IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GARY SAVAGE **50 Irving Street NW** **Washington, D.C. 20422**	:	**CASE NO.:** **JUDGE:** **JURY TRIAL DEMANDED**
Plaintiff,	:	
vs	:	CASE NUMBER 1:06CV00081 JUDGE: Royce C. Lamberth DECK TYPE: Personal Injury/Malpractic DATE STAMP: 01/17/2006
BIOPORT, INC. **3500 Martin Luther King Jr., Blvd** **Lansing, MI 48906**	:	
Defendant.	:	

JURY ACTION

COMPLAINT

PARTIES

1. Plaintiff Gary Savage is a resident of the District of Columbia where he resides at a Veteran's Medical Facility for treatment for injuries arising out of this matter. If he was not a patient at this facility he would remain a resident of the District of Columbia residing at 221 Rock Creek Church Road NW Washington, D.C. 20011.

2. Defendant BioPort, Inc. ("BioPort"), a Michigan corporation with its principal place of business located at 3500 Martin Luther King, Jr. Blvd., Lansing, Michigan 48906, is currently the sole manufacturer, designer, distributor, producer and seller of anthrax vaccine adsorbed ("A V A "), and does substantial and continuing business with the United States Department of Defense ("DOD.")

JURISDICTION AND VENUE

3. This Court has diversity jurisdiction based upon 28 U.S.C. 1332 of the United States Code.

4. Venue is proper because plaintiff is a resident of the District of Columbia and the defendant does business within the District of Columbia, including but not limited to the vaccination of

various service members with the defendant's product who are stationed and reside within the District of Columbia at facilities such as Fort McNair in the District of Columbia.

BACKGROUND FACTUAL ALLEGATIONS

5. The first anthrax vaccine was created in the 1950s as a way to protect animals from the deadly disease of cutaneous anthrax, the form of anthrax infection that occurs though the skin; humans can become infected with cutaneous anthrax by handling products from infected animals.

6. Another form of anthrax infection is inhalation anthrax which occurs by inhaling anthrax spores. Anthrax has been seen as a likely biological weapon when inflicted as an airborne poison.

7. The AVA manufactured, designed, produced and sold by the defendants is a cell free filtrate, which means it uses dead bacteria as opposed to live bacteria and is a sterile product made from a strain of the anthrax organism that does not cause disease.

8. The AVA was not licensed and has never been licensed to protect people from inhalation anthrax.

9. The AVA was only licensed for protection against cutaneous exposure to anthrax and must be taken in six doses on an 18 month schedule followed by annual boosters.

10. In 1960, Dr. Phillip S. Brachman, Dr. Herman Gold, Dr. Stanley Plotkin, Dr. F. Robert Fekevy, Milton Werrin, and Dr. Norman Ingraham conducted an efficacy study for a cutaneous anthrax vaccine. Though this study was done on an earlier vaccine, it has been used to justify the vaccine's effectiveness today.

11. In 1962, in a report titled "Field Evaluation of Human Anthrax Vaccine," researchers reported that the vaccine was still highly effective for cutaneous anthrax, though the case study focused only on local and systematic reactions and not long term adverse effects.

12. Before the AVA was licensed, the Centers for Disease Control performed an observational study of the current vaccine in order to demonstrate its safety. The investigators performed active surveillance for local vaccine reactions only, at 24 and 48 hours after administering the vaccine, but paid only cursory attention to systematic reactions.

13. On November 2, 1970, the United States Public Health Service issued the AVA license to the state-owned facility operated by the MDPH for protection against cutaneous anthrax only. (A copy of the A V A product insert extract, December 1979, is attached as Exhibit AA.") This was two years before efficacy data were required for licensing by the FDA.

14. Prior to the issuance of the AVA license, experiments with the AVA were performed under a program called Operation Whitecoat at Fort Detrick, Maryland, which was initiated by the DoD. No records were taken to fully investigate long term effects of the AVA.

