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GAYTHA BRYANT,	:	SUPERIOR COURT OF NEW
	:	JERSEY
Plaintiff,	:	LAW DIVISION
	:	MIDDLESEX COUNTY
v.	:	
	:	DOCKET NO. _____
NOVARTIS AG, NOVARTIS	:	CIVIL ACTION
CONSUMER HEALTH, INC., CIBA	:	
GEIGY, CIBA PHARMACEUTICALS	:	COMPLAINT AND
CORP., CIBA SELF MEDICATION,	:	<u>DEMAND FOR JURY TRIAL</u>
INC. and DOES 1 THROUGH 50,	:	
Defendants.	:	
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INTRODUCTION

1. This action arises from the catastrophic neurological and bodily injuries sustained by Gaytha Bryant who suffered a debilitating stroke in April 1995 at the age of 39 after ingesting Acutrim II Maximum Strength ("Acutrim"). Acutrim was an Over-The-Counter ("OTC") diet medication manufactured and distributed by defendants which contained the dangerous active ingredient phenylpropanolamine ("PPA"). Although defendants knew of and had access to numerous reports and studies linking PPA to the risk of stroke, at no time did defendants warn Ms. Bryant of the known, or reasonably knowable, stroke risks associated with Acutrim containing PPA. As a result, Ms. Bryant -- who at the time was only 39 years old and was in good health -- took Acutrim containing PPA and suffered a devastating hemorrhagic stroke which required her to be

hospitalized and to undergo dangerous and invasive surgery. She is now paralyzed on her left side, totally disabled and unable to work.

PARTIES

2. Plaintiff Gaytha Bryant is a resident of Doyline, Louisiana who was employed full-time and in excellent health before suffering the devastating stroke caused by defendants' Acutrim product.

3. Defendant Novartis AG ("Novartis") is a corporation organized and existing under the laws of Switzerland with its principal place of business in the United States at 564 Morris Avenue, Summit, New Jersey.

4. Novartis was formed in April 1996 when Sandoz Pharmaceuticals Corp. merged with defendant Ciba-Geigy Corp. ("Ciba-Geigy"). Following that merger, Novartis continued the business operations of Ciba Geigy, assumed all of the debts, obligations and liabilities of Ciba Geigy and continued to manufacture, market and distribute the Acutrim line of products.

5. Defendant Novartis Consumer Health, Inc. ("Novartis Consumer") is a Delaware corporation with its principal place of business at 560 Morris Avenue, Summit, New Jersey. At all relevant times, defendant Novartis Consumer has been authorized to and has conducted business in New Jersey.

6. As successors -in-interest to the Acutrim brand and line of products, defendants Novartis and Novartis Consumer continued the business operations of the Ciba Defendants (defined below), including the Acutrim line of products, manufactured, marketed and distributed Acutrim, and assumed all the debts, obligations and liabilities associated with Acutrim and the Acutrim line of products.

7. At all relevant times defendants Ciba Geigy, Ciba Consumer Pharmaceuticals Corp. ("Ciba Consumer"), and Ciba Self Medication, Inc. ("Ciba Self Medication") (collectively the "Ciba Defendants") were authorized to and did conduct business in New Jersey. Before April 1996, the Ciba Defendants maintained offices at 581 Main Street, Woodbridge, New Jersey. After the April 1996 merger that created Novartis, the Ciba Defendants maintained their principal place of business at 560 Morris Avenue, Summit, New Jersey. At all relevant times, the Ciba Defendants manufactured and distributed Acutrim containing PPA throughout the United States, including the Acutrim which Plaintiff ingested causing her injuries.

8. Plaintiff is unaware of the true names and capacities of the remaining defendants sued in this action by the fictitious names DOES 1 through 50. Plaintiff will amend this complaint when those names and those capacities are known to Plaintiff. Plaintiff is informed and believes that each of the fictitiously named defendants is in some manner responsible for the events and allegations set forth in this complaint.

Plaintiff Suffered A Debilitating Stroke After Ingesting PPA

9. Before suffering a stroke in April 1995, plaintiff was in excellent health with no preexisting medical problems. She was 39 years old and worked full time at Louisiana State University Medical Center. In April 1995, Ms. Bryant purchased OTC Acutrim containing PPA at K&B Drugs, 807 Humer Road in Minden, Louisiana and took the Acutrim for approximately six days for its intended use, in the manner intended and in the manner recommended.

10. After ingesting one dose of Acutrim on April 26, 1995, Plaintiff developed a severe headache, experienced excessive dry mouth and nervousness, and suffered a

hemorrhagic stroke. In a hemorrhagic stroke a blood vessel in the brain bursts, preventing normal blood flow and allowing blood to leak into an area of the brain and destroy it.

11. On April 26, 1995 Plaintiff was taken by ambulance to Minden Medical Center and then to Louisiana State University Medical Center.

