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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

Chang, Y.; **Chen, C.**; Chen, T-Y, individually and as successor in interest on behalf of **Chen, H.**; Chen, S. and Chen, C-Y, individually and as successors in interest on behalf of **Chen, K.** and **Chen, L-Y**; Huang, Y. and Chen, P., individually and as successors in interest on behalf of **Chen, N.**; **Chen, T.** and Shih, M; Chiu, C-F, individually and as successor in interest on behalf of **Chiu, F.**; **Ho, C.**; Hsieh, Y. and Hsieh C., individually and as successors in interest on behalf of **Hsieh, T.**; Yang, M., individually and as successor in interest on behalf of **Huang, Y.**; **Huang, Y-H**; Wu, M., individually and as successor in interest on behalf of **Lai, C-Y**; **Wu, M.**; **Huang C.**; **Li, C-H** and Wang, S.; Li P. and Li L-S, individually and as successors in interest on behalf of **Li, C-C**; **Li, P-W**; **Li, S.**; **Liao, C.**; Lin, C-M and Lin, C-F, individually and as successor in interest on behalf of **Lin, Che-H**; Lin, P., individually and as successor in interest on behalf of **Lin, C-H**; Lin, Y., individually and as successor in interest on behalf of **Lin, Chi.-M.**; Yang K., individually and as successor in interest on behalf of **Lin, S.**; Liu, C-A and Chang, Y-Y, individually and as successors in interest on behalf of **Liu, C.**; Liu, P., individually and as successor in interest on behalf of **Liu, H.**; **Liu, Y.** and Chuang, L.; Tai, A., individually and as successor in interest on behalf of **Tai, M.**; **Tsai, C-H**; Huang, M-Y, individually and as successor in interest on behalf of **Tsai, C-M**; Tsai, Y. and Huang, M-C, individually and as successors in interest on behalf of **Tsai, H-T**; Li, A., individually and as successor in interest on behalf of **Tsai, S.**; **Tseng, C.**; **Wang, M.**; **Yu, W.**

Plaintiffs,

v.

Civil Action No.: 3:04-CV-01925

This Case is Being Noticed as a Tag-Along Action to MDL 986

First Amended Complaint for Damages

Jury Trial Demanded

(1) Negligence
(2) Negligence Per Se
(3) Fraudulent Omission/Concealment
(4) Breach of Implied Warranty
(5) Fraudulent Inducement

Bayer Corporation, an Indiana corporation, successor to **Cutter Biological**, a California corporation and **Cutter Laboratories, Inc.**, a California corporation; **Baxter Healthcare Corporation**, a Delaware corporation, and its **Hyland** Division.

Defendants.

INTRODUCTION

1. Plaintiffs' claims arise from Human Immunodeficiency Virus ("HIV") and/or Hepatitis C Virus ("HCV") infection of certain Taiwanese hemophiliacs through virally contaminated anti-hemophiliac factor medication ("AHF"). Defendants are American corporations that manufactured AHF from human plasma for the treatment of hemophilia, a bleeding disorder. AHF was sold to hemophiliacs worldwide and in Taiwan despite Defendants' knowledge that plasma pools used in manufacturing AHF improperly included plasma from unhealthy, high-risk donors likely to be infected with blood borne viruses such as HIV and HCV. Defendants continued selling old stocks of HIV and HCV-contaminated AHF abroad and in Taiwan after the products were determined to transmit HIV and after introducing safer AHF in the United States. Plaintiffs are Taiwanese hemophiliacs or their families who contracted HIV and/or Hepatitis C through use of Defendants' virally contaminated products.

2. Defendants manufactured HIV and HCV-contaminated AHF at United States plants from thousands of paid American donors' plasma, including high-risk populations such as promiscuous, urban homosexuals, prisoners and intravenous drug users then known to be at substantial risk for carrying blood-borne diseases. Defendants intentionally recruited hepatitis-exposed homosexual plasma donors, despite regulations prohibiting these donations and despite knowledge that blood-borne viruses were prevalent in such populations. Defendants continued using high-risk prison plasma, even after promising the FDA that they would quit this practice. Defendants continued to process, sell and distribute in-progress AHF after learning that plasma from donors with AIDS had been included in plasma pools still undergoing manufacturing steps. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially

delay product recalls and safety measure implementations.

3. Defendants failed to fully and completely disclose AHF's known risks, including the risk of HIV/AIDS and Hepatitis C infection; failed to implement readily available screening tests that would have prevented HIV/AIDS and Hepatitis C transmission by excluding contaminated plasma; failed to use available methods to kill viruses, including heat, detergent and solvent-detergent treatments; and concealed and affirmatively misrepresented the extent of the health dangers of HIV/AIDS and Hepatitis C. Defendants continued shipping nonheat-treated AHF and to Taiwan—after they began selling heat-treated AHF in the United States—to maintain their profit margin on existing contracts and to sell off remaining stock that was no longer marketable. Defendants continued to sell old AHF—that had not been virally deactivated —in the United States, in Taiwan, even after introducing a safer, virally deactivated product.

4. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of hemophiliacs worldwide and in Taiwan who were needlessly infected with HIV and/or HCV. AIDS and Hepatitis are the leading cause of death for hemophiliacs who were treated with AHF in the 1980's, and the average life expectancy of hemophiliacs has decreased substantially.

5. Many surviving hemophiliacs with HIV suffer from AIDS. Some have temporarily postponed the onset of AIDS with antiretroviral therapy which itself has toxicities, damaging side effects, and diminishing effectiveness over time. Hepatitis C-infected hemophiliacs face cirrhosis and/or liver cancer unless they qualify for and respond to Interferon/Ribavirin combination therapy, a chemotherapy-like treatment with severe side effects including major depression. HIV and HCV coinfection accelerates the advance of each disease, making treatment riskier and more complicated.

6. Defendants' wrongful conduct has not only damaged and shortened the lives of hemophiliacs who used their contaminated products but has also severely injured their families and spouses.

JURISDICTION AND VENUE

7. Plaintiffs allege an amount in controversy in excess of $75,000.00, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants.

8. Plaintiffs are informed and believe and upon such information and belief allege that the unlawful, negligent, tortious, fraudulent activity alleged herein was carried out predominantly in the United States, and in particular, California. Baxter's manufacturing plant is and was in Los Angeles County, California. Bayer's manufacturing plants are and were in Berkley, California and Clayton, North Carolina. Defendants recruited high-risk, paid donors throughout the United States, including California and mixed such donors' plasma into pools at their California and North Carolina facilities. Defendants placed misleading labels on their products and affirmatively misrepresented their products' safety in California and North Carolina, which were relied upon by Plaintiffs and their doctors worldwide. Defendants' decisions—to recruit paid donors from high-risk populations, to refrain from disclosing their products' known risks, to forego implementing readily available viral transmission-prevention procedures, to continue shipping their unheated products to Taiwan after their heat-treated product was available and on the market, to assure customers afraid of AIDS and asking for heat-treated AHF that the unheated AHF was not hazardous and was safe—were primarily made in California. Defendants' acts of conspiracy, including trade association meetings, where they agreed to engage in wrongful conduct, also took place in the United States, and in particular, California.

9. Plaintiffs are informed and believe, and upon such information and belief, allege that the most evidence of the unlawful activity alleged herein is located in the United States, and in particular, California. Documents showing Defendants' policies, practices, and decisions regarding plasma donor recruitment, plasma mixing into the blood pools at their facilities, product labeling, advertising and promotion, disclosure or lack thereof of the products' risks, implementation or lack thereof of procedures to prevent their products from transmitting AIDS, false assurances of safety and lack of hazards and shipment of their products to Taiwan are located almost exclusively in the United States, and in particular, California. Document storage warehouses for Defendants are located in California and other U.S. states. Most fact witnesses who will testify to these policies, practices, and decisions are located in the United States and would not be subject to subpoena in other countries. Plaintiff and Defense expert witnesses are located in the United States, and in particular, California. Previous litigation and trials against these Defendants regarding HIV-

contaminated AHF having infected hemophiliacs have occurred in California as well as other U.S. states.

10. The Plaintiffs's medical records will be in California during the litigation and those not already in English will be translated into English. Additionally, the Plaintiffs' damages witnesses—such as family members—will travel to the United States to testify.

11. Plaintiffs' home country of Taiwan is an inadequate alternative forum due to chronic and lengthy court delays, lack of open discovery, unavailability of legal theories, procedures and remedies, and lack of subpoena power over physical evidence and witnesses located in the United States. Prohibitive filing fees (1.1% of the amount of claimed damages) could prevent these Plaintiffs—impoverished by AIDS and HCV illnesses and treatment—from proceeding in Taiwan. Further, these Plaintiffs may fall within the defined class(es) of a class-action lawsuit now pending in a Multi-District Litigation action in the United States District Court, Northern District of Illinois after being transferred from the Northern District of California which contains potential class members from around the world, including Italy, The United Kingdom, and Germany. That case will eventually be transferred back to California. Thus, litigating this action in a forum other than California could create the potential for inconsistent verdicts and results for similarly situated victims against these identical Defendants.

12. Plaintiffs are informed and believe, and upon such information and belief, allege that Defendants' unlawful activity was carried out in significant part in the Northern District of California. At all pertinent times, Defendant Cutter Biological("Cutter"), the predecessor of Miles, Inc. and Defendant Bayer Corporation("Bayer"), had its headquarters in Berkeley, California. Cutter Laboratories, Inc.("Cutter"), had its headquarters in Berkeley, California, and Cutter's Biological Management Committee met at its Berkeley headquarters. Decisions to recruit high-risk, homosexual donors from California locales—including San Francisco and West Hollywood —and to ship AHF overseas were made at the Berkeley headquarters. Additionally, at all pertinent times Defendant Baxter Corporation and/or its Hyland Division ("Baxter") had its main manufacturing plant in Glendale, California. Hyland's President, Medical Director, and Head of Donor Recruitment all had and continue to have offices in the Glendale facility. Defendant Baxter and/or its Hyland

Division also recruited homosexual donors from California, particularly from Los Angeles and San Francisco.

13. Plaintiffs are informed and believe and upon such information and belief allege that the evidence of Defendants' unlawful activity is located in significant part in the Northern district of California, where much of the unlawful activity was carried out. A substantial volume of documentary evidence proving liability is located in a San Jose, California, warehouse facility. Several pertinent fact and expert witnesses who have previously testified against these Defendants in hemophilia/HIV/AIDS cases are located in Los Angeles and San Francisco.

PARTIES

14. This action is for Taiwanese Plaintiffs who used nonheat-treated AHF manufactured, sold or distributed by Defendants in the period from 1978 until 1990 and who contracted HIV and/or HCV; the estates of such persons; and/or the surviving heirs as identified in California's intestate succession statutes (the wrongful death plaintiffs).

15. This action seeks, inter alia, compensatory and punitive damages for Plaintiffs who suffered dangerous, severe and often fatal adverse effects after using Defendants' contaminated AHF.

16. **Chang, Y.** is a citizen and resident of Taipei, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Chang, Y.** has suffered both special and general damages.

17. **Chen, C.** is a citizen and resident of Taipei County, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Chen, C.** has suffered both special and general damages.

18. Chen, T-Y is a citizen and resident of Taipei, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased son, **Chen, H.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Chen, H.** died from AIDS complications.

19. Chen, S. and Chen, C-Y are citizens of Taipei County, Taiwan. They appear herein both individually and as successors in interest to the estate of their deceased son, **Chen, K.**, a

hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Chen, K.** died from AIDS complications.

20. Chen, S. and Chen, C-Y are citizens of Taipei County, Taiwan. They appear herein both individually and as successors in interest to the estate of their deceased son, **Chen, L-Y,** a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Chen, L-Y** died from AIDS complications.

21. Chen, P. and Huang Y. are citizens of Taipei, Taiwan. They appear herein both individually and as successors in interest to the estate of their deceased son, **Chen, N.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Chen, N.** died from AIDS complications.

22. **Chen, T.** is a citizen and resident of Taipei, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Chen, T.** has suffered both special and general damages. He is married to Shih, M. who has suffered the loss of his financial and emotional support as well as love, comfort, care and society.

23. Chiu, C-F is a citizen and resident of Taipei County, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased son, **Chiu, F.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Chiu, F.**, died from AIDS complications.

24. **Ho, C.** is a citizen and resident of Taipei, Taiwan and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Ho, C.** has suffered both special and general damages.

25. Hsieh, Y. and Hsieh, C. are citizens of Taipei, Taiwan. They appear herein both individually and as successors in interest to the estate of their deceased son, **Hsieh, T.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Hsieh, T.** died from AIDS complications.

26. Yang, M. is a citizen of Taichung, Taiwan. She appears herein individually and as successor in interest to the estate of her deceased husband, **Huang, Y.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy.

Huang, Y. died from AIDS complications. At all relevant times, Yang, M. resided with her husband. She has suffered the loss of his financial and emotional support as well as love, comfort, care and society.

27. **Huang, Y-H** is a citizen and resident of Taipei, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Huang, Y-H** has suffered both special and general damages.

