Plaintiff, vs. WYETH, and JOHN, JANE and JOE DOES 1-20, Defendants.	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY DOCKET NO. 7718-03 MT *Case Code: 240* CIVIL ACTION DIET DRUG LITIGATION JURY TRIAL DEMANDED

PLAINTIFFS' AMENDED
MASTER LONG FORM COMPLAINT

I. PARTIES

1. The Plaintiffs are individuals who have taken, ingested, used, and otherwise been exposed to the drugs fenfluramine, dexfenfluramine and phentermine. All reference to "Plaintiffs" herein is intended to incorporate all manners of reference to Plaintiff, in the singular or plural.

2. This Original and Master Complaint encompasses any claim a Plaintiff may have and pleads all facts generally for all diet drug claims, including a Primary Pulmonary Hypertension ("PPH") claim, an intermediate opt-out claim ("IOO"), or a back-end opt-out claim ("BEOO"). Plaintiffs have therefore incorporated all facts, theories of liability, and damages relevant to these three types of claims. Plaintiffs will, in the Short Form Complaint, select and indicate the appropriate parties, products, and theories of liability specific to their individual claims. In an IOO or BEOO case, Plaintiffs do not intend to pursue any theory of recovery or damages prohibited by the Nationwide Class Action Settlement Agreement.

3. Defendant, Wyeth, is a corporation organized and existing under the laws of the State of Delaware, and having its principal place of business in the State of New Jersey. At all relevant times, Defendant was in the business of promoting, marketing, manufacturing, and distributing the pharmaceutical products, fenfluramine and dexfenfluramine. At all relevant times, Defendant formulated, developed, manufactured, marketed, distributed, and/or sold the aforementioned drugs to several million consumers in the United States, including the State of New Jersey. Defendant Wyeth is the successor entity and assumes all liability for American Home Products Corporation,[1] A.H. Robbins Company, Inc., Wyeth-Ayerst Pharmaceuticals, Inc., and Wyeth, Laboratories, Inc. in Fen-Phen diet drug litigation. Further, upon information and belief, Defendant is the parent and/or successor entity for The Wyeth-Ayerst Laboratories Division of American Home Products Corporation. In light of the forgoing, any and all references to Defendant are references to each of the above named entities.

4. John Does 1-20 are unidentified fictitious healthcare providers, (hereinafter healthcare defendants) including, but limited to physicians, who at all times relevant hereto provided fenfluramine, dexfenfluramine and/or phentermine, to patients and/or consumers.

5. Jane Doe are fictitious pharmacies, who at all times relevant hereto sold and otherwise made fenfluramine, dexfenfluramine and/or phentermine available to consumers. 6. Joe Does are fictitious clinics and weight loss facilities who at all times relevant hereto either distributed, promoted the use of or otherwise supplied fenfluramine, dexfenfluramine and/or phentermine to consumers.

II. SUMMARY OF MEDICAL ISSUES

6. Plaintiffs were prescribed or otherwise provided fenfluramine and/or

[1]American Home Products Corporations had its headquarters in Madison, New Jersey.

dexfenfluramine alone, or in combination with phentermine, to help them lose weight. As a result of their ingestion of the diet drugs, Plaintiffs now suffer from valvular heart disease or primary pulmonary hypertension.

7. Valvular heart disease causes plaque to accumulate on the heart valves. The plaquened valves become sclerotic and fail to seal properly, resulting in the flow of blood backward through the heart. This phenomenon is known as regurgitation. The presence of regurgitation forces the heart to work harder to provide the body with blood. Over time, persons with regurgitation experience elevated pulmonary pressures, valve degeneration, and other irreversible physiological alterations in their heart, including an enlarged left atrium. Ultimately, regurgitation may necessitate open-heart surgery to replace and/or repair the damaged valves.

8. Primary pulmonary hypertension (PPH) is a rare, but often fatal, lung disease. Diet drug users with primary pulmonary hypertension die by suffocation, usually over a period of a few years.

III. FACTS COMMON TO ALL COUNTS

9. In 1990, the Food and Drug Administration (FDA) approved fenfluramine for use as weight a reduction drug for the short term medical management of obesity. From that time until it was withdrawn from the market, fenfluramine was prescribed and used in combination with the drug phentermine to maximize weight loss. This combination was commonly known as Fen Phen.

10. The "Fen" consists of fenfluramine (Pondimin), a drug that effects the serotonin levels in the brain. The "Phen" consists of phentermine, an amphetamine that helps the body burn calories faster and counteracts the drowsiness caused by the "Fen". Despite the fact that

concomitant use of fenfluramine and phentermine was never approved by the FDA, these drugs were widely prescribed for use in combination with each other and or dexfenfluramine (Redux), as promoters of weight loss.

11. Defendants undertook a marketing strategy including a massive advertising campaign to aggressively promote and sell these drugs.

12. Development, testing, labeling, marketing and promotion of Pondimin and Redux were made or approved at Defendant's corporate headquarters in Madison, New Jersey. Additionally, some of the events described herein occurred in whole or in part, at Defendant's offices in Parsippany, New Jersey.

DEFENDANT'S MARKETING CAMPAIGN

13. Plaintiffs suffer from the diseases described above, in part, as a result of Defendant's effective marketing campaign. Fenfluramine was marketed under the trade name Pondimin. Defendant also marketed dexfenfluramine, the *d*-isomer of fenfluramine that contains the same active ingredient as fenfluramine, under the trade name Redux.