12. On May 8, 1995, Plaintiff had painful, dangerous and invasive surgery performed as a result of the stroke caused by the Acutrim containing PPA and on August 21, 1995 underwent a second dangerous and painful surgery as a result of the stroke.

13. Almost six years after ingesting the unreasonably dangerous Acutrim containing PPA, Plaintiff continues to suffer from paralysis on her left side, is totally disabled and is unable to work as a result of the injuries to Plaintiff caused by Acutrim containing PPA.

PPA's Pharmacology and Popularity

14. The Acutrim which Plaintiff ingested contained PPA, which is a sympathomimetic amine¹ similar in structure and function to amphetamine and ephedrine. PPA was first synthesized in 1910 and was used in the early 1930 as an alternative to ephedrine in maintaining blood pressure after surgery.

15. In the United States PPA has been used in two primary over-the-counter ("OTC") markets: as a decongestant in cough and cold products, and as an appetite suppressant in diet pills such as Acutrim. PPA was first used as an appetite suppressant in 1972 in Dexatrim™ for weight loss.

¹ Amine refers to nitrogen containing compounds. Sympathomimetic refers to something that mimics the effects of impulses of adrenergic fibers on the sympathetic nervous system.

16. In 1938, the Food and Drug Administration ("FDA") was created as part of the enactment of the Federal Food, Drug and Cosmetic Act of 1938 (the "Act"), 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301 et seq. (2000)). Under the Act, new drugs required FDA approval. Existing drugs were "grandfathered" under the Act and thus exempted from the testimony requirements of new drugs. No proof of safety was required for grandfathered drugs. Because PPA was on the market as a decongestant since 1936, PPA was exempt from the new drug approval process.

17. In 1962, the Drug Amendments to the Act, Pub. L. No. 87-781, 76 Stat. 780, required proof of effectiveness for all new drugs, including those approved between 1938 and 1962. The pre-1938 drugs which were previously "grandfathered" under the Act, such as PPA, continued their exempt status.

18. The FDA regulates all OTC drugs, which are classified by the FDA as Category I (safe and effective); Category II (not safe and effective); or Category III (insufficient data to assess safety).

19. In 1972, the FDA began to review OTC drugs for classification. As an OTC product marketed before 1972, PPA was allowed to continue on the market until a "final monograph" relating to the drug's category became effective. However, the FDA never finalized a monograph for PPA because of concerns about reports of hemorrhagic stroke associated with using this drug. Accordingly, PPA was never classified by the FDA as a Category I (safe and effective) OTC drug.

PPA's Association With Risk of Hemorrhagic Stroke

20. For more than twenty years, the OTC pharmaceutical industry (including the Novartis Defendants and the Ciba Defendants and their predecessors) has been aware

of reports of hemorrhagic stroke associated with the use of PPA. In fact, published reports of PPA use associated with hypertension (increased blood pressure) date back over thirty years. See Humberstone (1969) and Cuthbert (1969).

21. Since 1979, there have been over 30 published case reports in the respected medical literature concerning stroke and PPA ingestion, often after the "first use" of the product. A number of these authors, medical authorities and medical "Watch-Dog" agencies such as Public Citizen, called for the removal of PPA from the OTC market. Case reports and medical literature reviews of stroke after PPA exposure appearing in the scientific and medical literature include the following:

King (1979)
Elliot and White (1981)
Bernstein and Diskant (1982)
Johnson, Elter, and Reeves (1983)
Mueller (1983)
Pentel (1984)
Fallis and Fisher (1985)
Jackson (1985)
Kikta (1985)
McDowell (1985)
Stoessl (1985)
Edwards (1987)
Glick (1987)
Kase (1987)
Forman (1989)
Montalban (1989)
Barinagarmenteria, Mendez, et al. (1990)
Chung (1998)
Hamilton (2000)
Lake (2000)

22. In 1981, an editorial in the American Journal of Medicine and the consumer group Public Citizen recommended against PPA use in the OTC market because of safety risks, especially those related to hemorrhagic stroke.

23. In 1983, the FDA determined that PPA raises blood pressure and met with industry officials to discuss the need for more data to evaluate the safety concerns surrounding PPA and the associated life threatening adverse reactions including hypertension and stroke.

24. In 1984, the FDA banned the sale of products containing a combination of PPA and caffeine due to safety and health concerns.

25. In 1985, the FDA issued a tentative final monograph for classifying OTC nasal decongestants. PPA, however, was omitted from the monograph due to safety concerns.

26. In 1990, a subcommittee of the U.S. House of Representatives' Small Business Committee held hearings on diet drugs containing PPA. At the hearings, several scientific witnesses and one national society of physicians called for the removal of PPA from the OTC market because of safety and health concerns. After the hearings, the subcommittee's chairman, U.S. Representative Ron Wyden, wrote to the FDA expressing his concern about PPA and noted that an epidemiological study had demonstrated that PPA preparations led all other OTC products in the number of serious and fatal adverse effects in people under 29 years of age, as well as the number of contacts with Poison Control Centers each year.