15. There had been no appropriate clinical trials of the AVA prior to the issuance of the license.

16. On 1985, the Division of Biologic Standards, currently named the Food and Drug Administration ("FDA"), began licensing vaccines, and it reassessed the AVA previously approved.

17. By the Mid 1980s, after the efficacy of the AVA was demonstrated for cutaneous anthrax, the FDA approved the AVA for two limited markets: (1) individuals who may come in contact with animal products or high-risk persons such as veterinarians and others handling potentially infected animals; and (2) individuals engaged in diagnostic or investigational activities using anthrax. (A copy of the AVA Product Insert, 1987, is attached as Exhibit "B.")

18. From 1970 to 1990, only a limited number of individuals received the AVA as reported by Dr. Kwai Chan's General Accounting Office report to Congress.

19. In 1985, the DoD issued a Request for Proposal ("RFP") soliciting the development of a new anthrax vaccine. The RFP stated that there was no vaccine in current use that would safely and effectively protect military personnel against exposure to anthrax. (See a copy of the RFP DAMD17-85-R-0078 attached as Exhibit "C.")

20. On December 13, 1985, the FDA published a Proposed Rule for a specific product review of the AVA, stating that the vaccine's "efficacy against inhalation anthrax is not well documented." (See copy of Federal Register dated December 13, 1985 attached as Exhibit "D.")

21. On August 24, 1989, Assistant Secretary of Defense Robert B. Barker wrote in a letter to Senator John Glenn that "current vaccines, particularly the anthrax vaccine do not readily lend themselves to use in mass troop immunizations for a variety of reasons... a higher than desirable rate of reactogenicity and, in some cases, lack of strong efficacy against infection by the aerosol route of exposure." (See copy of letter to Senator Glenn attached as Exhibit "E.")

22. In March 1990, Army doctors Col Takafuji and Col. Phillip K. Russell described the AVA as a "limited use vaccine" and an "unlicensed experimental vaccine" in an article, "Military Immunizations," in Infectious Disease Clinics of North America.

23. Predecessors to the defendant company continued to produce and sell AVA but could not and did not test AVA's safety or efficacy for inhalation anthrax.

24. Beginning in 1990, despite the absence of any proof of safety or efficacy of the AVA, about 150,000 U.S. troops and personnel received at least one dose of the AVA during Operations Desert Shield and Desert Storm, purportedly for the purpose of protection against inhalation anthrax if it were used as a biological weapon by Iraq.

25. In 1991, MBPI a predeccessor to the defendant company and the U.S. Army entered into an agreement for the manufacture of the AVA.

26. Army Secretary Michael P. W. Stone approved a request to indemnify MBPI against all liability arising from "the unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the AVA." The indemnification concerns were a result of the limited use of the vaccine on too small a scale to permit accurate assessments of types and severities of adverse reactions and insufficient experience in mass immunization programs to evaluate the efficacy of the vaccine.

27. After the war, thousands of the Gulf War veterans suffered from what is known as Gulf War Syndrome that, upon information and belief, is caused by AVA.

28. On November 26, 1993, the Pentagon's deliberative process of mass vaccination of military personnel with the AVA began with the development and implementation of DoD's Directive 6205.3, DoD Immunization Program for Biological Warfare Defense.

35. In 1995, MBPI was created by Executive Order of the Governor of the State of Michigan in order to make the move from state owned and operated to private ownership. On August 31, 1995, the FDA issued a warning letter to MBPI requiring it to remedy the violations at its facility.

29. In 1995, the Department of the Army contracted with the Science Applications International Corporation ("SAIC") to develop a plan to obtain FDA approval for a license amendment for the AVA in order to add inhalation anthrax exposure to the product license and to enable the defendant to list on the product license that the AVA was effective against inhalation anthrax. The SAIC license amendment plan states that the AVA is not licensed as protection for aerosol anthrax exposure as expected in a biological warfare environment. (See copy of October 5, 1995 License Amendment Plan attached as Exhibit "G.")