28. Wu, M. is a citizen and resident of Taipei County, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased husband, **Lai, C-Y**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Lai, C-Y**, died from AIDS complications. At all relevant times, Wu, M. resided with her husband. She has suffered the loss of his financial and emotional support as well as love, comfort, care and society. During their marriage, **Wu, M.** herself contracted HIV and AIDS from her husband, Lai, C-Y. As a result, **Wu, M.** has suffered both special and general damages.

29. **Huang, C.**, is a citizen and resident of Taipei, Taiwan. She was a girlfriend of Lai, C-Y.(above), a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. During her relationship with Lai, C-Y, **Huang, C.** herself contracted HIV and AIDS. As a result, **Huang, C.** has suffered both special and general damages.

30. **Li, C-H** is a citizen and resident of Taipei, Taiwan, and a hemophiliac who used Defendants' AHF and was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Li, C-H** has suffered both special and general damages. He is married to Wang, S. who has suffered the loss of his financial and emotional support as well as love, comfort, care and society.

31. Li, P. and Li, L-S are citizen of Chang-Hwa County, Taiwan. They appear herein both individually and as successors in interest to the estate of their deceased son, **Li, C-C**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Li, C-C** died from AIDS complications.

32. **Li, P-W** is a citizen and resident of Taipei County, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or

conspiracy. As a result, **Li, P-W** has suffered both special and general damages.

33. **Li, S.** is a citizen and resident of Ilan City, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Li, S.** has suffered both special and general damages.

34. **Liao, C.** is a citizen of Taipei County, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Liao, C.** has suffered both special and general damages.

35. Lin, C-M. and Lin, C-F are citizens of Chang Hwa County, Taiwan. They appear herein both individually and as successors in interest to the estate of their deceased brother, **Lin, Che.-H.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Lin, Che.-H.** died from AIDS complications.

36. Lin, P., is a citizen of Taipei County, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased son, **Lin, C-H**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Lin, C-H** died from AIDS complications.

37. Lin, Y., is the 20-year-old, legally adopted daughter of **Lin, Chi-M** and is a citizen and resident of Taichung County, Taiwan. Her adoptive father, **Lin, Chi-M**, was a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or Defendants' conspiracy. **Lin, Chi-M** died from AIDS complications. At all relevant times, Lin, Y. resided with her father. She has suffered the loss of his financial and emotional support as well as love, comfort, care and society.

38. Yang, K., is a citizen and resident of Chiayi County, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased husband, **Lin, S.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Lin, S.** died from AIDS complications. At all relevant times, Yang K. resided with her husband. She has suffered the loss of his financial and emotional support as well as love, comfort, care and society.

39. Liu, C-A and Chang, Y-Y are citizens of Miaoli County, Taiwan. They appear

herein both individually and as successors in interest to the estate of their deceased son, **Liu, C.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Liu, C.** died from AIDS complications.

40. Liu, P. is a citizen of Taipei, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased son, **Liu, H.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Liu, H.** died from AIDS complications.

41. **Liu, Y.** is a citizen and resident of Taipei County, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Liu, Y.** has suffered both special and general damages. He is married to Chuang, L. who has suffered the loss of his financial and emotional support as well as love, comfort, care and society.

42. Tai, A. is a citizen of Taipei County, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased son, **Tai, M.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Tai, M.** died from AIDS complications.

43. **Tsai, C-H** is a citizen and resident of Taoyuen County, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Tsai, C-H** has suffered both special and general damages.

44. Huang, M-Y., is a citizen and resident of Hsin-Chu, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased husband, **Tsai, C-M**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Tsai, C-M** died from AIDS complications. At all relevant times, Huang, M-Y resided with her husband. She has suffered the loss of his financial and emotional support as well as love, comfort, care and society.

45. Tsai, Y. and Huang, M-C are citizens of Taoyuen County, Taiwan. They appear herein both individually and as successors in interest to the estate of their deceased son, **Tsai, H-T**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF

and/or conspiracy. **Tsai, H-T** died from AIDS complications.

46. Li, A. is a citizen of Taipei, Taiwan. She appears herein both individually and as successor in interest to the estate of her deceased son, **Tsai, S.**, a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. **Tsai, S.** died from AIDS complications.

47. **Tseng, C.** is a citizen and resident of Taipei, Taiwan, and a hemophiliac who was infected was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Tseng, C.** has suffered both special and general damages.

48. **Wang, M.** is a citizen and resident of Kaohsiung, Taiwan, and a hemophiliac was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Wang, M.** has suffered both special and general damages.

49. **Yu, W.** is a citizen and resident of Taoyuen, Taiwan, and a hemophiliac who was infected with HIV and contracted AIDS as a result of Defendants' AHF and/or conspiracy. As a result, **Yu, W.** has suffered both special and general damages.

50. The Plaintiffs contracted permanent injuries or diseases—including HIV, AIDS and/or Hepatitis C and associated symptoms and illnesses—as a direct and proximate result of using Defendants' AHF and/or Defendants' conspiracy.

51. The Plaintiffs would not have chosen to have been treated with Defendants' AHF blood products had they known or been informed by Defendants of AHF's plasma source and true health risks. Plaintiffs were unaware of any wrongful conduct by the Defendants at least until an investigative report was published on May 22, 2003 by the New York Times and republished in Taiwan regarding the distribution of unheated, HIV-contaminated AHF in non-US countries. Some Plaintiffs remained unaware until much later than the May 22 article. Defendants misinformed the Taiwanese government, Taiwan physicians, Taiwan hemophiliacs and their families regarding: the status of class and multi-district litigation in the U.S.; the verdict in the *JKB vs. Bayer* trial in favor of plaintiff; the Defendants' improper use of high risk donors; the Defendants' improper failure to implement available viable viral deactivation steps; Defendants' continuing to market unheated AHF after heat-treated AHF was available; failing to recall or notify families of AHF lots defendants had

determined had included donors with AIDS, AIDS characteristic donors, or donors positive for HIV; selling AHF made from donors whose plasma was collected prior to AIDS risk screening criteria were ordered by the FDA but who were later screened out as AIDS risk donors; shipping AHF to Taiwan that had already been recalled in the United States due to inclusion of a repeat donor with AIDS; the voluminous pool sizes and the impact of pool sizes on increasing the likelihood of viral transmission; immuno suppression, liver failure and splenomegaly in AHF users that predated the AIDS epidemic. These concealed and misrepresented facts led the Taiwan government, the Taiwan hemophilia community and the Taiwan public in general to believe that no wrongdoing had occurred that caused hemophiliacs to contract HIV and HCV.

52. At all pertinent times, Defendant Cutter, the predecessor of Miles, Inc. and Defendant Bayer, was a California corporation headquartered in Berkeley, California. At all pertinent times, Cutter and its successors, Miles, Inc., and Bayer, regularly and systematically engaged in human plasma harvesting, collecting and processing for AHF manufacture, marketing, sales and distribution, which AHF caused Plaintiffs' HIV and/or HCV infection.

53. Defendant Bayer (formerly Miles, Inc.) is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business in Elkhart, Indiana. Bayer's principal place of business is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205. At all pertinent times Bayer, Miles, Inc., and Cutter, regularly and systematically engaged in human plasma harvesting, collecting and processing for AHF manufacture, marketing, sales and distribution which AHF caused Plaintiffs' HIV and/or HCV infection.

54. Defendant Baxter is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia. Its principal place of business is located at One Baxter Parkway, Deerfield, Illinois, 60015. At all pertinent times, Defendant Baxter and/or its Hyland Division's main manufacturing plant was located in Glendale, California. At all times pertinent, Defendant Baxter, and/or its Hyland Division, and/or its wholly owned subsidiaries Travenol Laboratories and Fenwal Laboratories, regularly and systematically engaged in human plasma harvesting, collecting and processing for AHF manufacture, marketing, sales and distribution which

AHF caused Plaintiffs' HIV and/or HCV infection.

55. Defendants Bayer/Cutter and Baxter (collectively referred to as "Manufacturers") acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed HIV and/or HCV-contaminated AHF products worldwide and to Taiwan. Alternatively, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution and sale of AHF products worldwide, or assumed, became or are responsible for the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution or sale of AHF products worldwide and in Taiwan, without limitation thereto.

56. At all times herein mentioned, Defendants and each of them were fully informed of their agents and employees' actions and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions. Defendants and each of them thereby ratified those actions.

FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS HEMOPHILIA AND ITS TREATMENT

57. Hemophilia is primarily an inherited condition that causes uncontrolled bleeding. It is caused by a deficiency of certain plasma proteins essential to the coagulation process that stops bleeding. The most common form is Hemophilia A, characterized by a lack of a plasma protein Factor VIII. Hemophilia A affects approximately one in 10,000 males. Hemophilia B is characterized by the absence of another plasma protein, Factor IX, affecting about one in 40,000 males.

58. Hemophilia treatment involves intravenous introduction—called infusion—of the missing

plasma proteins required to stop bleeding. The two most prevalent treatment forms are cryoprecipitate and anti-hemophilia factor concentrates (AHF). Plasma, blood's fluid component,

contains several different complex proteins, including Factor VIII and Factor IX. Cryoprecipitate is a plasma product that contains a high concentration of Factor VIII protein. Cryoprecipitate is made by freezing plasma, then slowly thawing it to isolate the the Factor VIII proteins in the sediment that precipitates as the frozen plasma thaws. Cryoprecipitate is an effective therapeutic agent for hemophilia A patients. Hemophilia B patients have been effectively treated using fresh frozen plasma containing Factor IX proteins. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors who are generally unpaid volunteers.

59. By contrast, in the late 1960's and early 1970's, Defendants began marketing factor concentrates (AHF) which contained Factor VIII and Factor IX in substantially higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from thousands of donors at a time resulting in a "lot" of AHF comprised of 1,000 to 50,000 or more individual donations. The cryoprecipitate from these combined pools were then subjected to chemical processes to isolate and freeze dry Factors VIII and IX. The powder from each lot would be placed in vials with a specified level of Factor VIII or IX. When needed for preventing or stopping bleeds, the powdered vial would be mixed with a saline solution, then the reconstituted solution would be infused by the hemophiliac.

EVEN BEFORE THE DISCOVERY OF HIV AND AIDS, DEFENDANTS FAILED TO DISCLOSE OR WARN OF SERIOUS ADVERSE EFFECTS ASSOCIATED WITH FACTOR CONCENTRATES

60. Shortly after the initial commercial marketing of AHF in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. Even before the dissemination of HIV, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiffs or the medical community of these adverse effects, in violation of industry standards and federal regulations.

61. By 1976, only a few years after Defendants' AHF went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference entitled

"Unsolved Therapeutic Problems in Hemophilia." The research articles compiled from the conference discussed the high incidence of disorders—such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C)—in hemophiliacs who used Defendants' AHF. The articles concluded that these disorders were tied to AHF usage and emphasized the risks entailed in producing AHF from paid donors' plasma. For instance, Robert Gerety of the FDA Bureau of Biologics, Division of Blood and Blood Products, reported that the agent or agents of NANB Hepatitis "appear to be blood borne, perhaps to be associated with a form of chronic hepatitis, and to represent a considerable risk to recipients who repeatedly require the administration of blood products." (Gerety, et al., "Viral Antigens and Antibodies in Hemophiliacs," (1977). Gerety noted that "[t]he use of large plasma pools from paid donors no doubt contributes to the risk of HBV [Hepatitis B] infection from these products," and stated that "an all voluntary blood donor system is being pursued as a result of the known increased risk of PTH [post-transfusion hepatitis] from blood derived from commercial donors." But as described below, Defendants refused to implement a voluntary donor system and, instead, recruited paid donors precisely because their hepatitis exposure resulted in plasma with high levels of hepatitis antibodies from which Defendants could manufactuire other commercially lucrative products as well.

62. Several of the articles from the 1976 conference also raised alarm over the unprecedented emergence of immune disorders in the hemophiliac community and called for close medical monitoring of the situation. Dr. Peter Levine wrote, "one wonders whether our patients are suffering a sort of immune complex disease as a result of intensive bombardment with foreign antigens...." (Levine, "Unsolved Problems with Current Therapeutic Regimens for Hemophilia," (1977)). Shapiro warned of the possibility that "a new spectrum of disease may be seen in this population" and urged that it "behooves us to follow the suggested findings very closely over the coming years." (Shapiro, "Antibody Responses in the Hemophiliac," (1977)). Seeff concurred that "it is evident that continued surveillance of the hemophiliac population is mandatory." (Seeff, "Acute and Chronic Liver Disease in Hemophilia," (1977)).