27. Between 1969 and 1991, 29 cases of cerebro-vascular incidents associated with PPA use were reported to the FDA through its spontaneous adverse event reporting system. Of these 29 reports, 22 were hemorrhagic strokes associates with PPA use (16 appetite suppressant cases and 6 "cold" cases). Of these strokes, 55% occurred after just one dose of the PPA product.

28. In 1991, H.M. Johnson produced an internal report for the FDA that examined the reports of cerebro-vascular stroke in the FDA's spontaneous reporting system for PPA versus all other drugs for women (ages 10-59) for the period of 1969-1991. That analysis indicated that: cerebro-vascular stroke was the most common event for PPA - containing products; such events were also evident in cough-cold preparations; and such events were often associated with use of PPA products. Still, consumers were not being timely or adequately warned about the then-known association between PPA and stroke.

29. In 1991, the FDA held a public meeting to address the issues regarding the safety and effectiveness of PPA before publishing a final monograph for the drug. Reports of hemorrhagic stroke associated with PPA use were raised at the meeting.

30. Between 1991 and 2000, the FDA received an additional 22 reports of hemorrhagic strokes associated with PPA use (19 "cold and cough" cases and 3 appetite suppressant cases). Four of these consumers had died from their stroke injuries.

31. Thus, by the time Plaintiff ingested Acutrim, repeated reports of PPA-related hemorrhagic stroke had been made to the FDA. These numerous adverse reports were known, or should have known, to defendants as each participated in the distribution, marketing and sale of Acutrim and other PPA-laden products.

32. Despite the numerous published articles reporting hemorrhagic stroke in PPA users, the reports of adverse reactions of stroke in PPA users to the FDA, and the mounting concerns stated above, defendants marketed and distributed Acutrim containing PPA but never warned consumers, including Ms. Bryant, about the known risk of stroke associated with use of PPA.

The Yale Hemorrhagic Stroke Study

33. In March of 1993 the FDA issued a letter to the Nonprescription Drug Manufacturers Association outlining its concerns regarding the safety of PPA and informed the industry that it intended to classify PPA as a Category III (insufficient data) drug. To avoid this classification, manufacturers of PPA proposed a study, which later became known as the Yale Hemorrhagic Stroke Study (or "Yale Study"), to investigate the link between PPA and strokes. While the study was ongoing, the manufacturers were able to continue selling PPA products.

34. In 1992, the FDA began working with manufacturers of PPA and investigators at Yale University School Medicine to design the protocol for the Yale Study, a case-control epidemiological study.

35. The Yale Study, which was funded by the pharmaceutical industry, began in September 1994. It involved 702 patients and 11763 control subjects and was completed in June of 1999.

36. The Yale Study used epidemiological methodologies to confirm that the use of PPA substantially increases the statistical risk of hemorrhagic stroke. Use of PPA in an appetite suppressant was significantly associated with the risk of hemorrhagic stroke (odds ratio of 16.58). The "first use" of any PPA product involving "cough/cold" remedies was also associated with the risk of hemorrhagic stroke (odds ratio of 3.13).

37. Defendants were provided by Yale with the results of the Yale Study in the winter of 1999 and by the FDA with the final results in May of 2000.

38. On November 6, 2000, the summary results of the Yale Study appeared in the press. On December 21, 2000, the study and its results were published as an original,

lead article in the prestigious, peer-reviewed New England Journal of Medicine. Its authors concluded that the Yale Study, "provides strong epidemiological evidence of the association between the use of phenylpropanolamine and the risk of hemorrhagic stroke." Walter N. Keman et al., Phenylpropanolamine and the Risk of Hemorrhagic Stroke, 343 New Eng. J. Med. 1826, 1831 (2000).

39. Read in conjunction with the large body of prior published medical case reports, FDA adverse event reports and related clinical observations, the Yale Study establishes by every conventional legal criteria and standard the "general causation" principle: PPA causes hemorrhagic strokes in human beings.

The FDA Recommends That PPA Be Withdrawn from the Market

40. On October 19, 2000, members of the Non-Prescription Drugs Advisory Committee for the FDA's Center for Drug Evaluation and Research met to vote, in an advisory capacity, on the safety of PPA in light of the Yale Study findings. The 15 member panel voted overwhelmingly (13 in favor) that PPA was unsafe, and recommended to the FDA that PPA be removed from the marketplace.

41. On November 6, 2000, the FDA, in reliance upon its advisory committee, and the findings of the Yale Study, recommended that all makers of OTC pharmaceuticals that contain PPA voluntarily remove PPA from the pharmaceutical. The FDA also urged all manufacturers and sellers of OTC products containing PPA to cease immediately the distribution and sale of those products.