14. To market its drugs, Defendant placed advertisements in popular publications and in the media touting for example the use of Pondimin as a safe and effective method of weight control. In their advertisements, Defendant cited internally funded, ghostwritten and unsubstantiated scientific studies in which the safety of Pondimin or Redux had never been tested. Defendant's marketing campaign was so successful, and these drugs so pervasively prescribed, that in excess of eighteen (18) million prescriptions for Pondimin and Redux were written in the United States in 1996 alone.

15. Defendant actively encouraged and/or failed to effectively discourage, use of the combinations of these drugs by employing and/or contracting with commission based salespersons to promote the widespread prescribing of Pondimin, the fen-phen combination and Redux to patients who were not clinically obese.

16. Beginning in the 1990s, Defendant's strategy was to aggressively market Pondimin by encouraging its use in combination with phentermine while misleading potential users about its' serious side-effects.

17. Defendant specifically advised its sales representatives not to discuss the potential of these drugs to cause Primary Pulmonary Hypertension unless it was specifically raised by the physician.

WYETH DOWNPLAYED THE HEALTH RISKS ASSOCIATED WITH FEN-PHEN USE

18. Defendant intentionally and negligently downplayed the health risks associated with these drugs. Specifically, Defendant's product inserts negligently misrepresented facts concerning Pondimin and/or Redux, including the following:

a. The existence of adequate safety testing of the combination use of pondimin and phentermine;

b. Knowledge concerning the adverse effects associated with the use of these diet drugs;

c. The relative risks associated with the drugs including the prevalence of pulmonary hypertension, primary pulmonary hypertension, and valvular heart disease.

19. Pondimin and Redux were finally withdrawn from the market on September 15, 1997 after being sold to millions of people.

20. Based on information it had of adverse event reports of the fatal effects of these diet drugs reported in Europe and elsewhere in the world, Defendant knew of the serious and fatal side effects of Pondimin and/or Redux many years before the diet drugs were withdrawn.

21. Defendant knew that its drugs caused the debilitating and deadly diseases of valvular heart disease and primary pulmonary hypertension (PPH). In 1965, the diet drug Aminorex was introduced in Europe. Aminorex was touted as a wonder weight loss drug that worked by increasing brain serotonin and inhibiting re-uptake of serotonin. Pondimin and Redux belong to the same family of drugs as Aminorex. By 1967, evidence began to surface that Aminorex was associated with pulmonary hypertension, ultimately resulting in a ten-fold increase in primary pulmonary hypertension cases (PPH). As a result, Aminorex was removed from the European market in 1972.

22. In 1973, Defendant introduced Pondimin, the brand name for fenfluramine, into the United States market. It has the same mechanism of action as Aminorex.

23. In the early 1980's, several studies were published linking fenfluramine with pulmonary hypertension including, *Pulmonary Hypertension and Fenfluramine* authored by Dr. J.G. Douglas and published in the BRITISH MEDICAL JOURNAL in, 1981. and an article titled *Irreversible Pulmonary Hypertension after Treatment with Fenfluramine*, published in the BRITISH MEDICAL JOURNAL on January 25, 1986,

24. In 1984, in a study funded by the defendant Wyeth, Dr. Michael Weintraub published *A Double-Blind Clinical Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in Combination* in the ARCHIVES OF INTERNAL MEDICINE. While Dr. Weintraub noted some adverse effects associated with Pondimin, he failed to examine the long-

term safety of Pondimin. Instead, Dr. Weintraub focused on the short-term effectiveness of the drug used individually and in combination with other drugs.

25. As early as 1990, Wyeth was advised that the labeling for Pondimin might need to be updated as it was drafted in 1972 some 18 years earlier. Despite this warning from the predecessor manufacturer of Pondimin, Defendant did not update the inaccurate primary pulmonary hypertension label until 1997, and did not add the risk of valvular heart disease to the label until only weeks before Pondimin was pulled from the market entirely.

26. In 1992, Defendant again paid Dr. Weintraub to publish a series of articles in CLINICAL PHARMACOLOGICAL THERAPIES in which he reported his "research" regarding the long term use of Pondimin and phentermine for weight control. Dr. Weintraub never actually researched Pondimin for its long-term effects or its safety. Despite the lack of research concerning Pondimin's safety, Defendant promoted Dr. Weintraub's conclusion to physicians and the public that long-term combination use of Pondimin and phentermine was safe and effective for the management of obesity.

27. Following the publication of these articles by Defendant's well-funded doctor, the sale of Pondimin skyrocketed. While Pondimin usage doubled each year after 1992, total revenues were increasing at an even greater rate because, as the demand surged, Defendant increased the price. Total revenue from Pondimin went from about $8.5 Million in 1994 to over $45 Million in 1995 to over $150 Million in 1996. In each of these years, gross profit on sales of Pondimin was in excess of 90%. Pondimin sales were growing at such a frenzied pace that at times Defendant could not make it fast enough to supply demand.

WYETH IGNORED REPORTS OF VHD

28. As sales increased, Defendant began receiving reports of valvular heart disease in patients taking Pondimin and/or Redux. Beginning in 1991, Defendant received reports of valvular heart disease occurring in Belgium. In March, April, and May of 1994 Defendant received additional reports of valvular heart disease associated with Pondimin use, five of which were received on April 19, 1994.

29. In 1995, Defendant received further information about valvular heart disease in Pondimin users, which no responsible pharmaceutical company could ignore - yet Defendant did just that. Defendant received follow up reports on 7 of the cases of valvular heart disease, which had originally been reported in 1994 and 6 new reports of valvular heart disease.

30. Thus, on a single day in January of 1995, Defendant's safety surveillance department received 13 reports of valvular heart disease in Pondimin users. Additional reports continued to be reported throughout January, February, July, and August of 1995.