63. At all pertinent times, Defendants failed to adequately warn Plaintiffs or their physicians of these serious adverse side effects. Several such adverse effects, including

immunosuppression (suppression of the immune system) were not mentioned at all in the Defendants' package inserts, which were required to disclose adverse reactions pursuant to federal statutes, regulations and applicable standards of care. Although Defendants' inserts mentioned a risk that plasma "may" contain the causative agent of viral hepatitis, the warning was seriously deficient in that: (a) Defendants failed to disclose that the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while "hepatitis" simply means inflammation of the liver and may be a relatively benign, temporary condition, Defendants failed to warn that their product transmitted other forms of hepatitis believed to present a considerable risk of severe liver damage, cirrhosis, and significantly elevated risk of cancer; (c) Defendants misleadingly stated that the source plasma used in AHF's preparation had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that available testing methods were not sensitive enough to detect all units of potentially infectious plasma, while failing to disclose that Defendants had refused to implement the more sophisticated Hepatitis B Core Antibody (HBc) test which would have excluded essentially all Hepatitis B-contaminated plasma; and (d) Defendants' labeling disclosed that AHF was made from pools of fresh human plasma but failed to disclose the voluminous number of donations and that higher risk paid donors included in such pools increased the risk of disease and that Defendants had targeted particular groups of paid donors known to be the highest risk groups available.

DEFENDANTS RECRUITED PLASMA DONORS FROM HIGH-RISK POPULATIONS TO MANUFACTURE FACTOR VIII AND IX

64. The demand for and supply of AHF rapidly increased during the 1970s, with commercially-manufactured AHF accounting for a large proportion of the increase in supply. In 1977 a federal report projected that AHF manufacture would increase substantially by 1980. ("Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980," Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute (1977), at page 8; hereinafter "NHLBI Report").

65. In order to sell more AHF to this growing market, Defendants turned to the fastest

and cheapest way of obtaining sufficient plasma—paid donors. Defendants recruited paid donors from those populations most likely to donate in response to financial incentives: poor, inner-city residents, drug abusers, prisoners, and even residents of impoverished, developing countries such as Haiti and Nicaragua.

66. Defendants purposefully sought out paid donors despite knowing the far greater risk of blood-borne disease transmission from paid donors than volunteers. Because no test was available yet to detect the NANB Hepatitis virus (which had been identified in the early 1970s), preventing viral contamination of the plasma supply could only be accomplished through excluding donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors! Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy—adopted by the federal government in July 1973—advocated conversion to an all-volunteer blood supply. Yet Defendants not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations while resisting recommendations for an all-volunteer plasma supply.

67. Defendants had an additional financial incentive for recruiting paid donors. AHF-VIII and and IX are only two of many commercial products that can be made from human plasma. According to the NHLBI Report, by the late 1970's, human plasma was being manufactured—through a process called "fractionation"—into at least seventeen different therapeutic blood components. The NHLBI Report noted that, "as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma." (Id. at 65).

68. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer—or antibody level—for a corresponding antigen is "very expensive." (Id. at 41). Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. (Id.). But the NHLBI Report specifically advised that "plasma collected for high antibody titer cannot be used for fractionation into therapeutic products,"—such as Defendants' factor concentrate products. (Id.).

69. Defendants targeted donors with high titers to Hepatitis B antigens to use in

manufacturing Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Prisoners were "vaccinated" for some diseases—a process termed "hyper-immunization"—so that their bodies would generate specific antibodies, which were then harvested to make immune globulin products. Despite the NHLBI report's warning, Defendants manufactured immune globulins and Factor VIII and IX from the same high-titer plasma. Defendants thus sought to maximize profits by producing "as many products as possible from a liter of plasma," while ignoring industry standards that precluded high-titer plasma use for other therapeutic products.

70. Beginning in about 1978, Defendants Baxter and Cutter/Bayer began targeting homosexualdonors in known urban gay communities. Because urban homosexuals had been reported in the 1970s to have an exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable plasma source for commercially lucrative HBIG as well as general immune globulins.

71. By the 1970s the public health community was fully aware that urban homosexuals engaged in promiscuous sexual practices—which rapidly transmitted NANB Hepatitis and other diseases—could not be isolated nor identified, which caused serious, adverse consequences. Despite this knowledge, Defendants included urban homosexuals' plasma in plasma pools used to manufacture both HBIG, general immune globulins, and Factor VIII and IX.

72. Defendants continued this multiple use of high risk plasma even after federal reports warned of fatal immunosuppressive diseases rapidly spreading through the same homosexual population from which Defendants heavily recruited. On June 5, 1981, the United States Centers for Disease Control ("CDC") reported that five homosexual men had unusual and similar immunosuppressive disorders (Morbidity and Mortality Weekly Report, MMWR," June 5, 1981, at p. 250). On July 3, 1981, the CDC reported similar diseases in twenty-six homosexuals, noting that twelve patients tested positive for cytomegalovirus ("CMV"), evidenced "past or present CMV infection", and that previous hepatitis infections "were commonly reported." (MMWR, July 3, 1981, at p. 305). The CDC warned doctors to be alert for "opportunistic infections associated with immunosuppression in homosexual men." (Id., at p. 307). By August 28, 1981—less than two months later—the reported figure had grown to 108 cases with 40% fatalities; 94% of the 101 males

were homosexual or bisexual (MMWR, August 28, 1981, at p. 409). Given this information and the urban homosexual population's high incidence of hepatitis, Defendants knew or should have known by no later than the summer of 1981 that urban homosexual males were not "suitable donors" within the meaning of federal regulations and/or other applicable standards of care.

73. By the 1970s it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of high concentrations of intravenous (IV) drug-using prisoners. By 1974 the alanine aminotransferase ("ALT") test was available to screen for elevated levels of liver enzymes—called SGOT—which indicate hepatitis. Prisoners were associated with SGOT levels of over 60 IUs per ml, a level which increases the risk of Hepatitis C transmission by sixfold. Despite knowledge of this risk, Defendants actively recruited prisoners' plasma for manufacturing into Factor VIII and IX, while concealing or failing to disclose this health risk to Plaintiffs, their physicians, or the FDA.

74. On June 11, 1982, the CDC reported that 281 homosexual men and 33 IV-drug users had had been diagnosed with similar immunosuppressive and opportunistic infections, with a 43% fatality rate. Yet Defendants continued to recruit and use the accumulated plasma from these high-risk donors while concealing the health risks from Plaintiffs, their physicians and the FDA.

75. At a July 1982 meeting attended by the Defendants, the CDC publicly reported the first first three cases of opportunistic infections among hemophiliacs. Each was reported to be heterosexual. The CDC reported that the three hemophiliacs' clinical and immunologic features were strikingly similar to those recently observed among homosexual males and heterosexual IV-drug users, while observing that the hemophiliacs did not share the latter two groups' risk factors. The CDC stated, "Although the cause of the severe immune dysfunction is unknown, the occurrence among the three hemophiliac cases suggests the possible transmission of an agent through blood products." (MMWR, July 16, 1982, at p. 366).

76. In light of the Defendants' special knowledge of urban homosexuals and prisoners' disease patterns, and their recruitment of these donors' plasma for Factor VIII and IX manufacturing, Defendants had duties to: (a) promptly investigate the 1981 reports of opportunistic infections among urban homosexuals; (b) discontinue using high-risk donors; (c) disclose the health

risks to Plaintiffs, their physicians, and the FDA—including the ongoing risk of using Factor VIII and IX previously manufactured with high-risk plasma and still marketed to patients; (d) implement procedures to kill blood-borne diseases in their AHF; and (e) recall existing AHF stocks from distribution or further use.

DEFENDANTS FAILED TO USE THE AVAILABLE HEPATITIS B CORE (HBC) TEST TO EXCLUDE HIGH-RISK DONORS' PLASMA

77. By no later than 1978, Defendants knew that a new test was available to determine an individual's viral Hepatitis history; a core-positive test would have disqualified the donor from providing plasma for the Factor VIII and IX manufacture. By testing a person's serum for the presence of the core to the Hepatitis B antibody—the "HBc test"—a viral Hepatitis history could be verified. Published, peer-reviewed literature shows that researchers were using the HBc test to determine that homosexual AIDS victims had a viral Hepatitis history by no later than December 1981. (Gottlieb, et al., "Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men," New England Journal of Medicine 1981; 305:1425-1431).

78. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

79. Defendants' use of the HBc and ALT tests by 1981 would have eliminated the vast majority of the nations' blood-borne HIV and HCV transmissions, before the height of the AIDS and Hepatitis C epidemics. If Defendants had timely implemented this test, Plaintiffs would never have been HIV or HCV infected or suffered from AIDS or Hepatitis C as a result of using AHF.

80. Plaintiffs and thousands of other hemophiliacs worldwide became infected with the AIDS and Hepatitis C viruses through repeated exposures to AHF manufactured from combining large pools of plasma donors to create lots derived from 12,000 to 50,000 individual donations. Had Defendants used the HBc and ALT tests to decrease by 70% to 90% the number of HIV and HCV-positive plasma donations into a pool, AHF's infectivity would have decreased substantially. Consequently, hemophiliac infection rates would have slowed enormously, and the medical and

scientific community would have been given more time to react appropriately to the HIV and Hepatitis C epidemics.

81. As noted below, federal regulations required healthy plasma donors; donors with a "history of viral Hepatitis" were by definition unacceptable as blood or blood plasma donors. Persons with a viral Hepatitis history were excluded not only because of the Hepatitis B-transmission risk, but also because this history indicated the donor's precarious lifestyle and previous risky behavior—indicators that Hepatitis and any other viruses present were being transmitted. In 1978, a reasonable and prudent plasma fractionator could not have accepted a HBc positive plasma donor and still have considered itself in compliance with federal regulations.

82. In July 1982, after the first hemophilia AIDS cases were publicly reported, government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to eliminate plasma contaminated by the transmitter of AIDS or Hepatitis C. The CDC also strongly suggested HBc testing to Defendants at a United States Public Health Service ("PHS") meeting on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that the HBc test would have excluded and continued to conceal from Plaintiffs, their physicians, and the FDA, the dangerous practice of targeting donors at highest risk for the very diseases that disqualified their plasma. At a January 6, 1983, Defendant trade association meeting—the Pharmaceutical Manufacturer's Association—Defendants agreed not to implement the highly effective HBc donor screening, instead opting for ineffective donor questionnaires that did little to screen out AIDS/Hepatitis C high-risk donors.

83. As late as December 13, 1983—years after the HBc test was first available—a Cutter memorandum written by responsible head Stephen Ojala to various Cutter executives, reported on a meeting held by Defendants and shows that Defendants—and other fractionators—conspired to form a "task force" to "further" study HBc testing—an intentional, bad-faith "delaying tactic for the implementation" of the test.

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DEFENDANTS ALSO FAILED TO IMPLEMENT AVAILABLE HEAT AND SOLVENT DETERGENT TREATMENTS TO KILL BLOOD-BORNE DISEASES

84. In the late 1970s and early 1980s, it was recognized that all AHF products contained viruses. Heat, detergent and solvent-detergent treatments—which eliminated many of these viruses, including HIV and HCV—were available at that time. Although Defendants were required to take reasonable steps to eliminate contamination, they failed to timely implement these technologies to eliminate the viruses.

85. The 1977 NHLBI Report noted that albumin—another plasma product—was "heat treated to remove almost all danger of hepatitis." (Id., at p. 49). It was clearly known by no later than 1977 that heat treatment during manufacturing produced safer blood products, but Defendants wrongfully refused to implement such procedures as to AHF. In 1995, the National Institutes of Health Institute of Medicine ("IOM") issued a hemophilia/AIDS epidemic report which concluded that Defendants "did not seriously consider alternative inactivation processes," including heat treatment, and that "heat treatment processes to prevent the transmission of hepatitis could have been developed before 1980." Heat treated, HIV-free AHF was not introduced by any Defendant until 1983 and were not universally in use until 1985.

86. Besides heat treatment, detergent treatment was available to Defendants by the late 1970's as a simple and effective method of eliminating viruses from AHF. Solvent detergent effectively kills viruses such as HIV and HCV by destroying the viruses' lipid envelope. It is simpler than heat treatment and—unlike heat treatment—does not deactivate Factor VIII and IX blood clotting proteins.

87. By the 1970s, detergents were well known and commercially available, and peer-reviewed journals were publishing studies in which solvent-detergent treatment successfully disrupted viruses. In 1980 Dr. Edward Shanbrom, a former Baxter scientist and co-inventor of factor concentrates, received a patent for a detergent treatment process to virally deactivate AHF. Dr. Shanbrom describes the process as "as easy as washing your hands."

88. After receiving the patent, Dr. Shanbrom approached Defendants and others about using the detergent method, but Defendants wrongfully refused to implement the method. Defendants

refused to even commit any resources to investigating the method. However, in June 1985, the New York Blood Center ("NYBC") obtained a license from the FDA to implement the process for Factor VIII. The NYBC obtained a license to use the process in 1987. By 1987, all Defendants were using the process to virally inactivate their Factor VIII blood products.

89. Although heat treatment was effective in destroying the HIV virus, it was ineffective in destroying Hepatitis B and C (HBV and HCV). CDC study reported that "84% of previously untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis ... several case reports of probable transmission of HBV and HCV through vapor heat-treated and pasteurized products later appeared." (Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males: Soucie, Richardson, Evatt et al; Transfusion, 2001; 41:338-343)

90. The same CDC study reported that "solvent detergent treatment of blood components found to be more effective against enveloped viruses than heat treatment ... No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients..."

91. The study further reported "in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the licensing of solvent detergent treatment of factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions."