42. On the same day, the FDA's Nonprescription Drugs Advisory Committee issued the following advisory:

*Food and Drug Administration
Public Health Advisory*

*Subject: Safety of Phenylpropanolamine
November 6, 2000*

The Food and Drug Administration (FDA) is issuing a public health advisory concerning phenylpropanolamine hydrochloride. This drug is widely used as a nasal decongestant (in over-the-counter and prescription drug products) and for weight control (in over-the-counter drug products) FDA is taking steps to remove phenylpropanolamine from all drug products and has requested that all drug companies discontinue marketing products containing phenylpropanolamine.

Phenylpropanolamine has been marketed for many years. A recent study reported that taking phenylpropanolamine increases the risk of hemorrhagic stroke (bleeding into the brain or into tissue surrounding the brain) in women. Men may also be at risk. Although the risk of hemorrhagic stroke is very low, FDA recommends that consumers not use any products that contain phenylpropanolamine.

FDA's Nonprescription Drugs Advisory Committee (NDAC) recently discussed this study and other information on phenylpropanolamine NDAC determined that there is an association between phenylpropanolamine and hemorrhagic stroke and recommended that phenylpropanolamine not be considered safe for over-the-counter use.

Although this risk of hemorrhagic stroke is very low, FDA has significantly concerns because of the seriousness of a stroke and the inability to predict who is at risk. FDA does not consider the conditions for which phenylpropanolamine is used (over-the-counter or by prescription) as justifying the risk of this serious event. Other products are available for use.

In the meantime, consumers can identify over-the-counter cough-cold, nasal decongestant, and weight control products containing this ingredient by looking for "phenylpropanolamine" in the list of active ingredients on the label. Consumers can check with their health care provider or pharmacist to see whether their prescription cough-cold or nasal decongestant product contains phenylpropanolamine. We advise consumers to discuss alternative over-the-counter and prescription products with their health care provider or pharmacists.

43. FDA analysts, relying upon the Yale Study, estimate that 200 to 500 strokes occur per year in United States women age 18-49 resulting from ingestion of PPA products.

44. The FDA has concluded after internal and independent analysis that the Yale Study was "carefully designed," "conducted with great attention to detail," and constitutes a "careful analysis." Moreover, the FDA has confirmed the major findings of the Yale Study by conducting its own analysis of the epidemiological data. The FDA has concluded that the Yale Study "strongly supports" the working hypothesis that PPA use increases the risk of hemorrhagic stroke. Indeed, the FDA has concluded that the Yale Study results largely fulfill the criteria needed to establish "causality."

Defendants Withdraw and Reformulate Their PPA Products

45. On November 7, 2000, just one day after the FDA recommended that manufacturers remove PPA from the market, Novartis issued the following press release:

SUMMIT, N.J., Nov. 7/PRNewswire/ -- Novartis Consumer Health US is voluntarily withdrawing its phenylpropanolamine (PPA)- containing cold and allergy products from retail store shelves and has begun the process of reformulating all PPA-containing products. This is in response to an FDA request that companies "voluntarily discontinue marketing any drug products containing phenylpropanolamine" because of an alleged health risk to consumers. The Company has taken this action to ensure consumer confidence and trust when using Novartis Consumer Health products.

* * *

(emphasis supplied).

Defendants' Knowledge About The Risk of Stroke with Use of PPA

46. Defendants, as manufacturers and distributors of Acutrim, knew or should have known about the twenty-year history of numerous case reports in the medical literature establishing a meaningful clinical/medical association between PPA and the risk of hemorrhagic stroke, as well as from the fifty-plus adverse event reports filed with

the FDA, as well as numerous adverse reports from the Company's own internal safety surveillance database all of which related to hemorrhagic strokes arising from PPA exposure.

47. Defendants also were and are aware of the significant underreporting of adverse events associated with OTC drugs. The FDA has estimated that as few as 1% of all PPA-associated adverse events have been reported. Utilizing that learned estimate, the 44 FDA adverse reports between 1969 and 2000 which arose from cases of hemorrhagic strokes associated with PPA use would translate into 4400 such cases over the years in question.

48. Despite all of the foregoing knowledge, defendants failed to timely or adequately warn Plaintiff and the public about the risk of developing hemorrhagic stroke from Acutrim in violation of established regulations, including but not limited to 21 CFR § 330.10 ("Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs"), which under subpart (a)(4)(v), states as follows:

Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including the individuals of low comprehension, under customary conditions of purchase and use.

49. Indeed, when Ms. Bryant took the Acutrim which caused her stroke, Acutrim contained no warning at all about the risk of stroke associated with PPA.