31. Despite its knowledge of the reports of VHD, Defendant failed to investigate and/or conduct any testing and continued to market Pondimin without any additional warning.

32. By 1993, Defendant's labeling for Pondimin indicated that there were only four reported cases of pulmonary hypertension reported in association with the drug. Yet, that same year, in an article *Primary Pulmonary Hypertension and Fenfluramine Use* published in the BRITISH HEART JOURNAL, Dr. Brenot, its author identified 25 cases of primary pulmonary hypertension associated with the use of fenfluramine and/or dexfenfluramine. With such significant notice in a prominent medical publication, Defendant should have known that

Pondimin was unreasonably dangerous and that its labeling of Pondimin was false and misleading.

33. Defendant also failed to code these Adverse Drug Event reports appropriately so that valvular heart disease could be properly tracked and monitored. Up to and including September 1997, when the FDA asked Defendant to remove the drugs from the market, Defendant's tracking system contained no method by which Defendant could designate an adverse event of valvular heart disease. The manner in which Defendant's tracking system was set up made it impossible to code adverse events of valvular heart disease and report them to the FDA. Motivated by soaring profits, Defendant also labeled, or mis-labeled, VHD as "non-serious" to conceal the truth from the FDA, the public, and the physicians.

34. A particularly flagrant example of this type of intentional and negligent mischaracterization of its adverse event tracking was Defendant's treatment of a July 24, 1995 report that noted that a patient taking Pondimin experienced "aortic; mitral (stage 2/4); and tricuspid failure." Despite the fact this patient suffered failure of three out of her four heart valves, Defendant characterized this report as "non-serious" and did not report it to the FDA, the physicians, or the public.

WYETH IGNORES EVIDENCE OF ASSOCIATION OF DIET DRUGS WITH PPH

35. In a 1994 study, the International Primary Pulmonary Hypertension Study confirmed that fenfluramine-based anorexigens, such as Pondimin and Redux, dramatically increased the risk of primary pulmonary hypertension. Despite being aware of the preliminary

results, Defendant failed to apprise the public or physicians that the risk of pulmonary hypertension, primary pulmonary hypertension, or other cardio-valvular injury was many, many multiples of that previously reported by Defendant in its literature.

36. Defendant's knowledge was evident in its internal correspondence. For example, in a memo of June 24, 1994, Defendant's Safety Surveillance Monitor, Amy Myers, wrote to Defendant's Medical Monitor, Fred Wilson, that its database contained 37 cases of primary pulmonary hypertension associated with Pondimin. Despite this knowledge, Defendant concealed the number of cases of PPH associated with Pondimin.

37. In the summer of 1994, when Pondimin sales were sky-rocketing, Defendant acquired American Cyanamid, another pharmaceutical company that had previously acquired a license to market Redux in the U.S. and Canada, provided that the Redux New Drug Application (NDA) was approved by the FDA. With its acquisition of American Cyanamid, Defendant also acquired the rights to market Redux in the U.S. By fall of 1994, Defendant was touting Redux to the press as the "$5 Billion Drug" if approved by the FDA.

38. Defendant's market research demonstrated that if doctors became aware of the risk of primary pulmonary hypertension associated with Pondimin and Redux, sales of this potential "$5 Billion Drug" and Pondimin sales would be devastated.

39. For example, Defendant's Redux market research from June 29, 1995 stated that "the efficacy of Redux is not impressive, and is insufficient for the needs of the patients the doctors would like to prescribe it for . . . . If, however, Redux has a black box for PPH . . . this

would be an extremely strong negative. As you know, this is probably the biggest single factor remaining in future sales performance of the product."

40. In its zeal to get Redux approved, Defendant began lobbying and public relations efforts to pave the way for approval of the Redux NDA. Efforts were also initiated to de-schedule both Pondimin and Redux from the Controlled Substances List at FDA Advisory Committee meetings to be held in September of 1995.

41. Defendant's lobbying efforts paid off. Following a vote on July 19, 1995 in which the FDA Advisory Committee determined that the adequate safety of Redux had not been demonstrated. Defendant, through a senior FDA official, Dr. James Bilstad, planned for the next, and definitive vote, to take place on a day neuroscientists opposed to Redux could not be present. Moreover, members of the FDA Advisory Committee who had not been present for all of the testimony were allowed to vote on the second day. Thus, on November 16, 1995, Defendant won approval of Redux by a narrow 6-5 vote in the absence of those members most knowledgeable about the risks associated with the drug.

42. Dr. Roger Illingworth, a member of the FDA Advisory Committee, later testified that had he known about the reports of valvular heart disease, he would have not have voted to approve the Redux NDA. Instead, he would have advised the FDA that further studies needed to be initiated immediately and that the Pondimin labeling should be revised to warn physicians the risk of VHD.

WYETH FOUGHT HARD TO KEEP THE BLACK BOX FROM BECOMING WARNING PART OF THE LABEL

43. Once approved, Defendant distributed Redux with insufficient and inadequate warnings as to its potentially fatal side effects. Defendant calculated its profits from Redux with and without a black box warning and found that the 1998 projected sales of Redux were projected to be 314.2 million without a black box as compared to 144.6 million with a black box, a 50% reduction.

44. In a November 22, 1995 facsimile correspondence, Joseph Bathish, head of Regulatory Affairs for American Home Products, wrote to Fred Hassan, then Executive Vice President stating: "While we have a very difficult and arduous task of negotiating labeling and Phase IV commitments with the Agency over the next few weeks, every attempt will be made to ensure that no Black Box warnings, restrictions of use or negative statements find their way into the Redux labeling. I am sure that there are elements within the FDA who would like to make a variety of restrictions for the use of Redux. We will make every effort to neutralize such initiatives."

