1986. The designation of lots B71308, B71408 and B71508 derived from Pool #713 for Canadian export was based solely on the fact that samples of the specific lots to be exported to Canada were required to be submitted and approved by the BoB prior to its release for Canadian distribution. Lots of precisely the same product, manufactured from plasma from the same source and in accordance with precisely the same screening, look back, pooling and heat inactivation processes, were distributed throughout the world. Substantial quantities were distributed to the New York Blood Center, the largest distributor of blood products in the United States of America and the centre which employed Dr. Alfred Prince as its Head of Virology. There is no evidence of wanton or reckless conduct or of a marked or substantial departure from reasonable conduct in connection with the distribution of these lots.

Failed to withdraw

[282] Every seroconversion alleged to have been associated with Armour and all meaningful inactivation studies were matters of public record. No other regulatory agency other than the DHSS recommended the withdrawal of Armour's 60/30 product. Armour was not unreasonable in failing to withdraw it.

Labelling

[283] My finding with respect to Dr. Furesz applies here.

Failure to Notify

[284] The continuing dialogue with worldwide regulators, the responsible investigations related to alleged seroconversion and the responsive attitude of Armour and its legion of highly qualified healthcare professionals led Armour to the rational conclusion that it was in full compliance with any required notifications relating to its product. The findings with respect to Dr. Prince apply here.

[285] The conduct of Armour and Dr. Rodell was responsible, responsive and professional at all times. There is no element of blameworthiness that would tend to establish requisite element of wanton or reckless disregard for the lives and safety of others. It was alleged that Dr. Rodell was the directing mind of Armour. I do not make that finding for it was very clear from the evidence that decisions were made on the basis of a consensus. Interestingly, I found the conduct of all of the employees of Armour impressive. To a person, they demonstrated knowledge of the issues and care and concern for the public. I am convinced that they took the matter of public health seriously, acted responsibly and professionally. This speaks well of Armour as a corporation.

Count 5 – Common Nuisance

[286] Armour and Dr. Rodell, are charged with the commission of a common nuisance by the distribution or failure to prevent the distribution or infusion of Armour HT Factorate thereby placing the public at risk of HIV infection.

[287] The timeframe of the common nuisance as particularized is between April 12, 1985, the date on which Armour HT Factorate was licensed in Canada by the BoB and December 17, 1986 (it would appear that the date should read December 19, 1986, the date on which the Canadian Red Cross received the third and final lot implicated in the Canadian seroconversions). The particulars alleged mirror precisely the same allegations contained in the particulars set out in relation to counts 1 to 4 relating to the use of infected plasma, inadequate screening, look back, pooling and heat inactivation policies, the provision of an inaccurate product insert, the deficiencies in recall or withdrawal procedures and the failure to notify regulators and the public of the risk posed by HT Factorate.

[288] Armour and Dr. Rodell's conduct was professional, thoughtful and responsible throughout. There is no evidence of a marked departure from that which would be reasonable in the circumstances.

[289] The conduct of Armour and Dr. Rodell did not represent even a modest departure from conduct which was reasonable, and indeed responsible, in the circumstances. The protocol adopted by Armour in its exchange program of screened for unscreened product was endorsed by the FDA and was widely commended by the haemophiliac community.

Count 6

[290] Armour alone is charged with failing to immediately notify the Minister of a deficiency or an alleged deficiency in its viral inactivation process as described in the studies of Dr. Alfred Prince concerning the safety of Armour HT Factorate.

[291] The Prince experiments were so fraught with difficulties that they could not reasonably be construed to allege deficiencies in the viral inactivation process. Dr. Prince did not communicate deficiencies to Armour. As outlined above his studies produced no meaningful results. Dr. Prince did nothing to ensure that New York Blood Centre stopped distributing the HT Factorate. Neither Dr. Prince nor his studies communicated to Armour an "alleged deficiency".

[292] Armour and Dr. Rodell are acquitted of all the charges against them.

Dr. Michael Rodell

[293] It was alleged by the Crown that Dr. Rodell was the operating mind of Armour. He was also charged personally. Although he and Armour have been acquitted of all charges against them, a separate comment about Dr. Rodell is necessary.

[294] As with the other defendants, Dr. Rodell has had his integrity and professionalism called into question and repeatedly attacked. I have found absolutely no conduct on his part that would warrant those attacks. The evidence established, and I believe, that Dr. Rodell has a well-deserved and eminent reputation in the medical and scientific community for his knowledge, honesty, integrity and professionalism. His colleagues admired him and to a person described him in glowing terms. The evidence confirms those assessments.

Conclusion

[295] The evidence was detailed and extensive. It included the search for the causative agent of AIDS, the development of scientific knowledge about the virus and how to inactivate it, the treatment of haemophilia, the manufacture, licensing and distribution of blood products and the series of events up to and beyond the seroconversions in haemophiliacs. Many experts were called including highly respected scientists and physicians. People in levels of authority from administrative to high-level decision-making gave evidence.

[296] Usually the passage of time is an impediment to the search for the truth. However, what was remarkable here was not what was forgotten, but what was remembered. It starts with the pain of the victims. The haemophiliacs, their families and the close-knit haemophiliac community were devastated by their losses.

[297] The world-renowned expert on AIDS, Dr. Julio Montaner described the progression of the disease before 1996. That is when the dramatic change occurred for those infected and antiretroviral therapy became available. Before then, only the symptoms could be treated. They could be traumatic and included disfiguring lesions, warts, and oral thrush. As the opportunistic infections recurred on already damaged organs, it would lead to wasting and ultimately death. The hemophiliacs who contracted AIDS were victims. They were victims of a terrible confluence of events that they had no part in creating.

[298] Also remembered with clarity was the struggle of the scientific and medical world, and the concern on the part of those who had to make decisions.