31. On October 20, 1995, the Army Joint Program Office for Biological Defense noted that there was insufficient data to demonstrate protection against inhalation anthrax.

32. In 1996, the DoD sought and received permission from the FDA to begin vaccinations of all military personnel without obtaining a new licensed indication for the AVA.

33. Although the FDA was required to inspect the anthrax portion of the manufacturing plant every two years, it did not fulfill this obligation, but allowed the U.s. Army to perform its own inspections, which allowed MBPI to remain in business.

34. Once the FDA finally went into the facility, it found that the facility was not up to FDA standards; eleven lots of the vaccine were quarantined; and the use of prophylaxis against biological warfare was not an FDA approved indication for the vaccine. MBPI had to shut down for major repairs and renovations.

35. On September 20, 1996, as part of the Army/SAIC plan, MBPI submitted an IND application in order to modify the product's license to add an indication for inhalation anthrax. This IND application for license modification for inhalation anthrax has been supplemented and remains current and pending.

36. In 1997, MBPI executed another U.S. Army contract in order to maintain the AVA stockpile.

37. On March 11, 1997, even with the new contract, the FDA sent MBPI a Notice of Intention to Revoke because no real changes had been made to the facility.

38. On November 27, 1997, MBPI failed another FDA inspection.

39. Less then a month later, Secretary of Defense William Cohen announced the Anthrax Vaccination Immunization Program (AVIP) for all U.S. military personnel on December 15, 1997.

40. The AVIP that began in December 1997, intended to immunize over 2.4 million members of the military against the hypothetical threat of inhalation anthrax as a biological weapon.

41. The program required that between 1997 and 2003, all military personnel, including all new recruits, would begin receiving the six-shot series of the anthrax vaccination in the following inoculation program: (I) Phase I: Forces assigned now or rotating to high threat areas in Southwest Asia and Korea; (2) Phase 2: Early deploying forces into high threat areas; (3) Phase 3: Remainder of the force and new recruits; and (4) Phase 4: To Continue the Program, annual booster shots.

42. On February 20, 1998, the FDA issued a report finding that the manufacturing process for Anthrax was not validated and listed 11 pages of quality-control failures for anthrax vaccine production, including reuse of expired vaccine, grossly inadequate testing, and use of lots that failed testing.

43. Despite this report, the immunizations began in March 1998.

44. In April 1998, Army Secretary Togo West, Jr. took steps to approve a request to indemnify MBPI against all liability arising from "the unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the AVA." The indemnification concerns, according to Secretary West, were a result of the limited use of the vaccine on too small a scale to permit accurate assessments of types and severities of adverse reactions and, insufficient experience in mass immunization programs to evaluate the efficacy of the vaccine.

45. The inoculations were non-voluntary, and any soldier who refused the inoculations was disciplined.

46. No soldier was informed that the A V A for inhalation anthrax was unlicensed for use to prevent inhalation anthrax and no animal studies or human clinical trials demonstrated either safety or efficacy of the vaccine.

47. On September 4, 1998, BioPort purchased MBPI for approximately $24 million. BioPort's shares are owned by Intervac, LLC and Michigan Biologic Products, Inc., which is composed of MBPI's former lab directors.

48. BioPort became the sole licensed producer of the A V A in the United States by way of a privatization process initiated by the State of Michigan.

49. Within weeks after BioPort's purchase of MBPI, BioPort received a $29.4 million dollar contract with the DoD to supply 8.7 million doses of the A V A at a price of $4.36 per dose.

50. In 1999, BioPort was still unable to ship the A V A, and at BioPort's request, the DoD restructured BioPort's contract, providing BioPort with $24.1 million in relief, reducing the number of doses demanded to 4.6 million, and agreeing to raise the price per dose to $10.64.

51. On September 29, 1999, Dr. Kathryn Zoon wrote to Dr. Sue Bailey, Assistant Secretary of Defense Health Affairs, reiterating her position that the "VIP follow the FDA approved schedule.

52. In November 1999, BioPort's manufacturing plant was found to have about thirty (30) deficiencies in safety, sterility and consistency.