45. Defendant's success in neutralizing the FDA's request for a black box warning was celebrated in a February 27, 1996 e-mail to JoAlene Dolan, one of Defendant's medical monitors for Redux. The e-mail stated: "The meeting with FDA yesterday was a tremendous success! No black box!"

46. Not all were jubilant. Dr. Stuart Rich, one of the world's leading experts on primary pulmonary hypertension, appeared on the Today television show and stated that there were serious safety concerns with regard to Redux.

47. In April of 1996, the same month that Redux was approved, Defendant had additional notice that Redux and Pondimin caused valvular heart disease. Dr. Taylor Thompson had earlier been retained to evaluate primary pulmonary hypertension cases. In a report dated April 9, 1996, Dr. Thompson stated that a review of 32 cases of pulmonary hypertension with dexfenfluramine use revealed that 16 of the cases actually had secondary pulmonary hypertension -- i.e., pulmonary hypertension secondary to, or caused by something else -- with left heart failure, valvular heart disease, and congenital heart disease being the major causes of the secondary pulmonary hypertension.

48. Because congenital heart disease could have no relation to the drug use in an adult user of Redux, the results meant that valvular heart disease and left heart failure (which can itself be a result of valvular heart disease) were the major causes of the secondary pulmonary hypertension cases.

49. Dr. Leo Lutwak, the FDA employee with primary responsibility for reviewing the safety of Pondimin and Redux, reviewed Dr. Thompson's report and noted that it "raises the further issue that dexfenfluramine may potentiate causes for secondary pulmonary hypertension."

50. Defendant was aware of the rather obvious safety issue raised by Dr. Lutwak yet did absolutely nothing to evaluate whether Pondimin or Redux could potentiate or cause valvular heart disease as suggested by Dr. Lutwak's analysis.

51. Defendant knew that if Pondimin caused primary pulmonary hypertension and valvular heart disease then Redux would also cause these problems. Moreover, under Article 21

of the Code of Federal Regulations, the list of side effects associated with Redux would have to include all side effects associated with Pondimin and vice-versa. Even if Redux could be approved with a warning disclosing the risk of valvular heart disease and primary pulmonary hypertension, which it could not, Defendant knew that Redux's label would be required to include a black box for primary pulmonary hypertension if the truth about Pondimin was disclosed. Defendant's marketing research showed that Redux was not commercially viable with a black box warning, a fact known to Defendant's CEO.

52. Not only did Defendant belatedly change the Pondimin labeling regarding primary pulmonary hypertension two and a half years after its own medical monitor recommended it, but Defendant made virtually no attempt to update the Pondimin warnings in any other respect.

53. For example, on April 9, 1997, Dr. Kelly Davis, who took over as one of the medical monitors for Pondimin in early 1997, wrote to Patti Acri, the head of the group responsible for label changes for Pondimin, and stated, "Under Adverse Reactions, I am concerned that the list seems to be very brief -- certainly much less extensive than the Redux label. Has this section been updated as safety (spontaneous ADE) data has come in over the years? At the very least, it should include CHF [congestive heart failure], cardiac valvular disease, but I'm sure there are others."

54. About two weeks after her e-mail April 9, 1997 to Patti Acri, Dr. Kelly Davis wrote another memo that further informed Defendant of over 90 adverse reactions that needed to be added to the Pondimin labeling.

55. In February of 1997, Dr. Heidi Connolly, a physician at the Mayo Clinic, contacted Defendant about her discovery of valvular heart disease in a number of patients who had been using Fen-Phen. She also told the company that she was preparing a paper for submission to the New England Journal of Medicine to report her findings.

56. In March of 1997, Defendant sent Dr. Ginger Constantine and Dr. Philip DeVane from its Medical Affairs Department to the Mayo Clinic to meet with Dr. Connolly. Despite having received at least 30 reports of valvular heart disease in Pondimin users before the meeting, Defendant's representatives told Dr. Connolly that there had been no prior reports of valvular heart disease associated with either Pondimin or Redux.

57. Defendant's representatives advised Dr. Connolly of the company's plans to conduct animal studies on this issue in the future while not disclosing the existence of a Rat Study done years earlier, which had already found fibrosis in the hearts of exposed rats. Even then, Defendant continued its campaign to withhold critical information and feigned complete surprise at Dr. Connolly's findings of valvular heart disease in Pondimin users.

58. Not only did Defendant conceal relevant information from Dr. Connolly, it took the extraordinary step of concealing the information from the FDA and the general public. Amy Myers', Manager of Adverse Drug Experience (ADE), handwritten notes from the meeting on March 11, 1997 indicate that senior management instructed her to delete and re-code the reports of valvular heart disease received from Dr. Connolly. Moreover, defendant's personnel destroyed the physical documents related to the first ADE's received from the Mayo Clinic.

59. At this time, joint meetings of the two (2) companies manufacturing Pondimin and Redux (Wyeth and Interneuron) were being held concerning the oversight of Pondimin/Redux safety. Defendant actively sought to prevent a leak of information to the general public and prescribing physicians by keeping Interneuron in the dark about the Mayo Clinic findings.

60. Joint meetings were held because Wyeth and Interneuron recognized that the two drugs were so closely related that adverse reactions to one drug would likely be seen with use of the other. On April 8, 1997, at a regular meeting of the Pondimin/Redux Safety Overview Committee, Robert Levine, a member of Defendant's Safety Surveillance Department, began to discuss the reports of valvular heart disease from the Mayo Clinic. He was quickly interrupted by Dr. Ginger Constantine and told that it was not appropriate to discuss the issue in that meeting.