50. Defendants' failure to warn violates 21 CFR § 369.10, which states:

Necessary warning statements should appear in the labeling prominently and conspicuously as compared to other words, statements, designs, and devices, and in bold type on clearly contrasting background, in order to comply with the provisions of section 502(c) and (f)(2) of the act. The warning statements should be placed in juxtaposition with the directions for use and, in any case, should appear on the label when there is sufficient label space in addition to mandatory label information.

51. Had defendants complied with 21 CFR § 330.10 and § 369.10 as well as other laws, by properly warning about the risk of hemorrhagic stroke associated with use of Acutrim containing PPA, neither plaintiff, nor any other reasonable person in plaintiff's position, would have ingested Acutrim as a diet aid or weight loss product. With timely and adequate warning of the known risks, plaintiff would have not suffered the debilitating stroke or the resulting paralysis and physical problems.

52. Well before Ms. Bryant's stroke, defendants had actual knowledge not only that PPA -- the active ingredient in Acutrim -- made Acutrim unreasonably dangerous, but more so, had actual knowledge of a safer alternative design in lieu of PPA. Despite this knowledge, and the reasonable ease and feasibility of substituting another product for PPA, defendants chose not to warn or to make a safer product. However, upon learning of the FDA's November 6, 2000 advisory, defendants reformulated Acutrim and their other products which contained PPA.

53. Based on the foregoing and other information known or reasonably knowable to defendants, Acutrim with PPA was an unreasonably dangerous drug which warranted removal from United States marketplace long before the date plaintiff was caused to suffer a hemorrhagic stroke.

COUNT I

(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

54. Plaintiff incorporates all the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

55. Defendants had a duty to warn Plaintiff of the risks and/or defects that were known or reasonably knowable with respect to Acutrim containing PPA.

56. Defendants, however, failed to warn Plaintiff of the defect until November 2000, only after Ms. Bryant took Acutrim and suffered a debilitating stroke.

57. The Acutrim which Plaintiff ingested was defective and unreasonably dangerous when defendants placed it into the stream of commerce because, among other things, it contained PPA and created an unreasonable risk of stroke. The Acutrim was also defective because it was unaccompanied by proper, adequate warnings of known or reasonably knowable risks. In addition, any warnings given did not accurately reflect the scope and severity of defects and the possible side effects.

58. Plaintiff used the Acutrim in a foreseeable manner.

59. Plaintiff's use of the Acutrim as the product was intended involved a substantial danger that the Acutrim would cause Plaintiff to experience a stroke and to suffer debilitating injury. This substantial danger was not readily recognizable to an ordinary consumer. Given defendants' knowledge when they manufactured and distributed Acutrim, and their knowledge before Plaintiff ingested Acutrim, defendants failed to adequately warn of the dangers involved that were known or reasonably knowable to defendants.

60. As a direct, proximate and legal result of defendants' failure to warn of the dangerous, defective nature of Acutrim, Plaintiff suffered debilitating injury and has suffered from, and continues to suffer from, the effects of the stroke, including paralysis on her left side.

61. Plaintiff has required, and will require additional, medical and/or hospital care, attention, and services as a result of defendants' defective Acutrim.

62. By reason of the foregoing, Plaintiff has been damaged in an amount to be determined at trial.

63. Defendants acted knowingly and/or with reckless or conscious disregard or actual malice for the rights and safety of Plaintiff by failing to warn of the known and/or reasonably knowable defects. Exemplary damages, therefore, are appropriate.

COUNT II

(STRICT PRODUCTS LIABILITY FOR MANUFACTURING DEFECT)

64. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

65. The Acutrim which Plaintiff ingested was defectively and unreasonably dangerous when defendants placed it into the stream of commerce.

66. Defendants knew or were reckless in not knowing that Acutrim was defective and unreasonably dangerous when it was placed in the stream of commerce and that the product would not be inspected for defects before Ms. Bryant ingested it.

67. As a direct, proximate and legal result of the dangerous, defective nature of the Acutrim, Ms. Bryant has suffered a debilitating stroke and has suffered from, and continues to suffer from, the devastating effects of that stroke.

68. By reason of the foregoing, Plaintiff has been damaged in an amount to be determined at trial.

69. Defendants acted knowingly and/or with reckless or conscious disregard or actual malice for the rights and safety of Plaintiff by failing to warn of the known and/or reasonably knowable defects. Exemplary damages, therefore, are appropriate.

COUNT III

(NEGLIGENCE PER SE)

70. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

71. Defendants have an obligation to not violate the law.

72. Defendants have violated the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., related amendments and codes, the federal regulations promulgated thereunder, and other applicable state and federal laws.

73. Plaintiff, as a purchaser and consumer of Acutrim, is within the class of persons the statutes described above are designed to protect. These statutes are designed to prevent injuries due to (1) the failure to adequately warn of known or reasonably knowable defects; or (2) the failure to disclose all adverse events or adverse event reports.

