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U.S. DISTRICT COURT
EASTERN DISTRICT OF LA
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LORETTA G. WHYTE
CLERK

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: PROPULSID PRODUCTS LIABILITY LITIGATION	MDL NO. 1355 SECTION: L JUDGE FALLON MAG. JUDGE AFRICK
THIS RELATES TO:	SECT. L MAG. 3
VIRGINIA GAIL JONES, INDIVIDUALLY, And PATRICIA LUCKMAN, AS ADMINISTRATRIX OF THE ESTATE OF AMY LUCKMAN, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, Plaintiffs, vs. JOHNSON AND JOHNSON AND JANSSEN PHARMACEUTICA, INC., Defendants.	JURY TRIAL DEMANDED

MASTER CLASS ACTION COMPLAINT

Plaintiffs, Virginia Gail Jones and Patricia Luckman, as Administratrix of the Estate of Amy Luckman, on behalf of themselves and all others similarly situated, allege as follows:

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 (diversity) in that the state of citizenship of each representative Plaintiff is different from the state of citizenship of the Defendants, and the amount in controversy exceeds $75,000.00, exclusive of interest and

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costs.

2. Plaintiffs allege an amount in controversy in excess of $75,000.00 exclusive of interest and costs, as to themselves and each member of the proposed Class. In addition, the Class has an undivided interest in obtaining injunctive relief including the establishment of a medical monitoring program and revised drug warnings which exceed $75,000.00 in value.

3. Venue is properly set in the District Court pursuant to the order of the Judicial Panel on Multidistrict Litigation dated August 7, 2000.

II. PARTIES

4. Plaintiff, Virginia Gail Jones, is a citizen of Indiana. Plaintiffs Jones ingested Propulsid from August 1998 until the Defendants' withdrawal of the drug from the market in 2000. Mrs. Jones has experienced certain cardiac conditions that she believes necessitates ongoing and prospective medical monitoring.

5. Plaintiff, Patricia Luckman, is a citizen of the state of Washington, and appears on behalf of her deceased daughter, Amy Luckman. Amy Luckman ingested Propulsid for only 5 days in February 2000. On the fifth day of ingestion, Plaintiff, Luckman, died due to her consumption of Propulsid as stated on her death certificate.

6. Defendant Johnson and Johnson ("Johnson"), is a New Jersey Corporation with its principal place of business in New Brunswick, New Jersey. At all times material hereto, Johnson through its wholly-owned subsidiary, Janssen Pharmaceutica, was in the business of manufacturing, promoting, marketing and distributing the prescription drug Propulsid.

7. Defendant Janssen Pharmaceutica, Inc. ("Janssen"), a wholly owned subsidiary of Johnson, is a corporation with its principal place of business in Titusville, New Jersey. Janssen was

in the business of manufacturing, promoting, marketing and distributing the prescription drug Propulsid.

III. FACTS

8. Propulsid is the trade name for the prescription drug (known as cisapride) promoted and prescribed to treat gastroesophageal reflux disease (GERD). GERD is a motility disorder in which the muscles of the esophagus and stomach, as well as the esophageal sphincter, do not operate properly.

9. Propulsid was approved by the FDA and used as an adjunct to dietary changes to treat patients with GERD experiencing severe nighttime heartburn that was otherwise not adequately responding to other therapies.

10. At all times material hereto, Defendants Johnson and Janssen manufactured, labeled, marketed, advertised and otherwise distributed in interstate commerce, the product known as Propulsid from New Jersey.

11. The Defendants aggressively promoted their Propulsid prescription drug upon gaining approval from the Food and Drug Administration ("FDA") to market Propulsid in the United States in 1993. Propulsid was touted as one of an entirely new class of synthetic drugs called "prokinetic" agents.

12. Defendants' strategy, beginning in 1993, has been to aggressively manufacture, market and sell Propulsid by falsely misleading potential average consumers including the Plaintiffs concerning the safety, efficacy and the risks associated with the use of its drug and by failing to protect users from serious dangers which the Defendants knew or should have known would result from the use of its product.

13. The Defendants engaged in extensive advertising and marketing efforts directly to consumers and also targeted physicians and other healthcare providers, and disseminated false and misleading materials to them which failed to disclose the risks associated with the use of Propulsid.

14. Defendants' advertising program, by affirmative misrepresentations and omissions, falsely sought to create the impression that the use of Propulsid was safe for human use more effective than other presumptions or over the counter medications, and had fewer side effects and adverse reactions than other heartburn medications.

15. As part of defendant's aggressive marketing campaign, Defendants used a trained staff-known as "detail men"–to promote and market Propulsid to doctors and hospitals. Propulsid was one of the most heavily detailed pharmacological products. In 1994, Propulsid ranked 24th on a list of the thirty most heavily detailed products.

16. Within a short time of the drug's release, the Defendants began receiving reports of patients suffering from cardiac arrhythmia after taking Propulsid.