53. On March 22, 2000, Office of Inspector General, DoD, issued an audit report D-2000- 105, reporting that over $2 million in taxpayer funds advanced to BioPort was not spent on improvements to vaccine production but spent on office remodeling, furniture for the CEO, parking lot re-paving, unwarranted travel expenses, unsubstantiated consulting costs, and an unrelated medical program. Additionally, senior managers planned on rewarding

themselves $1.2 million in bonuses and a retired employee is collecting $10,000/month in severance and consulting fees.

54. On April 3, 2000, the Full Committee on Government Reform adopted the Subcommittee report recommending suspension of the AVIP.

55. As of April 12, 2000, 425,976 service members had received 1,620,793 doses of AVA.

56. In June 2000, the DoD had to curtail the anthrax program because of vaccine shortages at BioPort, forcing some soldiers to actually suspend vaccination mid-process. Still, BioPort was awarded a new contract which provided for $2 -$2.5 million per month to cover costs related to getting the company to pass FDA approval of renovated anthrax production facilities.

57. In August 2000, BioPort voluntarily recalled the AVA because wrong expiration dates were put on the labels; at the same time, BioPort's scientists sought royalties for their part in changing the anthrax vaccination process.

58. The AVA stockpile was old and many lots had expired but had been re-dated, as if they were new, with only a retest of potency and some lots used on service members were produced with bovine materials of unknown origin and squalene.

59. The defendant were far out of compliance with good manufacturing practices and have never had their anthrax line properly inspected.

60. During the manufacturing process of the AVA, defendants mishandled and contaminated the AVA, and lots of the AVA were left out in the open for more than 24 hours.

61. Since 1998, the AVA shipments from BioPort have been suspended by the FDA because of questions about the facility's quality control.

62. According to the U.S. General Accounting Office, Medical Readiness: Safety and Efficacy of the Anthrax Vaccine, Report GAO/SSIAD-99-148, 1999, there have been no completed studies

of the long-term side effects of AVA using active surveillance and the rate of acute adverse reactions to the AVA has ranged from 30-70 percent. The DoD has admitted that 5-35 percent of vaccines report muscle aches, joint aches, headaches, rash, chills, fever, nausea, loss of appetite, malaise, or related symptoms shortly after vaccination.

63. In fact, FDA inspections have repeatedly shown that BioPort still cannot produce the same vaccine of the same potency and consistency twice in a row.

64. The AVA is unlicensed for its use to prevent inhalation anthrax, the FDA has never officially approved the AVA for use against inhalation anthrax, and no animal studies or human clinical trials demonstrate either safety or efficacy for such use.

SPECIFIC FACTUAL ALLEGATIONS

65 In late 2002, the plaintiff, was a member of the United States Army having rank of E-5 Sergeant, stationed at Fort Benning Georgia. Sgt. Savage had always been in excellent health.

66. Commencing in early November of 2002 and continuing until mid December of 2002 Sgt. Savage received a series of anthrax vaccinations manufactured by the defendant in anticipation of being shipped to Kuwait prior to the commencement of the war in Iraq in the spring of 2003. Sgt. Savage was scheduled to deploy to Kuwait in January 2003. During this time period. Sgt. Savage received three series of shots of the anthrax vaccine.

67. Late in 2002, Sgt. Savage began felling ill and while jogging at Fort Benning on January 4, 2003 he collapsed and was transported to the emergency room at Fort Benning. He was later admitted to the Martin Army Hospital at fort Benning.

68. Because his circumstances and health continued to deteriorate, Sgt. Savage was transferred to Walter Reed Army Medical Center in Washington D.C. on or about January 10, 2003. Upon

admission to Walter Reed, Sgt. Savage's initial diagnosis was encephalitis related to a gastrointestinal infection. For the first time on or about January 17, 2003 medical staff at Walter Reed informed the plaintiff's mother that his condition could be related to his receipt of the anthrax vaccine some weeks earlier. Soon thereafter, plaintiff lapsed into a comma.