61. By June of 1997, the New England Journal of Medicine reviewed Dr. Connolly's article about the 24 cases of valvular heart disease she had observed and published. The New England Journal of Medicine was so concerned about the risk to the public health that it advised Dr. Connolly that she could contact the FDA about this problem and announce her findings publicly in advance of the publication of the article.

62. On June 27, 1997, Dr. Connolly informed Dr. Bilstad at the FDA of her findings. Several days later, on July 2, 1997, Dr. Murray Lumpkin, a senior executive at the FDA, wrote e-mails to Drs. Leo Lutwak and David Graham noting that the FDA had knowledge of only 28 reports of valvular heart disease (the 24 reports from Dr. Connolly and 4 other cases that were

already in their database that Defendant had reported back in 1995).

63. On or about July 8, 1997, the Mayo Clinic released its emergency report linking the use of Pondimin to unusual, potentially life-threatening, valvular morphology and regurgitation in 24 women. The report observed that cardiovascular testing procedures, principally the echocardiogram procedure, revealed that each of the 24 patients had valvular heart disease.

64. Additionally, the Mayo Clinic report observed that eight of the patients had newly-documented pulmonary hypertension. Cardiac surgical intervention to replace defective valves was required in five of the twenty-four patients as of the date of the study.

65. The emergency release of the Mayo Clinic study, well in advance of its scheduled publication in the NEW ENGLAND JOURNAL OF MEDICINE, appears to have been motivated by the extraordinary incidence of life-threatening valvular heart disease and primary pulmonary hypertension experienced in persons who were taking Pondimin.

66. The Mayo Clinic's study concludes that Pondimin users needed to be informed about the risks of pulmonary hypertension and valvular heart disease, particularly because these conditions are extremely rare in individuals in the general population.

67. On September 12, 1997, the FDA met with representatives of Defendant and Interneuron and presented information from five different medical centers demonstrating an alarming increased incidence of valvular regurgitation in asymptomatic users of Pondimin and Redux.

68. The FDA advised Defendant to remove Redux and Pondimin from the market and

Defendant complied.

69. At the meeting with the FDA on September 12, 1997, Defendant feigned ignorance of long-standing reports of valvular heart disease, including reports from Europe. However, a document prepared by Defendant before the meeting established that Defendant had received at least 30 reports of valvular heart disease in Pondimin and Redux users prior to March 1997, with about half of those reports coming from Europe.

70. At all pertinent times, Defendant knew or should have known that Pondimin and Redux caused valvular heart disease and primary pulmonary hypertension and that these risks were inadequately disclosed. As a result, Plaintiffs have suffered the physical injuries described in detail herein.

COUNT I

N.J.S.A. 2A:58C-1, et seq. PRODUCTS LIABILITY ACT

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

A. Defective Design and Inadequate Testing

72. At all times relevant herein, Defendant placed the diet drugs at issue into the stream of commerce with disregard for the public safety in that no adequate testing or other reasonable steps were taken to assure their products were safe and/or efficacious for the purpose of treating obesity. Whatever initial short term weight loss was achieved was negated by the likelihood that the user would regain whatever weight was lost once the product use was

discontinued. Insofar as the product cannot be used for prolonged periods or on a permanent basis, said product was ineffective for the purpose for which its use was promoted.

73. Defendant was the manufacturer and/or supplier of fenfluramine and/or dexfenfluramine and is strictly liable to Plaintiffs for designing, manufacturing, distributing, selling and placing into the stream of commerce fenfluramine and dexfenfluramine.

74. The fenfluramine and/or dexfenfluramine manufactured and/or supplied by Defendant was defective in design or formulation, in that, when it left Defendant's control, harm of said products outweighed any benefit derived therefrom which rendered same inherently dangerous and/or defective, thereby causing serious harm to the Plaintiffs.

75. The fenfluramine and/or dexfenfluramine manufactured and/or supplied by Defendant was defective in design or formulation in that, when it left the control of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

76. The diet drugs manufactured and/or supplied by Defendant were defective due to inadequate pre-market testing.

77. At all times relevant hereto, Defendant encouraged the use of fen-phen and dexfenfluramine as a regimen for weight loss despite its failure to test or otherwise determine the safety and efficacy of such off label use. As a direct and proximate result of the Defendant widespread promotional activity, physicians began commonly prescribing these drugs as a safe and effective treatment for weight loss despite its lack of efficacy and potential for serious and permanent side effects.

78. At all relevant times hereto the Defendant knew or should have known that physicians and other health care providers began commonly prescribing this combination of drugs as a safe and effective treatment for weight loss despite their lack of efficacy and potential for serious permanent side effects.

79. At all relevant times hereto, the Defendant knew and in fact advertised and promoted the concomitant use of the products, fenfluramine, phentermine and dexfenfluramine popularly known as "Fen-Phen", as a safe method of weight loss despite the fact no adequate testing for either safety or efficacy was carried out and that the use of said combination was not approved by the Food and Drug Administration.

80. At all relevant times hereto the Defendant knew or should have known that physicians and other health care providers were commonly prescribing this combination of drugs as a safe and effective treatment for weight loss despite their lack of efficacy and potential for serious permanent side effects.

81. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties and will continue to experience physical and mental pain and suffering, all of which damages will continue in the future.