92. The study stated that "the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those hemophiliacs born as late as 1989 at risk of infection." The study recommends testing for all hemophiliacs who received infusions of the defendant's blood products before 1992.

93. Defendants' failure to timely implement solvent-detergent, viral-inactivation techniques, to warn of the HBV/HCV related health risk from infusing heat-treated AHF, and to recall heat-treated products that posed this risk caused hemophiliacs by the thousands to be

needlessly HBV or HCV infected after 1984.

DEFENDANTS CONTINUED SHIPPING NONHEAT-TREATED AHF ABROAD AND TO TAIWAN AFTER THEY BEGAN SELLING HEAT-TREATED AHF IN THE UNITED STATES

94. Between 1983 and 1985, Defendants gradually stopped selling nonheat-treated AHF in the United States and introduced a vastly safer heat-treated version. But Defendants continued to ship their remaining nonheat-treated AHF stocks abroad and to Taiwan despite knowledge that the nonheat-treated AHF was HIV and/or HCV contaminated.

95. According to a New York Times article entitled "2 Paths of Bayer Drug in 1980's: Riskier Type Went Overseas," published on May 22, 2003, Cutter—Bayer's predecessor—sold millions of dollars of nonheat-treated AHF in Asia and Latin America for over a year after its February 1984 introduction of heat-treated AHF in the United States. Cutter records show that the company sought to maintain its profit margin on "several large fixed-price contracts" in Latin America and Asia—by continuing to sell its cheaper-to-produce nonheat-treated AHF—and avoid being stuck with old, unmarketable stock. Minutes from a November 1984 Cutter meeting reveal that "there is excess nonheated inventory," and that the company planned to "review international markets again to determine if more of this product can be sold." The company pursued this strategy even though Cutter's plasma procurement manager had acknowledged in a January 1983 letter that "[t]here is strong evidence to suggest that AIDS is passed on to other people through...plasma products," and despite Cutter's knowledge that the CDC had reported in the July 13, 1984 MMWR that 72 percent of hemophiliacs who used unheated AHF were HIV antibody positive. The editorial note stressed that "individuals in populations with increased incidences of AIDS...should comply with the March 1983 Public Health Service recommendations for prevention of AIDS to minimize the transmission of the syndrome." Further, the editorial note stated "that transmission has been only through intimate sexual contact, sharing of contaminated needles, or, ...blood products." Then in an October 1984 MMWR, the CDC reported that a Cutter study showed that heat treatment rendered HIV "undetectable" in AHF.

96. In late 1984 Cutter told a Hong Kong distributor voicing concerns regarding the rates of AIDS in hemophiliacs and therefore requesting heat-treated AHF that they should "use up stocks" of its old, nonheat-treated product first. Cutter later assured the same distributor that the nonheat-treated product posed "no severe hazard" and was "the same fine product we have supplied for years." In March 1985, a Cutter report stated that "the Far East has ordered 400,000 units" and that "in Taiwan, Singapore, Malaysia, and Indonesia, doctors are primarily dispensing nonheated Cutter" factor concentrate. The report stated that "Argentina has been sold 300,000 units." Cutter did not apply for a license to sell its new heat-treated product in Taiwan until July 1985—over a year after it began selling the new product in the United States. The Times article noted that over 100 hemophiliacs in Hong Kong and Taiwan alone were infected with HIV by nonheat-treated Cutter product sold after February 1984. A total of 100,000 vials of nonheat-treated Cutter AHF—$4 million dollars worth—was shipped abroad after the company began selling its heat-treated product in the United States.

97. Despite the July 13, 1984 and October 1984 MMWR reported data that 72% of hemophiliacs who infused non-heat treated AHF were testing HIV positive and that nonheat-treated AHF was HIV contaminated, Cutter continued to market and distribute infectious nonheat-treated AHF in Asia. In a November 29, 1984 telex, Cutter advised that they wanted to use up stocks of lower priced nonheat-treated AHF to meet Cutter's long term contract obligations in Hong Kong "because production cost of Koate-HT was expected to be higher and we have several large fixed price contracts."

98. On May 6, 1985, when Hong Kong's factor concentrated distributor, Luen Cheong Hong (LCH), frantically pressed Cutter for heat-treated AHF, Cutter was more worried about losing market share to their competitors—who had available quantities of heat-treated AHF—than providing a virus-free medication to hemophiliacs. Instead of referring LCH's pleas for heat-treated concentrate to another AHF manufacturer, Cutter's marketing representative attempted to persuade LCH to continue using Cutter's AHF, writing "Be assured there is no severe hazard from the regular Koate factor VIII concentrate now being supplied to Hong Kong and numerous other countries. It is the same fine product we have supplied for years." Based on the July and October 1984

MMWRs, Cutter knew this to be false. Astonishingly, Cutter defended its actions—over a year after non heat-treated AHF was removed from the US market—by noting that "[t]here is no ban on use of non heat-treated concentrates in the U.S. right now." A few days later, in response to accusations that Cutter was simply "selling off excess stocks of old AIDS tainted regular Koate into the less developed countries," Cutter made 350 vials of Koate-HT available to Hong Kong doctors' "most vocal patients." A Cutter internal memo dated May 8, 1985 describes the Hong Kong controversy over the demand for heat-treated AHF—noting that Alpha and Hyland are "stirring up trouble"—and ominously concludes, "[i]t appears there are no longer any markets in the Far East where we can expect to sell substantial quantities of non heat treated Koate."

99. Cutter's wrongful conduct in continuing to ship nonheat-treated AHF abroad is typical of Defendants' wrongful conduct worldwide. Upon learning of this conduct in May 1985, the FDA requested a meeting with Defendants to order their compliance with a voluntary agreement to withdraw nonheat-treated product from the market. Dr. Harry M. Meyer—who at that time was the FDA's blood products regulator—stated in later legal papers that "[i]t was unconscionable for them to ship that material overseas."

DEFENDANTS FRAUDULENTLY MISREPRESENTED AHF'S SAFETY AND CONCEALED AHF'S HEALTH RISKS

100. Defendants fraudulently concealed their dangerous practices, fraudulently understated the AIDS/HCV health risks, and fraudulently misrepresented the extent of their efforts to assure product safety, in order to maintain profits from AHF, HBIG and immune globulins. Defendants' fraudulent misrepresentations and concealment are as follows:

101. The CDC's report of three hemophiliacs who contracted AIDS resulted in a July 27, 1982 Public Health Service meeting. Cutter/Bayer and Baxter's (and other fractionators) responsible heads attended, along with National Hemophilia Foundation ("NHF"), CDC and FDA officials. Cutter/Bayer and Baxter knew that they had used cryoprecipitate—containing plasma from known, targeted homosexuals—in Factor VIII and IX manufacture. This AHF 's shelf life was two and three years, respectively, and it was either in production or already on pharmacy shelves waiting to be infused by hemophiliacs. Cutter/Bayer, Baxter and Alpha—another fractionator—failed to

disclose this information to CDC officials, Dr. Don Francis and Dr. Jeff Koplin, despite knowing that the CDC's primary concern at that meeting was Factor VIII and IX's contamination with the transmitter of AIDS—an illness which was already at epidemic levels in the targeted homosexual population. (Cutter memorandum dated August 3, 1982.)

102. In or about December 1982, Dr. Michael Rodell, Baxter's responsible head, entered into an agreement with FDA officials that Baxter would no longer use prison plasma in AHF production. In fact, Baxter—unbeknownst to the FDA—continued to use prison plasma in AHF through October 1983. (Baxter memorandum dated October 20, 1983.)

103. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California—the largest hemophilia treatment center in the United States. Cutter/Bayer and Baxter—along with other fractionators—were present at the meeting with treaters and patients. The meeting's purpose was to have Defendants' representatives answer patients' questions about AIDS transmission through AHF. The fractionator representatives were asked by a member of the audience the following question: "Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" None of the Defendants admitted targeting or using plasma from homosexuals, prisoners or inner city IV-drug abusers. Baxter's Dr. Jack Goodman—regarding Baxter's use of known homosexuals—answered: "We are changing the nature of questions to homosexuals to the best of our ability." Cutter/Bayer's responsible head, Stephen Ojala—and other fractionators— made no response. This partial and misleading response amounted to concealment of the true health risks created by using known homosexuals, IV-drug abusers and prisoners' plasma in AHF manufacture.

104. At the January 5, 1983 meeting—and in the presence of the patients—one of the treating physicians, Dr. Kasper, asked Cutter/Bayer's Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that Cutter/Bayer's first and largest plasma center was located at Arizona State Penitentiary. Cutter/Bayer also had a center at the Las Vegas Prison. Ojala

and Cutter/Bayer were well aware of the CDC and FDA's concern over use of prison plasma—due to the prison donor populations' homosexual practices and drug abuse. Many of Cutter/Bayer's centers were in inner-city areas—such as downtown Oakland, California—frequented by IV-drug abusers. Cutter/Bayer had also used plasma from centers which targeted known homosexuals. In August 1982, Cutter/Bayer quarantined Valley Medical Center plasma—a center which targeted known homosexuals—because a donor was hospitalized with full-blown AIDS. The plasma—which was intended for Factor IX and HBIG production— was not used because it had thawed enroute to the processing plant. Upon receiving an incident report from Cutter/Bayer, the FDA indicated a recall might have been necessary if the plasma had been incorporated into AHF final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding Cutter/Bayer's plasma center locations. (January 5, 1983, Cutter memorandum.)

105. On January 14, 1983, Baxter's Dr. Michael Rodell, Cutter/Bayer's responsible head, and other fractionators attended a National Hemophilia Foundation ("NHF") meeting. The meeting's purpose was to have Defendants explain to the NHF what steps they were prepared to take to safeguard the plasma supply from potential AIDS transmitters. Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented—consistent with the CDC's recommendation ten days earlier. Baxter, under Rodell's supervision, had already conducted a donor center survey to determine how many donors would be lost if HBc testing were implemented. Baxter had decided that up to 16% of their donors would fail the test. Further, Baxter's high-titered immunoglobulin donors would be eliminated. To defer a NHF recommendation that HBc testing be used, Rodell told NHF officials that surrogate testing was currently in the "R and D," or "Research and Development" stage. Rodell concealed from the AHF that the CDC had strongly recommended HBc Antibody testing as a screening device for donors at high risk for AIDS transmission. The HBc Antibody test was not in the "R and D" stage and was suitable for screening high-risk AIDS and Hepatitis C donors. In fact, the FDA had approved the HBc test in 1979 as a diagnostic test to ascertain a previous hepatitis B-infection history and as a blood and plasma donor screening device. The test was capable of identifying all donors with a viral hepatitis history. Pursuant to the federal regulations (21 C.F.R. § 640.63), donors with a hepatitis

history were specifically prohibited. Rodell acknowledged that HBc testing would eliminate high-titered immunoglobulin donors but failed to disclose that opposition to HBc testing was based on economic rather than safety concerns.

106. At the January 14, 1983 meeting, Cutter/Bayer, Baxter, and Alpha concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them to plasma centers which supplied high-titered plasma to the Defendants. Cutter/Bayer and Alpha concealed their extensive prison plasma use, and Baxter discussed plans to phase out prison plasma during the coming year. But none of the Defendants revealed their "gentlemen's agreement" with the FDA to discontinue using these plasma sources immediately. (Cutter Memorandum dated January 17, 1983.)

107. In response to hemophiliacs' growing concern about reports in the lay press of AIDS transmission through blood products, Cutter/Bayer issued a January 28, 1983 press release which advised that "Cutter has intensively involved its people and resources to contribute to a resolution of this segment of the AIDS problem." This statement was false because Cutter/Bayer was, or had been, actively engaged in using the plasma of prisoners, known homosexuals, and inner-city, IV-drug abusers to manufacture AHF. Plus, once they did start screening out these donors' plasma, they continued manufacturing and distributing AHF that had included plasma from such donors. Also, they left in the market place lots of AHF that had already been manufactured but which had a two or three year shelf life. Thus, even when the screening was belatedly implemented, AHF manufacturers such as Cutter/Bayer and Baxter created a false sense of safety since the products actually being used for years contained plasma from the sources determined to be too risky for AHF products. Cutter/Bayer had refused to comply with the CDC's recommendation to immediately implement HBc testing to eliminate these high-risk donors and had conspired with Baxter and other fractionators to conceal this plasma's use in manufacturing AHF that was currently on the market. Cutter/Bayer had formed an alliance with Baxter and other fractionators to avoid timely warnings, effective donor screening, and immediate recalls of high-risk blood products. (Alpha Memorandum dated January 20, 1983.)

108. Cutter published and distributed a magazine called ECHO, which was intended for

patients, treaters, and pharmacies. The May 1983 ECHO Magazine was entitled, "Special AIDS Issue." In ECHO's introductory statement, Medical Director, Dr. George Akin, advised: "We at Cutter want you to know that your welfare is our prime concern. We are doing everything possible to help researchers diagnose the syndrome as well as implement precautionary measures designed to minimize the risk for the person with hemophilia." This statement was false because: Cutter had engaged in concerted actions with Baxter and other fractionators to avoid recalls, timely warnings, appropriate HBc testing, donor screening, and the flow of accurate information through the NHF. They were engaged in aggressive, over promotion of Factor VIII—calculated to understate the AIDS and Hepatitis C health risks—in order to increase sales which had dropped due to information reported in the lay press regarding the risks of AIDS transmission. Cutter/Bayer's Steven Ojala, anticipating lawsuits from hemophiliac/AIDS victims as AHF sales increased in 1983-84, organized a coordinated legal defense plan. In a January 1983 memorandum, Cutter discussed its plan to "refute links to AIDS."