74. As a direct, proximate and legal result of Defendants' violations of the statutes described above, Plaintiff suffered, and continues to suffer debilitating injury.

75. Defendants are responsible to Plaintiff under the Doctrine of Negligence Per Se for injuries that Plaintiff incurred as a result of Defendants' acts and omissions which violated the statutes described above.

76. By reason of the foregoing, Plaintiff has been damaged in an amount to be determined at trial.

77. Defendants acted knowingly and/or with reckless or conscious disregard or actual malice for the rights and safety of Plaintiff by failing to warn of the known and/or reasonably knowable defects. Exemplary damages, therefore, are appropriate.

COUNT IV

(NEGLIGENCE)

78. Plaintiff hereby incorporates by reference, as if fully set forth herein, each allegation set forth above and further alleges as follows:

79. Defendants had a duty to exercise reasonable care in the design, testing, study, development, manufacture, promotion, sale, marketing and/or distribution of Acutrim. This duty included a duty to assure that that product did not cause users to suffer from unreasonably dangerous side effects and serious health problems which were foreseeable to defendants. Defendants also had a duty to warn of adverse drug reactions which they knew, or had reason to know, were inherent in the use of Acutrim containing PPA.

80. Before Plaintiff ingested Acutrim, defendants knew or should have known that there had been many case reports, adverse event reports and studies in the medical literature associating PPA with hemorrhagic stroke and that a safer, alternative design of Acutrim was available which eliminated PPA from Acutrim.

81. In light of their knowledge, Defendants had a duty to: (a) timely warn consumers of the known or suspected risks of, inter alia, hemorrhagic stroke arising from use of Acutrim containing PPA, (b) timely implement a safer, alternative design for

Acutrim; and (c) conduct further clinical trials and tests on animals and humans to determine the safety of PPA.

82. Defendants committed numerous acts of negligence in manufacturing, distributing and offering for sale the Acutrim ingested by Plaintiff, including, but not limited to the following:

- (a) failing to exercise reasonable care in the design, testing, study, development, manufacture, production, sale, marketing and/or distribution of Acutrim containing PPA;
- (b) failing to properly warn consumers of the actual and known risk of developing hemorrhagic stroke inherent in the use of Acutrim containing PPA;
- (c) failing to manufacture and distribute a safer alternative product, by eliminating PPA; and
- (d) promoting the use of Acutrim in a fraudulent manner, despite evidence as to its dangerousness due to its association with hemorrhagic stroke, without sufficient clinical trials and tests on animals and humans to determine the safety and effectiveness of Acutrim with PPA.

83. As a proximate result of the Defendants' negligence as well as the negligence of their agents and employees, Plaintiff developed a hemorrhagic stroke and has been seriously damaged. For such negligence, Plaintiff seeks all the damages to which plaintiff may be legally entitled.

84. Defendants acted knowingly and/or with reckless or conscious disregard or actual malice for the rights and safety of Plaintiff by failing to warn of the known and/or reasonably knowable defects. Exemplary damages, therefore, are appropriate.

COUNT V

(NEW JERSEY CONSUMER FRAUD ACT)

85. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:

86. Each defendant in its capacity as the manufacturers, distributors and marketers of Acutrim, is a "person" for the purposes of the Consumer Fraud Act, as codified in N.J.S.A. 56:8-1, *et seq.*

87. Plaintiff purchased and used Acutrim for personal use and suffered ascertainable loss as a result of defendants' action in violation of the Consumer Fraud Act.

88. OTC medication is "merchandise" as defined in N.J.S.A. 56:8-1(c).

89. Defendants violated the Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, as follows:

(a) Defendants engaged in unconscionable commercial practices, through deception, fraud, and making false promises and misrepresentations, including, but not limited to, the following:

(1) Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Acutrim containing PPA including, but not limited to, the risks of stroke. Furthermore, defendants have purposefully downplayed and/or understated the serious nature of the risks associated with Acutrim containing PPA;

- (2) Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Acutrim to and/or from the Federal Drug Administration ("FDA");
- (3) Defendants knew or should have known, and would have known, had appropriate testing been done, that the use of Acutrim containing PPA caused strokes;
- (4) Defendants engaged in calculated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding the use of Acutrim containing PPA, and did so because the prospect of huge future profits outweighed health and safety issues, all to the detriment of the public and the Plaintiff herein;
- (5) Defendants purposefully downplayed the side effects or provided misinformation about adverse reactions and potential harm from Acutrim containing PPA;
- (6) Defendants had a clear post-manufacture duty to warn which arose when they knew, or with reasonable care should have known, that Acutrim containing PPA was deadly or injurious.