B. Failure to Warn

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

83. At all relevant times hereto, Defendant knew and in fact advertised and promoted the use of fen-phen and dexfenfluramine as a safe method of weight loss despite the fact that no adequate testing for either safety or efficacy was carried out and that the combined use of fen-phen was not approved by the Food and Drug Administration.

84. Despite the fact that evidence existed that the use of diet drugs was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with its products and in fact, acted to deceive the medical community and public at large, including all potential users of the products by promoting these drugs as a safe and effective method of weight reduction, when in fact they were unsafe and not effective for permanent weight loss.

85. The fenfluramine and/or dexfenfluramine manufactured and/or supplied by Defendant was defective due to inadequate warnings or instructions because Defendant knew or should have known that the product created, among other things, a risk of pulmonary and cardiovascular harm to consumers and the Defendant failed to adequately warn of said risks, and the severity of such adverse effects.

86. The Defendant engaged in direct to consumer advertising which failed to provide adequate warning and/or information concerning the harms or potential harms and dangers of said products to Plaintiffs, including: (1) the possibility of becoming disabled as a result of the drug use; (2) the adverse side effects associated with the use of these drugs including, but not

limited to, heart valve defects and/or primary pulmonary hypertension, both of which may become protracted, debilitating, difficult and painful, necessitating lengthy surgery and/or doctor, clinic or hospital visits.

87. The Defendant failed to warn physicians and users of fenfluramine and dexfenfluramine of the aforementioned dangers and adverse side effects.

88. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties and will continue to experience physical and mental pain and suffering, all of which damages will continue in the future.

C. **Negligence Per Se**

89. The AHP defendants were negligent per se in violating 21 C.F.R. 1.21, 99.101, 201.56, 201.57, 202.1, 310.303, 314.70, 314.80, and 314.81. In particular, the AHP defendants were negligent per se for violating the following violations:

a. The labeling for Pondimin and/or Redux failed to contain a proper, complete and sufficient warning for pulmonary hypertension and/or primary pulmonary hypertension, and/or serious heart conditions as soon as there was reasonable evidence of its association with fenfluramine and dexfenfluramine in violation of 21 C.F.R. 1.21 and 201.57(e);

b. The labeling for Pondimin and/or Redux failed to notify the patient that use of fenfluramine and/or dexfenfluramine individually and/or in combination with phentermine may have harmful effects in violation of 21 C.F.R. 201.57(f)(2);

c. The labeling for Pondimin and/or Redux failed to list all adverse reactions reasonably associated with the use of the drugs and with drugs in the same pharmacologically active and chemically related class in violation of 21 C.F.R. 201.57(g)(1);

d. The "Adverse Reactions" section of the Pondimin and/or Redux labeling failed to list first the most severe adverse reactions of death, pulmonary hypertension, and/or primary pulmonary hypertension, and/or valvular heart disease in violation of 21 C.F.R. 201.57(g)(2);

e. The "Warnings" section of the Pondimin and/or Redux labeling failed to identify any potentially fatal adverse reaction in violation of 21 C.F.R. 201.57(g)(3);

f. There was inadequate information for patients regarding use of Pondimin and/or Redux, individually, and/or the concomitant use with phentermine, in violation of 21 C.F.R. 201.57(f)(2);

g. The labeling for Pondimin and/or Redux was not informative and accurate, and it was false and misleading and/or promotional in part, in violation of 21 C.F.R. 1.21 and 201.56(b);

h. There was inadequate information for patients for the use of Pondimin and Redux, individually or in combination, with phentermine in violation of 21 C.F.R. 201.57(f)(1);

i. The labeling for Pondimin and Redux lacked adequate and accurate information on the approximate "kind, degree and duration" of expected weight loss from for Pondimin and Redux by themselves and/or in combination with phentermine in violation of 21 C.F.R. 201.57(c)(3)(I); providing accurate information on this subject would have alerted consumers, pharmacists and physicians to the fact that these drugs were only minimally effective, if at all;

j. The labeling for Pondimin and Redux did not state that there was a lack of evidence to support the common belief in the safety and efficacy of fenfluramine and/or dexfenfluramine (Pondimin and Redux) and phentermine together in violation of 21 C.F.R. 201.57(c)(2), 201.57(c)(3)(i) & (iv);

k. The AHP defendants failed to properly maintain records and make reports related to the clinical experience or other data to make or facilitate a determination of whether there were grounds to withdraw FDA approval of Pondimin and/or Redux in violation of 21 C.F.R. 310.303(a);

l. The AHP defendants failed to change the labeling for Pondimin to add or strengthen the language pertaining to pulmonary hypertension and valvular heart disease without FDA approval as permitted by 21 C.F.R. 314.70(c)(2)(i);

m. The AHP defendants failed to promptly review all adverse drug experience

information, including available scientific literature, and failed to develop adequate written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experiences to the FDA in violation of 21 C.F.R. 314.80(b);

n. Advertising for Pondimin and/or Redux did not contain a "[T]rue statement" of information, and was false, misleading, and failed to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended in violation of 21 C.F.R. 202.1;

o. The AHP defendants entirely failed to report serious and unexpected adverse drug experience information as defined by 21 C.F.R. 314.80(a), regarding Pondimin and Redux to the FDA in some instances, and failed to report the information timely in others, in violation of 21 C.F.R. 314.80(c)(1)(i);

p. The AHP defendants failed to promptly investigate all the adverse drug experiences that were the subject of post-marketing 15-day "Alert Reports" regarding Pondimin and Redux in violation of 21 C.F.R. 314.80(c)(1)(ii);