109. Cutter/Bayer had failed to conduct any independent investigation into any hemophiliac/AIDS victims. Cutter/Bayer had been told by two of the foremost authorities in the field, Dr. Lou Aledort and Dr. Peter Levine, that AIDS in hemophiliacs may be caused by foreign proteins and alloantigens as well as unidentified viruses in AHF, rendering continued use of the products extremely dangerous. AHF had previously been associated with chronic, active hepatitis, splenomegaly, lymphadenopathy, severe thrombocytopenia, T-cell abnormalities, and high levels of circulating immune complexes. Older hemophiliacs were at increased risk for full-blown AIDS. These facts indicated that the more AHF infused, the higher the risk of contracting AIDS.

110. On March 15, 1983, the CDC's Dr. Bruce Evatt had informed Cutter/Bayer that—based upon the observed T-cell abnormalities in hemophiliacs—he expected one half of hemophiliacs to develop full-blown AIDS. Cutter/Bayer, Baxter and other fractionators met with the FDA with a common goal of averting a complete recall—the only responsible option available to them.

111. Cutter's Dr. Akin did not reveal that Cutter/Bayer was using or had used a substantial amount of plasma from prisoners, known homosexuals with a Hepatitis B history, and

inner-city dwellers with a high risk for IV-drug abuse. These practices exponentially increased the AIDS and Hepatitis C risk, in direct contradiction to Cutter/Bayer's misrepresentation that it was taking all precautions to minimize AHF's health risks.

112. In the May 1983 ECHO, Cutter published an article called "AIDS, the Unfolding Story," in which this statement appeared: "In addition, NHF is working collaboratively with the CDC on a nationwide epidemiologic survey of all hemophilia treatment centers and affiliates and has obtained special federal funding for AIDS research for the CDC plus increased funding for NIH." This misleading statement did not reveal that the CDC and NHF's epidemiologic survey demonstrated that heavy Factor VIII users were displaying severe immune abnormalities and T-Cell imbalances—but cryoprecipitate users were not. The article did not disclose that by December 1982 the CDC considered these hemophiliacs to be at increased risk for AIDS because of the immune abnormalities reported in the survey. The statement was also misleading because the NHF was presented as an independent authority, when the NHF was essentially a conduit for industry views. In fact, a 1993 report by the National Institute of Health's Institute of Medicine concluded that the NHF had serious "conflicts of interest"—which precluded objective analysis—because of its "interdependence" with the Defendants.

113. In the May 1983 ECHO, Cutter also understated the AIDS risk by presenting the view of Dr. Louis Aledort, NHF Medical Co-Director and New York's Mount Sinai Hospital hemophilia treater. In the article, "Put AIDS Disease in Perspective," Dr. Aledort wrote: "AIDS should not be viewed as a "panic signal" or a reason to change a hemophilia patient's therapy." Cutter chose to print this statement in enlarged text. This statement falsely and misleadingly implied that therapy should remain the same—when many physicians had in fact already changed their patient's therapy based on scientific evidence that Factor VIII and IX were transmitting the AIDS virus. In short, by May 1983 there was substantial evidence to justify a change in therapy and a complete recall of unscreened Factor VIII.

114. Dr. Aledort's May 1983 ECHO article continued: "There is no evidence to support that AIDS is transmitted in either cryoprecipitate or concentrate, although it is possible." This statement directly contradicted the evidence which led the Public Health Service ("PHS") to

conclude—following the January 4, 1983 CDC meeting—that at-risk-for-AIDS donors should be identified and eliminated from the blood supply. The statement also ignored the March 24, 1983 PHS recommendations regarding blood and plasma donor mandatory screening guidelines to reduce the AIDS risk—because of the growing evidence that AHF transmitted the AIDS virus. It is also contrary to Dr. Aledort's repeated expert opinion—in sworn depositions and trial testimony—that progression to AIDS was associated with AHF use due to repeated exposure to foreign proteins and alloantigens in intermediate purity factor concentrates until 1984, when the AIDS virus was isolated and identified. (ECHO Magazine, May 1983 "Special AIDS Edition")

115. In the summer of 1983, Cutter conducted an AIDS Forum at the World Hemophilia Federation Meeting in Stockholm, Sweden. Cutter invited several hemophilia- treatment experts to participate and later published their "statements" in a pamphlet entitled "Cutter Forum: AIDS and Hemophilia Treatment." These "expert statements"—selected by Cutter—included: "The physician who wants to test a patient for AIDS runs the risk of putting the patient into a state of terror." "Many at the conference warned colleagues to avoid fueling patients' fears by giving them inconclusive data." "The major concern I have is that physicians or others who deliver healthcare will magnify the panic by telling patients they have 'pre AIDS' or AIDS, based on the methodology we have used for the last four or five years in defining T-Cell populations." Another M.D. added, "With the anxiety our fellow physicians are causing patients, we're going to see more fear of AIDS than actual cases of AIDS." The statements attributed to these "experts" are misleading. In fact there was no medical or scientific support for any of the anonymous conclusions stated by the "M.D.s" in the article. By the summer of 1983, T-cell testing was sufficiently advanced so that it formed the basis of numerous reliable studies with conclusions about AIDS in hemophiliacs and other risk groups. For example, there was no scientific methodology supporting the statement that fear of AIDS would outnumber actual AIDS cases. Instead, Cutter's motive was to understate the risk and maintain sales, while continuing to conceal the use of high-risk plasma to manufacture Factor VIII and IX.

116. The Cutter 1983 "Forum" article also attributed this statement to an "expert" treater: "A physician who has dealt with AIDS directly also doubted the validity of T-Cell tests." This statement was false because by the summer of 1983, T-cell abnormalities over time were a clear

AIDS risk factor. The article also stated, "Another M.D. added, 'I have to sit down individually with all the patients and discuss the AIDS problem with them. But I stress that I am not very concerned because the majority of our hemophiliacs are not affected by it.'" This statement was very misleading because the growing epidemiological evidence—that hemophiliacs were coming down with AIDS—clearly supported the substantial AIDS risk associated with extensive AHF usage; And defendants knew the CDC had projected that half of all hemophiliacs would develop AIDS.

117. The Cutter 1983 "Forum" article went on to say: "One researcher put the situation into perspective this way: 'The very essence of our treatment programs could potentially be threatened by the fear of a disease that has not even killed ten hemophiliac people since 1982... I had eight patients die of trauma and cerebral hemorrhage last year, and I didn't have any die of AIDS. I think we have to remember that our patients are getting hit on the head or mugged, that they're falling down stairs, they're bleeding to death, and that those problems are much more immediate than anything having to do with AIDS.'" This statement was misleading because in the summer of 1983, Cutter conducted an analysis which acknowledged the risk that 2,000 to 5,000 United States hemophiliacs would die from AHF-transmitted AIDS.

118. The above statement misleadingly perpetuated the false dichotomy between the benefits of AHF therapy and the risk of AIDS. In fact, the benefits of such therapy could and should have been provided—with little or no AIDS risk—by avoiding high-risk homosexual and IV-drug user donors, treating plasma to kill viruses, and HBc testing. This statement also contradicted existing medical, scientific and epidemiological evidence at the time of the conference seminar on July 1, 1983. The AHF-related AIDS risk was already close to one in 100 for severe type-A hemophiliacs. If T-cell abnormalities were taken into consideration, the risk was closer to one out of two for heavy AHF users. And, as noted previously, the CDC had predicted several months before the Cutter Forum was published that 50% of hemophiliacs would suffer from full-blown AIDS. (Cutter document entitled "Cutter Forum, AIDS and Hemophilia Treatment" around July l, 1983)

119. In late October 1983, Cutter was notified that an Austin, Texas, plasma donor had died of AIDS within 30 days of his last donation. Because the donor's plasma had been manufactured into numerous Factor VIII and IX lots over the previous two years, Cutter ordered

those lots to be recalled. On November 1, 1983, Cutter issued a press release which assured that "No adverse reactions involving these lots have been reported." This statement misleadingly implied that the lots were safe when it was virtually impossible for Cutter to know whether or not any patients who had infused these lots had reported adverse reactions to their physicians. The AIDS donor's plasma was pooled—along with other plasma—for production of thousands of AHF doses with varying lot numbers. In fact, abnormal T-cell ratios, along with lymphadenopathy and numerous other side effects associated with a pre-AIDS condition, had undoubtedly been reported in some hemophiliacs who infused AHF lots containing the AIDS donor's plasma. The November 1983 press release added, "Although medical authorities consider the possibility of AIDS being transmitted through these products exceedingly remote, Cutter is taking the action on its own initiative as a precautionary measure." This statement is false because CDC health authorities had advised Cutter on March 15, 1983, that they expected one-half of the hemophilia patients who had infused AHF to develop full-blown AIDS. Cutter had been repeatedly advised by public health officials that the AIDS observed in at-risk-for-AIDS persons was only the "tip of the iceberg." Cutter had conducted its own in-house investigations entitled "AIDS scenarios" and concluded that a possible outcome would be full-blown AIDS in 5,000 U.S. hemophiliacs. The public health consensus was that hemophiliacs were at high-risk for contracting AIDS because of their AHF usage. Cutter was within days of applying to the FDA for a Factor VIII labeling change that would include a stronger warning. (Cutter Press Release dated November 1, 1983.)

120. Alpha, another fractionator, organized a seminar consisting of hemophilia treaters and CDC and NIH physicians in connection with a March 1983 American Blood Resources Association ("ABRA") meeting held in Puerto Rico—the "ABRA Plasma Forum." Cutter/Bayer, Baxter and other fractionators were ABRA members who attended the forum, and ABRA itself organized meetings of fractionators, including Cutter/Bayer and Baxter, to plan strategies to understate the AIDS risk. Alpha published excerpts from the 1983 Forum which understated AHF risks compared to other therapies, such as the statement attributed to the AHF's Dr. Lou Aledort: "[More recent, unpublished data show that immune system abnormalities develop in hemophiliacs no matter what sort of treatment they receive, concentrate or cryo, Factor VIII or IX, high doses or

low, and whether they are young or old, or whether their disease is mild, moderate or severe." Dr. Aledort also cautioned that "measuring T-Cell changes is technically difficult, and that the methodology used in some studies has been faulty." This statement contradicted the current medical and scientific evidence. Older, more severely factor-deficient hemophiliacs—who had used more AHF—were demonstrating more severe immune abnormalities and opportunistic infections. Factor VIII users, who were exposed to greater quantities of concentrate, were more immune suppressed than Factor IX users. Cryoprecipitate users had fewer immune abnormalities than either Factor VIII or IX users.

121. The 1983 Alpha/ABRA Forum included this remark attributed to Dr. Nemo: "It is not at all clear, Dr. Nemo said, that an infectious AIDS agent, if one exists, can be spread by blood products. The link between AIDS and its possible transmission by blood products is very tenuous indeed." By March 1983, Cutter/Bayer and Baxter knew that this statement was demonstrably false since the overwhelming scientific evidence supported the conclusion that AIDS was transmitted by blood products such as AHF. (Highlights from the 1983 ABRA Plasma Forum, A Professional Service of Alpha Therapeutic Corporation, March 1983.)

122. On or about December 15, 1983, fractionator Armour's Dr. Michael Rodell told federal Blood Product Advisory Committee (BPAC) members and FDA officials that the fractionators, including Baxter and Cutter/Bayer, wanted a three month deferral in implementation of any BPAC or FDA recommendations that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, all fractionators, including Baxter and Cutter/Bayer, had agreed to seek the three month hiatus as a "delaying tactic" against implementing the test. In other words, the deferral request was made in bad faith. (Cutter memorandum dated December 13, 1983.)

123. The September 1985 ECHO also contained numerous false and misleading statements. Cutter stated, "The ability to screen donors was hampered by not knowing what caused the disease. However, as soon as it became known that there was a possibility of transmitting AIDS through blood products, Cutter Laboratories began to screen donors in an effort to exclude any who were in the high risk groups." This statement was misleading because it was not necessary to

determine what actually caused Factor VIII to transmit AIDS in order to screen out high-risk-for-AIDS-transmission donors. On July 27, 1982, the CDC strongly suggested that AIDS had a viral etiology similar to Hepatitis B because of the risk groups involved. These risk groups comprised a substantial portion of Cutter's plasma donor sources. Cutter took no meaningful action to screen out donors at the highest risk for AIDS and Hepatitis C transmission at any time during the epidemic. In fact, throughout 1982, 1983, and 1984, they continued to market worldwide blood products containing these high-risk groups' plasma. Even more egregiously, Cutter and Baxter continued to market high-risk nonheat-treated AHF abroad after ceasing or winding down United States sales of such product in favor of vastly safer heat-treated product.