90. Defendants breached their duty of care, constituting negligence, as follows:

- (a) Defendants failed to conduct adequate testing of the drug;
- (b) Defendants failed to properly monitor and evaluate the drug's effect;

- (c) Defendants concealed the clinical experience of the drug from the medical community and the public;
- (d) Defendants failed to fulfill the standard of care required of a reasonable, prudent pharmaceutical company engaged in the manufacture of a drug intended specifically for OTC use;
- (e) Defendants failed to adequately warn of the dangers which they knew or should have known that PPA posed;
- (f) Defendants failed to report adverse results of tests to the FDA, as required by law;
- (g) Defendants placed Acutrim with PPA in commerce for sale and recommended its use without providing adequate warning about the risks associated with its use;
- (h) Defendants failed to properly market, advertise or distribute the Acutrim containing PPA, an inherently dangerous product, when they knew or should have known that there existed dangers to users of Acutrim containing PPA arising from the foreseeable and recommended use of the product;
- (i) Defendants failed to disclose to the public, and to the Plaintiff, in particular, facts relative to Acutrim containing PPA being unsafe and a cause of dangerous side effects or complications, including stroke;
- (j) Defendants failed to heed or further investigate adverse reaction reports submitted by the medical community in order to determine whether Acutrim containing PPA should be withdrawn from the market.

91. Defendants' actions as set forth herein constitute knowing omission, suppression, or concealment of material facts, made with the intent that others will rely upon such concealment, suppression or omission, in connection with the marketing of Acutrim containing PPA in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, *et seq.*

92. Defendants' actions as described above evidence lack of good faith, honesty in fact and fair dealing so as to constitute an unconscionable commercial practice, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8, *et seq.*

93. Such unconscionable commercial practices made defendants liable to Plaintiff under N.J.S.A. 56:8-2, which provides that "[a]ny person violating the provisions of the act shall be liable for a refund of all moneys acquired by means of any practice declared to be unlawful."

94. As a proximate result of these violations of the Consumer Fraud Act, Plaintiff suffered ascertainable economic loss, including the purchase price of the Acutrim, costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Plaintiff's ingestion of a harmful and defective product.

95. As a direct and proximate result of Plaintiff's use of Acutrim containing PPA, Plaintiff suffered serious bodily injury, including suffering a stroke which led to partial paralysis and other physical and/or emotional conditions.

96. Defendants are further liable to Plaintiff for treble damages under N.J.S.A. 56:8-13, 19.

97. Plaintiff is also entitled to recover attorney's fees and costs, as well as treble damages, from defendants jointly and severally under N.J.S.A. 56:8-19.

COUNT VI

(NEW JERSEY PRODUCTS LIABILITY ACT)

98. Plaintiff incorporates by reference, as if fully set forth herein, each allegation set forth above and further alleges as follows:

99. Defendants are manufacturers and/or sellers of Acutrim within the meaning of N.J.S.A. 2A:58C-8.

100. The Acutrim manufactured and/or supplied by defendants was unaccompanied by proper warnings regarding all possible adverse side-effects associated with the use of Acutrim, and the comparative severity and duration of such adverse effects, and the warnings given did not accurately reflect the symptoms and/or scope of severity of the side effects.

101. Defendants failed to warn the FDA of material facts regarding the safety and efficacy of Acutrim containing PPA.

102. Defendants failed to perform adequate testing in that adequate testing would have shown that Acutrim containing PPA possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

103. The Acutrim manufactured and/or supplied by defendants was defective due to inadequate warnings to users or consumers of the product and defendants continued to promote the product aggressively after they knew or should have known of the risk of injury from using Acutrim containing PPA.

104. The Acutrim manufactured, supplied, and/or sold by defendants was defective in design or formulation in that when it left the hands of the manufacturer

and/or sellers, the foreseeable risks exceeded the benefits associated with the design or formulation.

105. Alternatively, the Acutrim manufactured, supplied and/or sold by defendants was defective in design or formulation in that when it left the hands of the manufacturer and/or supplier/seller, it was unreasonably dangerous, and was more dangerous than an ordinary consumer would expect.

106. The Acutrim manufactured, supplied and/or sold by defendants was defective in design due to inadequate warnings and/or inadequate testing.

107. The Acutrim manufactured and/or sold by defendants was defective in design due to inadequate post-marketing warning or instruction because, after defendants knew or should have known of the risk of injury from using Acutrim containing PPA, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

108. As a result of the defective condition of the Acutrim as manufactured and/or supplied by defendants, and defendants' failure to warn of the risk of harm resulting from consumption and use of Acutrim containing PPA, Plaintiff suffered serious bodily injury, including but not limited to suffering a stroke, partial paralysis and other physical and/or emotional conditions.

109. Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Acutrim containing PPA to and/or from the FDA, that had the FDA known of such facts, Acutrim containing PPA would have been withdrawn from the market.

110. Because defendants knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, punitive damages against defendants are warranted.