q. The AHP defendants failed to properly report all the adverse drug experiences that were the subject of post-marketing 15-day "Alert Reports" regarding Pondimin and Redux in their periodic reports in violation of 21 C.F.R. 314.80(c)(2)(i) & (ii);

r. The AHP defendants failed to promptly report all adverse drug experience information available in the scientific literature pertaining to the association

between Pondimin and Redux and pulmonary hypertension and primary pulmonary hypertension in violation of 21 C.F.R. 314.80(d) & (e);

s. The AHP defendants failed to properly summarize in their annual reports the adverse drug experiences related to pulmonary hypertension, primary pulmonary hypertension and valvular heart disease that would have affected the safety and effectiveness, or labeling of Pondimin and Redux in violation of 21 C.F.R. 314.81(a)(2)(ii); and

t. The AHP defendants disseminated written information about fenfluramine and dexfenfluramine concerning the effectiveness and benefits of using the drugs in a manner not described in the approved labeling, which failed to comply with the procedure for disseminating such information in violation of 21 CFR 99.101.

90. Any presumption that Defendant's warnings were adequate because they were approved by the FDA is rebutted by the facts set forth in paragraphs 17 through 89 above.

91. As a direct and proximate result of Defendant's negligence per se, Plaintiffs have suffered permanent and continuous profound injuries, have required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and will continue to experience physical and mental pain and suffering.

COUNT II

BREACH OF IMPLIED WARRANTY

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

93. At all relevant times herein, Defendant marketed, manufactured, promoted, distributed and/or sold fenfluramine and/or dexfenfluramine for use by the public at large including Plaintiffs. Defendant knew the use for which its product was intended and impliedly warranted said products to be of merchantable quality, safe and fit for use.

94. The Plaintiffs reasonably relied on the skill and judgment of Defendant, and as such its implied warranty, in using the aforementioned products. These products were not of merchantable quality or safe or fit for their intended use, because said products used either individually or in combination, are unreasonably dangerous and unfit for the ordinary purpose for which they were intended to be used.

95. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties and will continue to experience mental and physical pain and suffering, all of which damages will continue in the future.

COUNT III

BREACH OF EXPRESS WARRANTY

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

97. The aforementioned manufacturing, designing, distributing, marketing, and promoting of diet drugs was expressly warranted to be safe for Plaintiffs and members of the public generally. At the time of the making of the express warranties, Defendant had knowledge of the purpose for which the aforementioned product at issue was to be used and warranted same to be safe, effective and proper for such purpose.

98. The diet drugs did not conform to these express representations because they are not safe or effective and produce serious side effects, including among other things life threatening cardiovascular and pulmonary injury.

99. As a direct and proximate result of the breach of said warranties of the Defendant, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties and will continue to experience mental and physical pain and suffering, all of which damages will continue in the future.

COUNT IV

NEGLIGENT MISREPRESENTATION

100. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if

fully set forth here and further allege as follows:

101. Defendant, having undertaken the manufacturing, marketing, distribution, and/or promotion of the diet drugs described herein, owed a duty to provide accurate and complete information regarding its products.

102. Defendant falsely represented to Plaintiffs, in direct to consumer advertising, and indirectly through misrepresentation to their prescribing physicians, that the diet drugs were safe and effective for use in weight reduction. The representations by Defendant were in fact false and the drugs were not safe for said purpose and in fact dangerous to the health of Plaintiffs.

103. At the time the aforesaid representations were made, Defendant concealed from Plaintiffs and their prescribing physicians information about the propensity of the drugs to cause great harm. Defendant negligently misrepresented claims regarding the safety and efficacy of said drugs despite the lack of information regarding same.

104. The aforementioned misrepresentations were made by Defendant with the intent to induce Plaintiffs to use the drugs individually and in combination with other drugs, to Plaintiffs' detriment.

105. At the time of Defendant's misrepresentations and omissions, Plaintiffs were ignorant of the falsity of these statements and reasonably believed them to be true.

106. Defendant breached its duties to Plaintiffs by providing false, incomplete and/or misleading information regarding its products. Plaintiffs reasonably believed Defendant's representations and reasonably relied on the accuracy of those representations when purchasing and using diet drugs.

107. As a direct and proximate result of one or more of these wrongful acts or

omissions of the Defendant, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties and will continue to experience mental and physical pain and suffering, all of which damages will continue in the future.

COUNT V

COMMON LAW FRAUDULENT MISREPRESENTATION AND CONCEALMENT

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

109. Defendant, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of the diet drugs described herein, owed a duty to provide accurate and complete information regarding its products.

110. Defendant fraudulently misrepresented information regarding diet drugs including, but not limited to, their propensity to cause serious physical harm.

111. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiffs were unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

112. Defendant breached its duties to Plaintiffs by providing false, incomplete and

misleading information regarding diet drugs in direct to consumer advertising and indirectly through prescribing physicians.

113. Defendant had a duty and obligation to disclose to Plaintiffs that the diet drugs were dangerous and likely to cause serious health consequences to users.

114. Neither Plaintiffs nor their prescribing physicians were aware of the facts set forth above and, had they been aware of said facts, would not have prescribed and/or taken these drugs. In addition, these drugs would have been removed from the market years before September 15, 1997.

115. Plaintiffs reasonably relied upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

116. As a proximate result of defendant's fraudulent misrepresentations, Plaintiffs have suffered physical and emotional harm.

117. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties and will continue to experience mental and physical pain and suffering, all of which damages will continue in the future.

COUNT VI

THE NEW JERSEY CONSUMER FRAUD ACT NJSA 56:8-1 et seq.

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

119. Defendant engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts with the intent that others rely upon such concealment suppression or omission.

120. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries which required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; all of which damages will continue in the future.

121. Plaintiffs suffered an ascertainable loss of money or property as a result of defendant's use or employment of unconscionable commercial practices as set forth above, and seeks treble damages, attorney's fees and costs of suit.

PRIMARY PULMONARY HYPERTENSION (PPH) PLAINTIFFS

122. PPH Plaintiffs incorporate the allegations of all of the foregoing paragraphs and counts of this complaint as though fully set forth herein.

123. PPH Plaintiffs suffered severe, life threatening injuries to their lungs which has or may require lung and or heart transplant surgery, great pain, suffering and emotional distress, a loss of earnings and impairment of future earning capacity, great pain, suffering and emotional distress.

124. PPH Plaintiffs seek all compensatory, punitive and treble damages sustained, reasonable attorneys' fees, filing fees, costs of suit and such further relief as this Court deems necessary, just and proper.

PUNITIVE DAMAGES

125. Plaintiffs incorporate by reference all other paragraphs of the Complaint as if fully set forth here and further allege as follows:

126. At all times relevant herein, defendants:

a. knew that drugs were dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiffs, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiffs, their physicians, pharmacists, hospitals and medical providers and the public in general as previously delineated herein as to the safety and efficacy of the drugs;

d. with full knowledge of the health risks associated with the aforementioned products and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold and/or distributed drugs for routine use.

127. The defendant by and through an officer, director, managing agent, authorized sales representatives, employees and/or other agents to engage in malicious, fraudulent and oppressive conduct towards the Plaintiff and the public thereby acted with willful, wanton and/or conscious, reckless and egregious disregard for the safety of plaintiff and the general public.

128. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; has become and will become liable for medical and hospital expenses; lost and will lose financial gains; has been and will be kept from ordinary activities and duties; continue to experience mental and emotional and physical pain and suffering, all of which damages will continue in the future.

VALVULAR HEART DISEASE PLAINTIFFS

129. Valvular heart disease claimants incorporate by reference paragraphs 1 through 117 of the complaint as though fully set forth herein, as permitted by the United States District Court overseeing MDL 1203:

130. Plaintiff is an intermediate or back end opt-out of the *Brown v. American Home Products* (Diet Drugs) National Class Action Settlement. All prerequisites to opting out of the class action settlement and filing an individual lawsuit have been met.

131. Plaintiff ingested Fenfluramine and/or dexfenfluramine.

132. Plaintiffs who exercised an Intermediate Opt Out right under the Class Settlement first had an echocardiogram and were diagnosed with a heart condition known as FDA positive or greater severity between September 30, 1999 and July 3, 2003. Plaintiffs who exercised a Back-End Opt Out right under the Class Settlement had an echocardiogram and were diagnosed with a condition known as FDA positive after the commencement of diet drug use and were diagnosed with a "matrix level" condition after September 30, 1999.

133. Plaintiff is asserting claims based on heart valve damage to Plaintiff diagnosed by

a qualified physician and as a result of the use of fenfluramine and/or dexfenfluramine.

134. Plaintiff ingested the diet drugs and suffers from valvular heart disease. The diet drugs sold by Defendant were a proximate and producing cause of Plaintiff's injuries.

COUNT VII

LOSS OF CONSORTIUM[2]

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

136. As a result of Defendant's acts, the spouse of each Plaintiff has suffered and will suffer loss of each Plaintiff's consortium.

137. Each Plaintiff's spouse has and will suffer injuries as a direct and proximate result of one or more of Defendant's wrongful acts or omissions.

COUNT VIII

WRONGFUL DEATH ACTION

138. As a result of defendants' actions, plaintiff's decedent, died as a result of either valvular heart disease or primary pulmonary hypertension suffered as a result of taking fenfluramine or dexfenfluramine.

139. Plaintiff heirs claim damages for loss of consortium arising from decedent's illness and death.

140. Plaintiff seek damages for plaintiff's decedent's pain, suffering and expenses

[2]In the short form complaint, a loss of consortium claim will be pled individually where applicable.

under N.J.S.A. 2A:15-3 (or any successor statute) and damages for wrongful death under N.J.S.A. 2A:31-1 et seq. (or any successor statute), damages for loss of services, support, society, companionship, comfort, advice and consortium arising from decedent's illness and death. Plaintiff further seeks additional damages recoverable under the laws of this State, plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

PRAYER FOR RELIEF

141. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries which are permanent and progressive in nature; required medical treatment and hospitalization; has become liable for medical and hospital expenses; lost financial gains; has been kept from ordinary activities and duties; and has experienced mental and physical pain and suffering, all of which damages will continue in the future. Plaintiffs seek damages for injuries to their heart valves and for all conditions resulting from heart valve regurgitation.

WHEREFORE, Plaintiffs demand judgment against Defendant for all available compensatory damages together with interest, costs of suit, and such other relief as the Court deems proper. Valvular Heart Disease Plaintiffs seek all damages, and only those damages, they are entitled to seek under the Class Action Settlement Agreement. Valvular Heart Disease Plaintiffs acknowledge that no claim for punitive, exemplary, or multiple damages is asserted.

Attorneys for Plaintiff

By: _____

Dated

#3687212

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

Attorneys for Plaintiff

By: _____

Dated

CERTIFICATION PURSUANT TO RULE 4:5-1

Pursuant to Rule 4:5-1, upon information and belief the undersigned certifies that the matter in controversy is not the subject of any other action pending in any other court or of a pending arbitration proceeding nor is any other action or arbitration contemplated.

Attorneys for Plaintiff

By: _____

Dated:

#3687212