69. Sgt Savage remained in a comma for many weeks and upon emerging from the comma, he was unable to walk, talk or care for himself for that matter. Since then, his condition has improved somewhat, but he remains in the care of the Veteran's Administration for injuries sustained after receiving the anthrax vaccine manufactured by the defendant.

COUNT ONE - NEGLIGENCE

70. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

71. Defendants were careless, negligent, breached its duties and obligations owed to Gary Savage by various sections of the Restatement of Torts, 2d, breached duties pursuant to Section 402(a) of the Restatement of Torts, 2d, and are liable for causing injuries to Gary Savage for the following reasons:

a. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product in a defective condition;

b. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was unreasonably dangerous to the user;

c. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was not safe for normal handling and consumption;

d. failing to have adequate warnings on the product;

e. failing to provide adequate warnings;

f. failing to provide instructions to be followed with regard to the use of this product;

g. failing to warn users of the dangers inherent in using this product;

h. failing to instruct users of this product on its safe use;

i. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which could have been designed more safely;

j. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which lacked all necessary safety features to protect users of said product;

k. failing to have proper warnings and instructions concerning the use of this product accompanying the same;

1. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product wherein it was foreseeable that someone would injure themselves based on the product's design and assembly;

m. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which could not be safe during normal use;

n. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was not safe for its intended use;

o. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was lacking of one or more elements necessary to make it safe for its intended use;

p. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was defective and which could cause injury to the user;

q. failing to exercise reasonable care in the design of this product;

r. failing to adequately and properly test said product;

s. failing to use reasonable care under the circumstances;

t. violation of Section 402(a) of the Restatement of Torts, 2d;

u. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which defendant knew or should have known would cause injury to the user;

v. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was defective and could cause injury to the user;

w. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product that defendant knew or should have known increased the risk of harm to the user;

x. failing to fix the conditions which increased the risk of harm to the users during the times when this product was serviced;

y. violation of application sections of the Restatement of Torts, 2d;

z. engaging in other acts regarding the manufacturing, designing, maintaining, preparing, producing, distributing, installing, advising and selling of this product as will be learned in discovery.

72. As a result of the carelessness and negligence of defendants, and their failure to conform to is obligations and duties as designers, manufacturers, producers, assemblers, distributors, suppliers, installers, services, and sellers under Section 402(a) of the Restatement of Torts, 2d, other sections of the Restatement of Torts, 2d, and at Common Law, Gary Savage was caused to suffer extreme pain and suffering and continues to do so.

73. As a result of the carelessness and negligence of defendants, in violation of Section 402(a) of the Restatement of Torts, 2d, other sections of the Restatement of Torts, 2d, and Common Law, Gary Savage incurred medical care and treatment and/or other financial expenses or losses for himself to her great detriment and expense.

WHEREFORE, Gary Savage demands judgment against defendants for a sum in excess of Ten Million ($10,000,000.00) Dollars in damages, punitive damages, attorneys fees, interest and cost of suit.

COUNT TWO - BREACH OF WARRANTIES

74. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

75. Defendants breached their expressed and implied warranties, that the AVA, designed, assembled, installed, produced, distributed, supplied, delivered, serviced and sold by them was safe and proper for its intended use, was designed and manufactured in accordance with prevailing and existing standards in the industry, and was properly and adequately manufactured, designed, maintained, prepared, produced, distributed, sold, installed and had proper warnings.

76. Defendants breached their expressed and implied warranties by designing, manufacturing, producing, servicing, assembling, distributing, delivering, installing, supplying, and selling the

AVA which was unsafe, defective, of non-merchantable quality and was not reasonably safe for its intended purpose or use.