[299] A conviction for criminal negligence requires conduct on the part of the accused that demonstrates wanton and reckless disregard for the lives or safety of others. A conviction for common nuisance requires conduct that represents a marked departure from that of a reasonable person in the circumstances. The circumstances at the time were established in order to judge the conduct of the accused. Their actions and their omissions were considered.

[300] Dr. Perrault, responsible for the distribution of blood products in Canada is an expert in transfusion medicine. His conduct was cautious and careful. He consulted extensively with his highly qualified staff. During extremely difficult times, it is clear that he agonized over decisions that had to be made. Those decisions were well thought out, well supported and reasonable. Dr. Perrault was acquitted of all charges.

[301] Dr. Furesz, responsible for the regulation of blood products in Canada is an expert in fractionation. He is highly respected both personally and professionally. In pressured situations, he made careful, reasoned and informed analysis and then did what his job required him to do: make a decision. Dr. Furesz was acquitted of all charges.

[302] Likewise, Dr. Boucher who reported to Dr. Furesz acted reasonably throughout. Dr. Boucher was acquitted of all charges.

[303] Armour Pharmaceutical Company, the manufacturer of the product, through its representatives, followed the scientific developments, maintained open communication with the authorities and responded quickly and responsibly when problems arose. It is clear that its corporate culture encouraged open debate, discussion and consensus-based decisions. Armour was acquitted of all charges.

[304] Dr. Rodell, an officer of Armour was responsible and professional throughout, consistent with his well-deserved reputation for integrity. Dr. Rodell was acquitted of all charges.

[305] The burden of proof in a criminal case is proof beyond a reasonable doubt. To acquit the accused on this basis however would be to "damn with faint praise".[70] There was no conduct that showed wanton and reckless disregard. There was no marked departure from the standard of a reasonable person. On the contrary, the conduct examined in detail for over one and a half years confirms reasonable, responsible and professional actions and responses during a difficult time. The allegations of criminal conduct on the part of these men and this corporation were not only unsupported by the evidence, they were disproved.

[306] I return to the quotation of Churchill. He was speaking of events which, despite sincere efforts, turn tragic so that:

> we are so often mocked by the failure of our hopes and the upsetting of our calculations.

[307] The events here were tragic. However, to assign blame where none exists is to compound the tragedy.

GRO-C

MADAM JUSTICE M.L. BENOTTO

Released: October 1, 2007

[70] Borrowed from Alexander Pope: Epistle to Dr. Arbuthnot

Glossary Of Terms And Acronyms

60/30	Heat treatment nomenclature: heated at 60°C for 30 hours
68/72	Heat treatment nomenclature: heated at 68°C for 72 hours
AHF	Anti hemophilic factor
AIDS	Acquired immune deficiency syndrome
Assay	A test method used to measure how much HIV is present
Blood coagulation product	Product used to aid blood clotting
Blood Products Division	A division of Health Canada
BoB	Bureau of Biologics. A division of Health Canada
BTS	Blood Transfusion Service. A division of Canadian Red Cross (CRC)
CDC	Center for Disease Control (U.S.)
CRC	Canadian Red Cross
CRC-BTS	Canadian Red Cross Society's Blood Transfusion Service
DHSS	Department of Health and Social Services (U.K.)
FDA	Food and Drug Administration (U.S.)
Food and Drug Act	Canadian legislation
Fractionation	Process for separating constituent parts of blood plasma to create clotting factors
Generation I	Intermediate purity H.T. Factorate. Distributed in Canada.
Generation II	High purity H.T. Factorate. Not distributed in Canada.
H.T. Factorate	Commercial blood coagulation product manufactured by Armour
Haemophilia	Genetic disease wherein certain clotting factors as absent from the blood
Haemophilia Society	(Canada)
Heat labile	Subject to change with the addition of heat
HIV	Human Immunodeficiency Virus. The virus that causes AIDS, previously known as HTLV-III, HRI and LAV
HRI	Term previously used for HIV
HTLV-III	Term previously used for HIV
JCI	*Journal of Clinical Investigation*
Kaposi's sarcoma	Form of cancer that is generally relatively benign but was fatal to many AIDS patients in the 1980s
Krever Inquiry	Royal Commission of Inquiry on the Blood System in Canada
LAV	Term previously used for HIV
LCDC	Laboratory Centre for Disease Control. (Canadian agency in Ottawa)
Log	A measurement on a logarithmic scale
Lyophilizing	Freezing
MASAC	Medical and Scientific Advisory Council of the National Haemophilia Foundation
MMWR	Morbidity and Mortality Weekly Report. (Center for Disease Control publication)

National Institute for Biological Standards and Control	(U.K.)
National Institute of Health	(U.S.)
NHF	National Haemophilia Foundation (U.S.)
Phylogenetic testing	Genetic comparisons of different samples to determine whether the samples are related
Plasma	Fluid component of blood
Plasma pool	Collected plasma donations from numerous individual donors
Plasmapheresis	Removal of plasma from donors and subsequent return of red blood cells and other blood components to the donor
Product insert	Information about a pharmaceutical product provided by the manufacturer and included with the product
Viral kill	Rates used to measure viral inactivation
Viral load	Measurement of the amount of a particular virus in the blood (or other bodily fluid) of a given individual
Viral titre	Concentration of virus in a particular sample

COURT FILE NO.: P51/04
DATE: 20071001

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:

HER MAJESTY THE QUEEN

- and –

ARMOUR PHARMACEUTICAL COMPANY, MICHAEL RODELL, ROGER PERRAULT, DONALD WARK BOUCHER, and JOHN FURESZ

REASONS FOR JUDGMENT

BENOTTO J.

Released: October 1, 2007