COUNT VII

BREACH OF WARRANTY

111. Plaintiff incorporates by reference, as if fully set forth herein, each allegation set forth above and further alleges as follows:

112. Defendants manufactured, sold, distributed, marketed and/or promoted the Acutrim that was ingested by Plaintiff before Plaintiff suffered a stroke.

113. The Acutrim ingested by Plaintiff which led to her stroke was expected to and did reach Plaintiff without a substantial change in condition.

114. Defendants, their agents and employees, in manufacturing, selling, distributing, supplying, marketing and/or promoting Acutrim expressly and impliedly warranted that Acutrim was not unreasonably dangerous and was merchantable and fit for its intended use by Plaintiff.

115. Defendants, their agents and employees, breached those warranties in that Acutrim was not merchantable, was unfit for its intended use, and was unreasonably dangerous in light of the risk of stroke associated with its use and in light of other risks of serious injuries to users.

116. Defendants, their agents and employees, also failed to provide adequate warnings with Acutrim rendering it unreasonably dangerous and unfit for the ordinary purposes for which it is used, in breach of those warranties.

117. As a direct and proximate result of defendants' breaches of warranty, warranties upon which plaintiff relied in taking Acutrim, Plaintiff developed a hemorrhagic stroke and was seriously damaged. For such breaches of warranty Plaintiff respectfully seeks all damages to which Plaintiff is legally entitled.

COUNT VIII

(INTENTIONAL MISREPRESENTATION AND FRAUD)

118. Plaintiff hereby incorporates by reference, as if fully set forth herein, each allegation set forth above and further alleges as follows:

119. When defendants manufactured, designed, marketed, sold, and distributed Acutrim for use by Plaintiff, defendants knew of the use for which Acutrim was intended and knew of the serious risks and dangers associated with such use of Acutrim containing PPA.

120. Defendants intentionally made false representations as to the risks and benefits of Acutrim with reckless indifference to the truth of such representations. Plaintiff relied on defendants' representations as to the risks and benefits of Acutrim containing PPA. Defendants' conduct was fraudulent.

121. As a direct and proximate result of defendants' intentional misrepresentations, Plaintiff suffered damages.

122. Defendants' acts and omissions toward Plaintiff were characterized by malice, evil motive, intent to injure, ill will, and fraud for which Plaintiff seeks the additional award of punitive damages.

COUNT IX

(NEGLIGENT MISREPRESENTATION)

123. Plaintiff hereby incorporates by reference, as if fully set forth herein, each allegation set forth above and further alleges as follows:

124. When defendants manufactured, designed, marketed, sold, and distributed Acutrim containing PPA for use by the Plaintiff, defendants knew or should have known of the use for which the product was intended and knew or should have known of the serious risks and dangers associated with such use of Acutrim containing PPA.

125. Defendants owed a duty to Plaintiff to accurately and truthfully represent the risks and benefits of Acutrim but defendants breached that duty by misrepresenting the risks and benefits of Acutrim.

126. As a direct and proximate result of such negligent misrepresentation by defendants, Plaintiff suffered damages.

COUNT X

(INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS)

127. Plaintiff hereby incorporates by reference each allegation set forth above, as though fully set out herein and further alleges as follows:

128. The acts, omissions, and representations of defendants in connection with the manufacturing, distribution, and marketing of Acutrim containing PPA as described above were intentional, reckless, extreme, and outrageous. As a result of such conduct, Plaintiff suffered severe emotional distress.

129. The aforesaid acts by defendants toward Plaintiff are characterized by malice, evil motive, intent to injure, ill will, and fraud for which the Plaintiff seeks the additional award of punitive damages.

REQUEST FOR RELIEF

130. WHEREFORE, Plaintiff demands judgment against Defendants and requests the following relief:

- (a) awarding Plaintiff compensatory damages;
- (b) awarding Plaintiff special damages according to the proof, including past, present and future medical expenses;
- (c) awarding Plaintiff punitive or exemplary damages;
- (d) awarding Plaintiff the costs and expenses of this suit, including attorneys' fees and expert fees;
- (e) awarding Plaintiff prejudgment and postjudgment interest at the highest rate allowed by law; and
- (f) awarding Plaintiff such other and further relief as may be just and proper.

JURY DEMAND

Plaintiff demands a trial on all issues triable by a jury in this action.

Dated: May 16, 2001

JOSEPH R. SANTOLI, ESQ.

By: _____
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CERTIFICATION PURSUANT TO RULE 4:5-1

Plaintiff is not aware of any other pending or contemplated action involving the matter in controversy in this action. Further, upon information and belief, Plaintiff is not aware of any other party who should be joined in this action.

JOSEPH R. SANTOLI, ESQ.

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Dated: May 16, 2001

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Joseph R. Santoli, Esq. and the law firm of Squitieri & Fearon, LLP are hereby designated as trial counsel in this matter.

JOSEPH R. SANTOLI, ESQ.

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