124. In the same ECHO issue, Cutter presented Dr. Margaret Hilgartner, a Cornell Medical Center hemophilia treater, who understated the AIDS risk and exaggerated the need for AHF: "The current risk of persons with hemophilia developing AIDS is directly related to their need for blood products to stop bleeding. The risk is extremely low. Although most persons with hemophilia who have been treated with concentrate and some who have been treated with cryoprecipitate have been exposed to the virus in the past, less than .1 percent of the 20,000 persons with hemophilia in the United States have developed AIDS." This statement was misleading for several reasons:

(1) The risk was very close to 1% for severe, Type-A hemophiliacs, who were the heaviest users and most likely to be exposed to HIV in Factor VIII. The CDC had reported 71 cases in such persons by September 1985. Since there were approximately 8,000 severe, Type-A hemophiliacs using AHF regularly, the risk was close to one in one hundred. A 1 % risk of contracting AIDS, a fatal disease, is not "low" as stated by Dr. Hilgartner. Cutter's medical director, Dr. George Akin, affirmed this misrepresentation in his forward to the Hilgartner article.

(2) The article did not disclose the CDC's Dr. Evatt's March 1983 report to the fractionators, including Cutter/Bayer and Baxter, at an ABRA meeting in which he projected that one half of all hemophiliacs would get full-blown AIDS based upon their known T-Cell abnormalities which were tied to Factor VIII exposure. (Cutter March 14, 1983 memorandum.)

125. As they had done throughout, the fractionators, including Cutter/Bayer and Baxter,

misleadingly represented that Factor VIII benefits outweighed AIDS and Hepatitis C risks, when, in fact, AHF benefits could and should have been provided with minimal risk through use of normal healthy donors and proper safety precautions.

126. In the September 1985 ECHO, Dr. Hilgartner further advised, "[A] positive test result does not mean that the person will actually get AIDS." This statement was misleading because no scientific basis existed in September 1985 to conclude that a positive ELISA test— the then-existing test for the presence of HIV antibodies—did or did not mean eventual full-blown AIDS in a patient; Dr. Hilgartner's statement created a false sense of security in hemophiliacs—even in view of a positive test result. In fact, AHF manufacturers knew that severe T-Cell abnormalities and a positive ELISA test were determined to be reliable HIV-infection predictors—with the potential for full-blown, and possibly fatal AIDS.

127. Dr. Hilgartner's article concluded, "There is no evidence to warrant changing the current use of Factor VIII or Factor IX." This statement was also false. In fact, the evidence was just the opposite: Nonheat-treated, intermediate purity products were known by September 1985 to be HIV contaminated due to CDC testing in the summer of 1984. These tests demonstrated that 70% of severe Type-A and 40% of Type-B hemophiliacs were HIV positive. In addition, Dr. Hilgartner had reported to the New York Academy of Sciences in 1983 that Factor VIII was associated with extremely serious side effects, including lymphocyte loss, thrombocytopenia, liver damage, renal failure, splenomegaly, and abnormally high levels of circulating immune complexes. Many of these same diseases were reported in hemophiliac/AIDS victims. Thus, strong medical and scientific evidence indicated that continued use of nonheat-treated, intermediate purity factor concentrates should be avoided. (ECHO magazine Vol. 6, No. 3, dated September 1985.)

128. These facts demonstrate that the fractionators, including Cutter/Bayer and Baxter, jointly and individually, fraudulently misrepresented AHF's AIDS and Hepatitis C health risks, failed to disclose accurate warnings of the health risk to Plaintiffs or their physicians, and fraudulently purported to be improving safety and minimizing health—when in fact they were maximizing the risk (1) by recruiting high-risk donors, (2) by resisting and obstructing HBc testing, and (3) by failing to implement viral inactivation treatments and other measures that would truly have reduced the risk.

DEFENDANTS' ACTIVITIES DID NOT COMPLY WITH THE STANDARD OF CARE SET FORTH IN APPLICABLE FEDERAL REGULATIONS

129. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq. 21 U.S.C. § 331(b) prohibits "adulteration or misbranding of any ... drug, ..." 21 U.S.C. § 351(a)(2)(B) provides that "[a] drug . . . shall be deemed to be adulterated . . . if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ." 21 U.S.C. § 352 provides that "[a] drug... shall be deemed to be misbranded. .. if its labeling is false or misleading in any particular." 21 U.S.C. § 352(f)(2) provides that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use. .. where its use may be dangerous to health." 21 U.S.C. § 352(n) provides that a drug shall be deemed to be "misbranded" unless the labeling includes information concerning side effects and contraindications as required in federal regulations. 21 U.S.C. § 321(n) provides that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

130. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided mandatory warnings requirements—as concerns information to be included with the sale of Defendants' products—"Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved."

131. At all times material to this Complaint, 21 C.F.R. § 200.5 provided for special

informational mailings: "Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read."

132. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, et seq., set forth additional good manufacturing practices for blood and plasma biologicals.

133. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided: "Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective."

134. At all times material to this Complaint, 21 C.F.R. § 640.60 defined "Source Plasma (1-human)" as "the fluid portion of human blood which has been stabilized against clotting, collected by plasmapheresis, and is intended as source material for further manufacture into blood derivatives (a portion of pooled plasma separable by chemical means) intended for injection."

135. At all times material to this Complaint, 21 C.F.R. § 640.63©), entitled "Qualification of Donor," provided as to source plasma donors: "Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can he determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; ... ."

136. Further, 21 C.F.R. § 640.63(a) provided that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

137. At all times material to this Complaint, 21 C.F.R. § 606.140 provided: "Laboratory control procedures shall include: (a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to ensure that blood and blood components are safe, pure, potent and effective."

138. The foregoing statutes and regulations mandate the minimum standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX.. Defendants violated these regulations and/or failed to comply with applicable standards of care by: (a) marketing unsafe "adulterated" products by failing to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products by misleadingly failing to disclose/warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with the product; (d) failing to exclude unsuitable plasma donors—IV-drug users; (e) failing to exclude unsuitable donors—those with a viral Hepatitis history; (f) affirmatively soliciting unsuitable donors—those known to have viral Hepatitis antibodies and prisoners, who were known to have a high incidence of IV-drug abuse—for inclusion in plasma pools used to manufacture Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure their products' safety.

CONSPIRACY, CONCERT OF ACTION AND GROUP LIABILITY

139. Cutter/Bayer and Baxter, and fractionators Alpha and Armour (who are not defendants herein) and each of them, acted in concert and participated in a conscious and deliberate conspiracy to negligently, fraudulently, willfully, and wantonly disregard blood product users' rights and safety in the unsafe collection of constituent plasma and manufacture of AHF.

140. After 1978 four United States's corporations produced AHF. Two of these companies, Defendants Cutter/Bayer and Baxter, shipped AHF to Taiwan during the time frame material to this Complaint. Defendants Cutter/Bayer and Baxter, along with Alpha Therapeutic Corporation ("Alpha") and Armour Pharmaceutical Company ("Armour") tacitly and explicitly agreed to avoid upgrading industry standards. For example, the technology to virally inactivate AHF existed in the early 1970s but was not seriously investigated by Defendants or other fractionators until the early 1980s, despite its effective use in Europe. HBc antibody testing—to eliminate Hepatitis B-carrier donors and to identify donors with a viral Hepatitis history—was known science by 1978. The HBc test was reported to be an effective surrogate test for both AIDS transmission and NANB-Hepatitis carriers by 1982—neither Cutter/Bayer nor Baxter or any other fractionator

implemented this test until April 1984.

141. Cutter/Bayer and Baxter (and another fractionator) used donors from predominantly homosexual donor centers, prisons, and inner-city areas with the highest IV-drug abuse risk. After July 1982, when this conduct culminated in reported cases of fatal immune suppresion in three AHF-infusing hemophiliacs, this concert of action took on a more overt and active form.

142. By December 1982, the FDA demanded that fractionators, including Cutter/Bayer and Baxter, stop using plasma from prisoners, donors from hepatitis and AIDS-transmission high-risk areas, and known homosexuals. Rather than making good faith efforts to comply with the FDA requests, fractionators, including Cutter/Bayer and Baxter, collectively argued for a far less onerous and less effective donor screening program. They jointly proposed a donor-education system comprised of posting a placard in the donor center stating who were identified as AIDS-transmission risk groups and advising donors that members of these groups would be deferred. Later—in private—a donor would be required to complete a questionnaire. If the donor indicated he was in a high-risk group, he would be permanently deferred.

143. At a January 6, 1983 meeting of fractionators' trade association, the Biological Section of the Pharmaceutical Manufacturer's Association ("PMA"), fractionators, including Cutter and Baxter, agreed not to implement highly effective HBc donor screening, instead electing to implement less effective donor "screening" questionnaires that left open the possibility of donors' lying in order to continue to be paid for their plasma, thus failing to actually eliminate high-risk-for-AIDS-transmission donors. The fractionators, including Cutter/Bayer and Baxter, agreed to communicate with each other about what they were doing so that a consistent low standard of care could be maintained.

144. HBc testing had been strongly suggested by the CDC at the January 4, 1983 Public Health Service ("PHS") meeting. On January 14, 1983, fractionators, including Cutter/Bayer and Baxter, acted jointly to persuade the NHF not to advocate AIDS and Hepatitis C surrogate testing via the HBc test. Fractionators, including Cutter and Baxter, persuaded the NHF that HBc testing was in the "R and D" stage and not practical to implement at that time.

145. The fractionators, including Cutter/Bayer and Baxter, jointly agreed to oppose AHF

recall at the January 6, 1983, Pharmaceutical Manufacturers' Association ("PMA") meeting. Beginning with this meeting and continuing through at least July 19, 1983, fractionators, including Cutter/Bayer and Baxter, met at various times to prepare a strategy to prevent the FDA from advocating a far-reaching AHF recall. Defendants knew that their enormous pooling and blending of lots—resulting in lots averaging 12,000 to 30,000 donations, with some lots comprised of blended lot remnants ranging from 30,000 to over 50,000 donations of high-risk plasma—were causing their AHF to be contaminated with the AIDS agent. Nevertheless, fractionators, including Cutter/Bayer and Baxter, acted in concert and lobbied the FDA to issue recommendations limiting recalls to circumstances in which an identified donor had died of AIDS within a specified time after that donor's plasma had been pooled. The fractionators, including Cutter/Bayer and Baxter, were well aware that plasma from contaminated, asymptomatic donors—that was being mixed into huge plasma pools—was contaminating virtually every AHF lot. The fractionators, including Cutter/Bayer and Baxter, successfully deferred any FDA Blood Products Advisory Committee ("BPAC") recommendations for a general AHF recall at the July 19, 1983 BPAC meeting. This joint action allowed fractionators, including Cutter/Bayer and Baxter, to avoid ever recalling any product except when a donor died of AIDS.

146. Additionally, during the January 6, 1983 PMA meeting, the fractionators, including Cutter/Bayer and Baxter, proposed a unified strategy to deal with increasing AIDS-risk knowledge. The fractionators, including Cutter/Bayer and Baxter, agreed to postpone submitting any request to the FDA for permission to amend their warning labels or package inserts. They further agreed not to apply to the FDA for warnings enhancements until all four companies had agreed to apply for warning enhancements and to make the warnings similar in content. At the time of the meeting, the fractionators, including Cutter/Bayer and Baxter, had been informed by various reliable health authorities, including the PHS, of evidence linking AHF usage and AIDS-transmission.

147. On December 13, 1983, Cutter/Bayer's responsible head, Stephen Ojala, documented by written memorandum that the fractionators, including Cutter/Bayer and Baxter, had met and jointly agreed to propose a "study" of the HBc surrogate screening test, as a "delaying tactic" to avoid implementing the HBc test.

148. Thereafter, at various times throughout 1983-1985, the fractionators, including Cutter/Bayer and Baxter, attended meetings or otherwise communicated to assure joint efforts to avoid recalling product; to avoid warning patients of the true risk; to market product when sales dropped—due to information in the lay press linking AIDS transmission to AHF; to avoid recall of nonheat-treated product after heat-treated products were available; to avoid implementing HBc testing; and to coordinate a joint legal defense plan in anticipation of litigation by patients afflicted with AIDS through AHF usage. The fractionators, including Cutter/Bayer and Baxter, also operated through trade organizations—such as ABRA and PMA—to issue public statements minimizing AIDS and Hepatitis C risks and to over promote AHF benefits in order to achieve their financial goals.

149. Cutter/Bayer and Baxter are likely to have caused harm to Plaintiffs and thus are parties to this lawsuit because their unsafe, non-virally deactivated products were shipped to Taiwan through 1986.

150. Cutter/Bayer and Baxter's conduct with respect to their Factor VIII and Factor IX products products and related plasma-collection methods was tortious.

151. The harm to Plaintiffs resulted from the conduct of one or more of the Defendants and through no fault of the Plaintiffs. There may be uncertainty as to which one or combination of Defendants caused the harm. Thus, the burden of proof should be upon each Defendant to prove that that Defendant has not caused Plaintiffs' harm.