77. Defendants breached their expressed and implied warranties, duties and obligations and thereby caused injury to Gary Savage, and did so by:

a. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product in a defective condition;

b. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was unreasonably dangerous to the user;

c. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was not safe for normal handling and consumption;

d. failing to have adequate warnings on the product;

e. failing to provide adequate warnings

f. failing to provide instructions to be followed with regard to the use of this product;

g. failing to warn users of the dangers inherent in using this product

h. failing to instruct users of this product on its safe use;

i. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which could have been designed more safely;

j. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which lacked all necessary safety features to protect users of said product;

k. failing to have proper warnings and instructions concerning the use of this product accompanying the same;

l. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product wherein it was foreseeable that someone would injure themselves based on the product's design and assembly;

m. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which could not be safe during normal use;

n. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was not safe for its intended use;

o. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was lacking of one or more elements necessary to make it safe for its intended use;

p. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was defective and which could cause injury to the user;

q. failing to exercise reasonable care in the design of this product;

r. failing to adequately and properly test said product;

s. failing to use reasonable care under the circumstances;

t. violation of Section 402(a) of the Restatement of Torts, 2d;

u. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which defendant knew or should have known would cause injury to the user;

v. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product which was defective and could cause injury to the user;

w. designing, manufacturing, producing, assembling, servicing, maintaining, distributing, delivering, selling and/or supplying a product that defendant knew or should have known increased the risk of harm to the user;

x. failing to fix the conditions which increased the risk of harm to the users during the times when this product was serviced;

y. violation of application sections of the Restatement of Torts, 2d;

z. engaging in other acts regarding the manufacturing, designing, maintaining, preparing, producing, distributing, installing, advising and selling of this product as will be learned in discovery .

78. As the manufacturer of the AVA, defendants have committed themselves to the responsibility of producing a safe and effective product that does what they claim.

79. Defendants broke this Agreement to make a quality vaccine.

80. Defendants did not produce the AVA to follow their claim to protect people from inhalation anthrax.

81. As a result of defendants' breach of their implied and expressed warranties, Gary Savage was caused to experience great pain and suffering and continues to experience great pain and suffering.

82. As a result of defendants' breach of expressed and implied warranties, Gary Savage incurred medical care and treatment and/or other financial expenses or losses, all to his great detriment and expense.

WHEREFORE, Gary Savage demands judgment against defendants for a sum in excess of Ten Million ($10,000,000.00) Dollars in damages, punitive damages, attorneys fees, interest and cost of suit.

COUNT THREE - STRICT PRODUCTS LIABILITY

83. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

84. Defendants manufactured and supplied the vaccine that caused great physical pain and suffering to Gary Savage.

85. Defendants breached their duties and obligations to Gary Savage by various sections of the Restatement of Torts, 2d, including Section 402 A and are liable for causing injuries to her by:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. failing to have adequate warnings on the product;

d. failing to warn users of the dangers inherent in using this product;

e. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

f. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

g. failing to ensure that ultimate users were advised of the dangers of said product;

h. failing to exercise reasonable care in the design of this product;

i. failing to adequately and properly test this product:

j. producing a product which was defective and could cause injury to the user;

k. supplying a product which was defective and could cause injury to the user;

l. failing to adequately and properly test the product after its design and manufacture;

m. failing to investigate and analyze prior adverse reactions and information in order to warn and/or notify ultimate users of the product defects and dangers.

86. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing injuries to Gary Savage.

WHEREFORE, plaintiff Gary Savage demands judgment against defendants for a sum in excess of Ten Million ($10,000,000.00) Dollars in damages, punitive damages, attorneys fees, interest and cost of suit.

PUNITIVE DAMAGES

87. Plaintiffs hereby incorporate all of the above Paragraphs as if each were set forth in full herein.

88. Defendants' actions were intentional, wanton, willful and outrageous.

89. Defendants were grossly negligent and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interest, welfare and safety of Gary Savage.

WHEREFORE, plaintiff Gary Savage demands judgment against defendants for a sum in excess of Ten Million ($10,000,000.00) Dollars in damages, punitive damages, attorneys fees, interest and cost of suit.

JURY TRIAL DEMAND

Please take notice that the plaintiffs demand a trial by jury as to all issues in the above matter.

Respectfully submitted,

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