152. The fractionators, including Cutter/Bayer and Baxter, manufactured AHF using the same fractionation method. As such, during the relevant years from 1975 until 1985, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regard to brand names of the drugs.

153. Cutter/Bayer and Baxter's AHF during the relevant years from 1975 until 1985 contained the same design flaws: (1) AHF was manufactured from high-risk, HBV/HCV/HIV-transmitting, paid-donor plasma; (2) AHF was manufactured from multiple large plasma pools consisting of approximately 5,000 to each pool, with multiple pools being mixed to comprise single lots derived from 12,000 to 30,000 donations, and sometimes remnants of lots were blended

resulting in lots derived from over 50,000 donations—which further magnified viral-transmission risks.

154. AHF was not virally inactivated during this time period. Therefore, all AHF carried a significant viral-transmission risk. Additionally, Defendants' AHF was misbranded and mislabeled since it failed to warn of the known risks this complaint enumerates.

155. In large part because of the fungibility of Defendants' AHF, many hemophiliacs infused more than one Defendant's AHF during the time frame when all AHF was HCV and HIV-infected. It may not be possible to identify which Defendants' AHF actually caused each Plaintiff's infection. By suing the named Defendants, Plaintiffs have joined all those manufacturers who could have caused their HCV and/or HIV infection. Plaintiffs allege that Defendants have joint, several, and alternative liability for Plaintiffs' injuries.

156. Plaintiffs will make all reasonable efforts through discovery and use of experts to make a good faith determination as to which of the Defendants' product(s) caused their respective HCV and/or HIV infections. However, if it is not possible to make such a determination, Plaintiffs respectfully request that in the event that they prove that one or both Defendants breached a duty to a Plaintiff that caused his HIV and/or HCV infection—but which Defendants' product(s) caused this harm cannot be proven—the court-awarded damages consistent with each Defendant's market share at the relevant time.

CUTTER/BAYER AND BAXTER'S FRAUDULENT INDUCEMENT OF PLAINTIFFS TO ACCEPT A "HUMANITARIAN PAYMENT"

157. During 1997, Cutter/Bayer and Baxter began settlement negotiations with Taiwan's Ministry of Health and HIV-infected Taiwanese hemophiliacs who had infused contaminated AHF. A hemophiliac patient representative, Bayer's representatives and Karl Tzan, an attorney volunteer, participated in the negotiation which took place at the Ministry of Health in Taipei, Taiwan. Mr. Tzan was present only to assist with reviewing the settlement's wording and terms. The negotiation was based on a draft settlement prepared by Cutter/Bayer and/or Baxter. Mr. Tzan was unaware of the negligence and fraud described herein and would have opposed "Humanitarian Payment"

agreement had he known.

158. During the negotiations, Cutter/Bayer and/or Baxter advised that HIV contamination of AHF could not have been avoided or prevented due to the technology that was available at the time. Thus, Cutter/Bayer and/or Baxter advised that it had not been negligent in marketing and selling HIV-contaminated AHF to Taiwanese hemophiliacs. During the negotiations Cutter/Bayer and or Baxter did not produce any relevant internal documents to show that the company had not been negligent. Cutter/Bayer and/or Baxter advised that because the company had not been negligent, the payment offered was for humanitarian purposes only and not compensation for negligent acts.

159. According to the information made available to Taiwan's Department of Health in 1997, it was generally believed (1) that HIV-contamination of AHF—thereby transmitting the AIDS virus to hemophiliacs who infused AHF—was an unfortunate event that could not have been avoided; (2) that premature technology—which prevented the manufacture of safe, virus-free AHF—had caused hemophiliacs to become HIV infected; and (3) that AHF manufacturers were not liable for HIV infection of AHF-infusing hemophiliacs.

160. Based on the foregoing information, Taiwan's Ministry of Health requested a humanitarian payment from Cutter/Bayer and Baxter to assist hemophiliac AIDS patients. This payment was based on an alleged, open exchange between the parties—and the information Cutter/Bayer and/or Baxter provided to Taiwan's Department of Health—without any proof of Cutter/Bayer and/or Baxter's liability. Taiwan's Department of Health believed that the settlement was appropriate, fair and reasonable, based upon Bayer's representations. A settlement was reached in 1998 to pay each HIV-infected Taiwanese hemophiliac two million N.T. or approximately US $ 60,000.00. At the Taiwan government's recommendation, most of the Plaintiffs herein signed the settlement agreement, hereinafter referred to as the "Humanitarian Payment" agreement. Had Taiwan government officials, in particular, members of the Ministry of Health, known the facts alleged herein, they would not have recommended the "Humanitarian Payment" agreement to Taiwan's hemophiliacs and their families.

161. The 1998 Humanitarian Payment agreement provided that "[t]he manufacturers have

denied any legal responsibility for the infection incident of petitioners, but based on humanitarian considerations, will provide compensations to the petitioners." Further, the agreement provided "[i]f there is any part of this contract being considered ineffective, not executable, violating public order or law, and if that part is not a major consideration of both parties making this contract, the rest of the clauses are still considered effective." Finally, the agreement provided "[a]fter the manufacturers provided compensation to some of the petitioners conformed to this contract, if they later decide to raise the sum of compensation in item 1 of this contract or offer extra benefit to seek settlement with other petitioners for the infection incident, the manufacturers should also provide the same amount of added sum of money or extra benefit to the petitioners already paid."

162. On or about May 22, 2003, some Plaintiffs discovered—through the New York Times and Associated Press articles referenced herein—that the 1998 Humanitarian Payment agreement was procured by fraud, misrepresentation and/or deceit because Cutter/Bayer and Baxter, misleadingly, fraudulently, and deceitfully misrepresented and failed to disclose material facts upon which the settlement was based. The New York Times article, which was republished in Hong Kong's South China Morning Post, reported that Cutter/Bayer sold millions of dollars of AHF that carried a high risk of transmitting AIDS in Latin America and Asia—including Taiwan —while selling a new, safer product in the West. By selling older stocks of AHF, Cutter/Bayer was "trying to avoid being stuck with large stores of a product that was proving increasingly unmarketable in the United States and Europe." Allegations that Defendants continued shipping nonheat-treated AHF abroad and to Taiwan even after they stopped selling nonheat-treated AHF in the United States—found in previous paragraphs of this Complaint—are incorporated by reference as if fully set forth here.

163. These international and domestic news articles revealed that there was evidence indicating that at the time of the 1998 Humanitarian Payment agreement—in the period between 1997 and 1998—Cutter/Bayer and Baxter had deliberately concealed facts which indicated that they had knowledge that their nonheat-treated AHF was contaminated with the AIDS virus.

164. During the period of negotiation, on February 14, 1998, Cutter/Bayer fraudulently misrepresented in Taiwan's United Daily News that they "were not at fault on this issue" and "had

won all relevant cases worldwide" and deliberately concealed that the family of an Indiana hemophiliac who died from AIDS had won a US $2 million verdict against Bayer in March 1997. Moreover, Cutter/Bayer and Baxter fraudulently misrepresented during the period of negotiation that they were not legally responsible for the "incident infection" and deliberately concealed that Cutter/Bayer's national counsel had stipulated on January 28, 1997, in the Indiana litigation that during the 1970s Cutter Laboratories obtained plasma from high-risk sources to make AHF. Further, during the period of negotiation Cutter/Bayer and Baxter deliberately concealed that jurors in the Indiana litigation found that Cutter/Bayer had failed to warn that their AHF-manufacturing process carried a high risk of AIDS transmission.

165. Also, the February 14, 1998 news article indicates that Cutter/Bayer and/or Baxter resisted paying any compensation until Taiwanese Department of Health officials added pressure by suggesting that it would "suspend importation of Bayer's and Baxter's new medicines." Bayer's representative described the settlement negotiation as "dealing with the issue based on the perspective they were providing humanitarian aid, not compensation." This misrepresentation and pretense of "humanitarian aid" was used to prevent the Plaintiffs from filing lawsuits and discovering the Defendants' wrongdoing in using high-risk donors and failing to safely manufacture AHF.

166. Additionally, the February 14, 1998 news article states that "[t]he compensation shall not be different from other countries." However, upon information and belief, during the period of negotiation Cutter/Bayer and Baxter fraudulently misrepresented and failed to disclose that in 1996 they and other fractionators had reached a US$100,000/per infection class settlement with American hemophiliacs and that they had reached a US$450,000/per infection settlement with Japanese hemophiliacs. The 1998 Humanitarian Payment agreement to pay $60,000US was a little more than one half the lowest amount that had previously been paid.

167. During the settlement negotiations, Cutter/Bayer and Baxter misrepresented their legal responsibility by fraudulently concealing their high-risk plasma use during the early 1980s and failing to disclose that virtually all the AHF shipped during the relevant time period was HIV contaminated. For example, shipping records show that Cutter/Bayer AHF lots NC8530, NC9117, NC9139, NC8465, NC8466, NC8476, NC8493, 20A001, 20A004, 20A005,

50N003, 50N008, C1277, C1279, NC8351 and NC8383 were shipped to Taiwan during the relevant time period. Each of these lots included plasma from an average of 30 to 50 donors that had later tested HIV-positive, and during the settlement negotiation, Cutter/Bayer and/or Baxter knew or should have known this information—which they failed to disclose.

168. Additionally, during the settlement negotiations, Cutter/Bayer and/or Baxter misrepresented their legal liability by fraudulently concealing and failing to disclose that they had shipped a recalled AHF lot to Taiwan. On November 4, 1983, Cutter's Quality Recall Coordinator, Jean Huxsoll, notified Cutter personnel that a recall letter was being issued for Factor VIII and IX products which contained plasma from a donor who was diagnosed with AIDS after his last donation. According to Ms. Huxsoll, 51 million units of AHF were involved —including lots NC9117, NC8465, NC8466, NC8476, NC8493—all of which were distributed in Taiwan. Plaintiffs had no knowledge of this recall—either at the time of the recall or during the settlement negotiations and did not learn of this contaminated-AHF recall until after publication of the May 22, 2003 United Daily News article described herein. Moreover, Plaintiffs have recently learned that 2,542 units of recalled, HIV-contaminated AHF lot NC8493 were returned to Cutter by January 24, 1984. The very next day—January 25, 1984—Cutter shipped 810 units of that same recalled, HIV-contaminated lot—NC8493—to Taiwan.

169. Likewise, Plaintiffs have recently learned that although on March 15, 1984, Cutter ordered ordered the destruction of unpooled plasma from a donor found to have anal herpes and to be at risk for AIDS. However, this donor's plasma that had already been pooled was not destroyed and was used in manufacturing AHF lot 50N003. Units of 50N003 were shipped to Taiwan in June, July, August and September 1984—many months after Cutter knew or should have known that these lots—which included plasma likely to be HIV contaminated—should never have been manufactured in the first place and should have been destroyed instead of being shipped to Taiwan.

170. During settlement negotiations Cutter/Bayer and/or Baxter misrepresented, concealed and failed to disclose (1) that they had actively solicited and paid high-risk donors for plasma which was used in manufacturing AHF by, for instance, advertising in gay magazines; (2) that they were seeking high-risk donors with high levels of antibodies needed for immunoglobulin

products; (3) that they were manufacturing multiple products—including AHF—from the same plasma pools; (4) that they were not using normal, healthy donor plasma to manufacture AHF; (5) that they were aware of the connection between high-risk plasma sources and the appearance of AIDS in hemophiliacs but concealed this connection to avoid alarming hemophiliacs and prevent a decrease in AHF sales; (6) that they had failed to use available technology to provide safer, cleaner, non-HIV-contaminated AHF. These allegations are further detailed in this Complaint's preceding paragraphs and are incorporated herein by reference.

171. The 1998 Humanitarian Payment agreement's paragraph 9 provides "[a]fter the manufacturers have provided compensation to some of the petitioners conformed to this contract, if they later decide to raise the sum of compensation in item 1 of this contract or offer extra benefit to seek settlement with other petitioners for the infection incident, the manufacturers should also provide the same amount of added sum of money or extra benefit to the petitioners already paid."

172. Since 1998, other hemophiliac petitioners have received settlements several times larger than that provided in the 1998 Humanitarian Payment agreement. Defendants have failed to provide commensurate compensation to the Taiwanese hemophiliacs who participated in the 1998 Humanitarian Payment agreement.

173. Defendants fraudulently induced Plaintiffs to enter into the 1998 Humanitarian Payment Payment agreement with promises made that they had no intention of performing. To this day, Defendants have failed to compensate Taiwanese hemophiliacs commensurately for the "infection incident" and to provide the "extra benefit" that has been offered to other similarly situated hemophiliacs for the "infection incident" in accordance with the terms of the 1998 Humanitarian Payment agreement, paragraph 9.

174. Plaintiffs justifiably relied to their detriment on Cutter/Bayer and/or Baxter's material misrepresentations, deceit and/or fraudulent conduct in covenanting to enter into the 1998 Humanitarian Payment agreement. Had Plaintiffs known the true facts they would not have entered into the contract.

TOLLING OF APPLICABLE STATUTES OF LIMITATION

175. Any and all potentially applicable statutes of limitations have been tolled by

Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation defenses. Such acts include but are not limited to intentionally covering up and refusing to disclose high-risk plasma use; selling known-to-be-contaminated AHF abroad and to Taiwan; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning AHF's HIV and HCV-transmission risks. Additionally, Plaintiffs are filing this action within one year of May 22, 2003, the first date that they could have discovered Defendants' fraudulent conduct, concealment and misrepresentation of material facts that formed the basis for the 1998 "Humanitarian Payment" agreement.

176. Because of their fraudulent concealment and misrepresentations alleged above, Defendants are estopped from relying on any statutes of limitation. Defendants were under a duty to disclose AHF's HIV and HCV-transmission risks because this is nonpublic information which they exclusively controlled; Defendants knew that this information—not readily available to Plaintiffs—was relevant and crucial to Plaintiffs in deciding whether to use Defendants' AHF.

177. Until very recently, and not earlier than May 22, 2003, Plaintiffs had no knowledge that Defendants had engaged in the wrongdoing alleged herein. Because of the fraudulent and active concealment of Defendants' wrongdoing including but not limited to deliberate efforts—which continue to this day—to give Plaintiffs the materially false impression that Defendants undertook all feasible safety precautions to reduce HIV and HCV-transmission risks from their contaminated AHF, Plaintiffs could not have previously discovered the wrongdoing by exercising reasonable, ordinary or due diligence prior to this time. Nor could Plaintiffs, as a practical matter, have taken legally effective action given the unavailability to them until very recently of evidence—internal memoranda and other documents (as generally described herein)—supporting their claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

CLAIMS FOR RELIEF

NEGLIGENCE

178. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully

set forth here and further alleges as follows:

179. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiffs and knew or should have known that Plaintiffs would use their Factor VIII and/or Factor IX blood products.

180. Defendants owed Plaintiffs a duty to exercise reasonable care in light of the generally recognized and prevailing best scientific knowledge.

181. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, the Defendants breached their duties to Plaintiffs. The following paragraphs summarize Defendants' breaches of duties to Plaintiffs and describe categories of acts or omissions constituting breaches of duty by Defendants; each and/or any of these acts or omissions establishes an independent basis for Defendants' liability in negligence:

182. Failure to exercise reasonable care in producing Factor VIII and Factor IX blood products that were free of viruses, including the HIV virus that causes AIDS and the HCV virus that causes Hepatitis C;

183. Failure to exercise reasonable care in assuring that only suitable plasma would be used in manufacturing Factor VIII and Factor IX blood products;

184. Failure to exercise reasonable care in testing plasma used in manufacturing Factor VIII and and Factor IX blood products for virus contamination;

185. Failure to exercise reasonable care in recruiting and screening donors of plasma used in manufacturing Factor VIII and Factor IX blood products;

186. Failure to employ anti-viral techniques, including heat treating, in the manufacture of Factor VIII and Factor IX blood products;

187. Over promotion of Factor VIII and Factor IX blood products;

188. Understating the relative value of hemophilia treatments that constituted alternatives to Defendants' Factor VIII and Factor IX blood products;

189. Failure to warn physicians, Plaintiffs, and the hemophilia community of the dangers associated with Factor VIII and Factor IX blood products and/or the viruses and foreign bodies contained within the plasma used in manufacturing Factor VIII and Factor IX blood products;

190. Failure to exercise reasonable care by complying with federal regulations then applicable to plasma collection and the manufacture of Factor VIII and Factor IX blood products;

191. Failure to exercise reasonable care in disseminating information about Defendant's methods of manufacturing Factor VIII and Factor IX blood products and the risks that were created by said methods; and

192. Failure to exercise reasonable care in recalling Factor VIII and Factor IX blood products.

193. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiffs and other hemophiliacs, would use and did use Defendants' Factor VIII and/or Factor IX products to the detriment of their health, safety and well-being.

194. As the direct, producing and legal cause and result of the Defendants' negligence, Plaintiffs have been injured and have incurred damages, including but not limited to permanent physical injuries to their person, medical and hospital expenses in the past, past disability, past loss of use of the body, past physical and mental pain and suffering, and will incur in the future medical and hospital expenses, permanent disability, future loss of use of the body, and future physical and mental pain and suffering and loss of the enjoyment of life. Plaintiffs herein who are wrongful death beneficiaries of decedents infected with HIV or HCV caused by Defendants have suffered and will suffer loss of support, services, society, companionship, guidance and all other available wrongful death damages. Decedents, through their successors in interest, suffered losses such as income, medical bills, and all other available survival action damages.

195. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

196. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and was such as warrants an award of punitive damages.

NEGLIGENCE PER SE

197. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege:

198. Defendants violated applicable federal statutes and regulations relating to prescription drugs. Plaintiffs are persons whom these statutes and regulations were meant to protect.

199. Defendants' violation of these statutes or regulations constitutes negligence per se.

200. Defendants' violation of these statutes or regulations was the direct, producing and legal cause of Plaintiffs' injuries and damages. As the direct, producing and legal cause and result of the Defendants' negligence, Plaintiffs have been injured and have incurred damages, including but not limited to permanent physical injuries to their persons, medical and hospital expenses in the past, past disability, past loss of use of the body, past physical and mental pain and suffering, and will incur in the future medical and hospital expenses, permanent disability, fixture loss of use of the body, and fixture physical and mental pain and suffering and loss of the enjoyment of life. Plaintiffs herein who are wrongful death beneficiaries of decedents infected with HIV or HCV caused by Defendants have suffered and will suffer loss of support, services, society, companionship, guidance and all other available wrongful death damages. Decedents, through their successors in interest, suffered losses such as income, medical bills, and all other available survival action damages.

201. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

202. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and was such as warrants an award of punitive damages.

FRAUDULENT OMISSION AND CONCEALMENT

203. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege:

204. Defendants had a confidential and special relationship with Plaintiffs due to (1) Defendants' vastly superior knowledge of the health and safety risks relating to Factor VIII and Factor IX, (2) Defendants' sole and/or superior knowledge of their dangerous and irresponsible plasma collection practices; and (3) Defendants' direct communications with the hemophiliac community through newsletters that purported to accurately convey the risk of AIDS. As a result,

Defendants had an affirmative duty to fully and adequately warn the hemophiliac community, including Plaintiffs and their physicians, of the true health and safety risks related to the Factor VIII and Factor IX blood products and constituent plasma and a duty to disclose their dangerous and irresponsible plasma collection practices. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the products to Plaintiffs and their physicians.

205. Misrepresentations made by the Defendants about the health and safety of their factor concentrate products independently imposed a duty upon Defendants to fully and accurately disclose to the hemophiliac community, including Plaintiffs and their physicians, the true health and safety risks related to Factor VIII and Factor IX and its constituent plasma and a duty to disclose their dangerous and irresponsible plasma collection practices.

206. In connection with their Factor VIII and Factor IX products, Defendants fraudulently and intentionally concealed important and material health and safety product risk information from Plaintiffs, the hemophiliac community, and their physicians, all as alleged in this Complaint.

207. Any of the following is sufficient to independently establish Defendants' liability for fraudulent omission and/or concealment:

208. Defendants fraudulently concealed the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with their Factor VIII and Factor IX blood products and related plasma collection activities;

209. Defendants fraudulently concealed their practice of using unsuitable plasma from unsuitable donors in the manufacture of Factor VIII and Factor IX blood products;

210. Defendants fraudulently concealed their practice of avoiding the use of available technology to detect viruses in Defendants' blood products and the components thereof;

211. Defendants fraudulently concealed their practice of avoiding the use of available technology to destroy viruses in Defendants' blood products and the components thereof;

212. Defendants fraudulently concealed information about the known comparative risks and benefits of the use of Factor VIII and Factor IX and the relative benefits and availability of

alternate products and therapies.

213. Defendants knew that Plaintiffs, the Taiwan hemophiliac community, and their physicians would regard the matters Defendants concealed to be important in determining their course of treatment, including their decision whether to use Factor VIII and/or Factor IX.

214. As a direct and proximate result of Defendants' fraudulent concealment and suppression of material health and safety risks relating to Factor VIII and Factor IX and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiffs have suffered and will continue to suffer injury, harm and economic loss. As the direct, producing and legal cause and result of the Defendants' fraudulent concealment and suppression of material health and safety risks relating to Factor VIII and Factor IX and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiffs have been injured and have incurred damages, including but not limited to permanent physical injuries to their persons, medical and hospital expenses in the past, past disability, past loss of use of the body, past physical and mental pain and suffering, and will incur in the future medical and hospital expenses, permanent disability, future loss of use of the body, and future physical and mental pain and suffering and loss of the enjoyment of life. Plaintiffs herein who are wrongful death beneficiaries of decedents infected with HIV or HCV caused by Defendants have suffered and will suffer loss of support, services, society, companionship, guidance and all other available wrongful death damages. Decedents, through their successors in interest, suffered losses such as income, medical bills, and all other available survival action damages.

215. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

216. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at the Plaintiffs and was such as warrants an award of punitive damages.

217. Plaintiffs are informed and believe that Defendants utilize retention policies that provide for scheduled destruction of documents and other items, which may result in the knowing, negligent, or inadvertent destruction of documents, data, and materials relevant and necessary to adjudication of this action, including, but not limited to, records identifying batch or lot numbers of

Defendants' products shipped to particular treatment facilities abroad, which may facilitate product tracing. This risk warrants an order from this Court that such evidence (including all documents, data compilations, and tangible things within the meaning of Rule 26 of the Federal Rules of Civil Procedure) be preserved and maintained for use in these proceedings.

BREACH OF IMPLIED WARRANTY

218. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege:

219. Defendants' factor concentrate products were intentionally designed, manufactured, promoted, distributed and sold to be introduced into the human body.

220. Defendants breached the implied warranties of merchantability and fitness because Defendants' factor concentrate products cannot pass without objection in the trade, are unsafe, are not merchantable, are unfit for their ordinary use when sold, and are not adequately packaged and labeled.

FRAUDULENT INDUCEMENT

221. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege:

222. Through the conduct described in the foregoing and subsequent paragraphs of this complaint Defendant materially breached their duties to Plaintiffs by:

223. Misrepresentation to Plaintiffs that no technology existed that would have prevented HIV-contaminated AHF.

224. Misrepresentation to Plaintiffs that at all times AHF was manufactured with the strictest standard of care.

225. Failure to advise Plaintiffs that AHF was manufactured using high-risk plasma from HIV-infected donors.

226. Failure to advise Plaintiffs that AHF was manufactured using plasma pools of thousands of donors.

227. Failure to advise Plaintiffs that virtually every nonheat-treated vial of AHF was HIV contaminated.

228. Failure to advise Plaintiffs that a significant "lag time" existed between when Defendants knew their AHF was HIV contaminated and when they were willing to provide safer AHF to Taiwan.

229. Misrepresentation to Plaintiffs that this was an unforeseeable and inevitable tragedy.

230. Misrepresentation to Plaintiffs that Defendants had won all relevant cases worldwide.

231. Deliberate concealment of US$2million verdict against Defendants Cutter/Bayer.

232. Deliberate concealment of the January 28, 1997, Cutter/Bayer stipulation that Cutter was using high-risk plasma.

233. Deliberate concealment of Indiana jury verdict stating that Cutter/Bayer failed to warn that their AHF-manufacturing process carried a high risk of AIDS transmission.

234. Deliberate concealment of material facts establishing that Defendants knew that their their nonheat-treated AHF was HIV-contaminated.

235. Deliberate concealment of material fact that HIV-contaminated, recalled lots of AHF were shipped to Taiwan.

236. Failure to advise Plaintiffs that technology existed that would have prevented HIV-contaminated AHF.

237. Misrepresentation to Plaintiffs that Defendants had intentionally sold nonheat-treated and HIV-contaminated AHF in Taiwan.

238. Failure to advise and disclose that Defendants were marketing nonheat-treated AHF to Taiwan at a time when nonheat-treated AHF was ceasing to be marketing in the U.S.

239. Defendants' fraud, concealment, misrepresentation, and unfulfilled promises, with the intent to deceive, fraudulently induced Plaintiffs to enter into the 1998 Humanitarian Payment agreement. Defendants suggested facts which were not true and positively asserted facts in a manner that were not warranted by the information known at the time. Defendants knew and suppressed the true facts.

240. As a result, Plaintiffs have been injured and have incurred damages. They are therefore entitled to seek damages in an amount to be proven at trial, together with interest and

costs.

241. Defendants' conduct was malicious, intentional, outrageous and constituted willful and wanton disregard for the rights of others. Such conduct was specifically directed at Plaintiffs and as such warrants an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

1. For compensatory damages sustained by Plaintiffs against all Defendants, jointly and severally, in an amount to be determined at trial;

2. For punitive and exemplary damages according to proof against all Defendants;

3. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees;

4. For damages resulting from Defendants' fraudulent misrepresentations and non-disclosures for the purpose of inducing Plaintiffs to enter into the 1998 Humanitarian Payment agreement;

5. For injunctive relief in the form of an order requiring Defendants to preserve all relevant documents; and

6. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

Dated: May 24, 2004

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PLAINTIFFS DEMAND A TRIAL BY JURY

Dated: May 24, 2004

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