17. Defendants' product warnings in effect during the relevant time period on Propulsid were wholly inadequate and failed to warn prescribing physicians and consumer patients, including the Plaintiff(s) and the proposed Class, of the actual cardiac risks associated with the product.

18. On a number of occasions since Propulsid's introduction in 1993, the FDA requested that the Defendants provide specific safety cautions on the drug's labeling concerning heart risks.

19. The medical literature demonstrates that dangerous heart beat irregularities developed when Propulsid is combined with certain drugs or certain identifiable disorders.

20. As early as 1993, the Defendants became aware of heart problems associated with the ingestion of Propulsid through adverse drugs reports.

21. Despite knowledge of the serious cardiotoxic medical risks related to the use of Propulsid by the proposed Class, Defendants failed to adequately disclose or warn physicians and consumers including the Plaintiffs concerning the health hazards and risk to the heart associated with the use of Propulsid.

22. For example, in 1995, Defendants expanded their marketing efforts to include an extensive direct-to-consumer advertising campaign targeting individuals who suffer from nocturnal heartburn. The direct consumer promotion included advertising by the national and regional broadcast media, magazines, and newspapers. In addition, Defendants also employed the use of a 1-800 number to promote use of Propulsid. As of February 1998, Defendants had collected over 300,000 names in its GI patient database through 1-800 number callers. Callers received customized mailings "with one specific thing in mind, converting them to get a script for Propulsid," said Janssen Gastroenterology and Mycology Group Director, Joseph Sanger, in January, 1998.

23. Defendants also targeted managed care as part of their efforts to manufacture demand for Propulsid.

24. However, in December 1996, the FDA's Division of Drug Marketing, Advertising and Communications criticized Defendants promotional brochure for Propulsid for implying that acid suppressing agents were less effective than Propulsid for treating GERD. The FDA also concluded that Defendants brochure was misleading and lacked in fair balance in that it minimized the significance of potential drug interactions with Propulsid.

25. Defendants' aggressive and relentless efforts were nevertheless an astonishing success. The drug at one time was available in 89 countries and has been prescribed more than 30 million times since its debut in 1993.

26. Defendants reaped significant income from the drug whose gross annual revenues exceeded $1 billion. In 1999, Propulsid ranked 63rd in prescriptions filled among all prescription drugs.

27. Defendants falsely and fraudulently misrepresented material facts regarding Propulsid, including, but not limited to the following:

a. Defendants had conducted adequate testing of its Propulsid product, prior to selling to Plaintiffs and the proposed Class and targeting the healthcare industry when in fact the Defendants had not done so;

b. Defendants failed to disclose that the use of Propulsid caused cardiac arrhythmia and related deaths;

c. Defendants failed to disclose that the use of Propulsid may cause serious cardiovascular problems resulting in heart failure and death.

28. On June 29, 1998, the FDA issued a public health advisory concerning its receipt of reports from patients who had experienced dangerous irregular heartbeats and cases of sudden death. Despite the public health advisory, the Defendants continued to aggressively market and promote the use of Propulsid.

29. The Defendants failed to adequately conduct post-marketing studies concerning Propulsid.

30. The 1993 approval of Propulsid by the FDA only pertained to usage by adults. The Defendants failed to obtain approval from the FDA concerning the use of Propulsid for pediatric use, although they marketed a cherry flavored liquid suspension formulation that was primarily for pediatric use. Defendants failed to provide adequate warnings concerning the use of Propulsid by

children or the recommended dosage for use by children. Nevertheless, Defendants marketing efforts resulted in numerous prescriptions by misinformed pediatricians to their patients. As a direct and proximate result of the Defendants omissions, the use of Propulsid has resulted in the deaths of children.

31. On January 24, 2000, the FDA issued a strong warning to doctors about the possible dangers of Propulsid. The FDA's actions were prompted by continuing reports of heart rhythm disorders and deaths associated with the ingestion of Propulsid, as well as a then recent analysis of 270 adverse event reports, including 70 fatalities. These figures were later updated so that as of December 31, 1999, use of cisapride had been associated with 341 heart rhythm abnormalities including 80 reports of death. From January 1, 2000 to March 28, 2000 there have been reported 23 additional deaths associated with Propulsid. More than half of these additional deaths were of people less than 60 years old, including one nine month old infant.

32. The Defendants have been on notice that the ingestion of Propulsid was associated with significant adverse heart problems, including death, since not long after its introduction into the stream of commerce in 1993.

33. Nonetheless, upon information and belief, the Defendants failed to initiate any animal studies or clinical investigations to determine the nature and extent of these relationships and failed to provide any warning concerning these relationships until the severe problems were brought to the public's attention by the FDA in June of 1998.

34. Based upon the above findings, there is substantial evidence to support the conclusion that the Defendants were negligent in failing to ascertain and report the existence, nature and extent of the risk of heart problems posed by Propulsid which was marketed for use by over 30 million

human beings within the United States.

35. There is also substantial evidence that the significant risk of heart problems posed by the ingestion of Propulsid far outweighs any benefit afforded it by the drug.

36. The Defendants placed into the stream of commerce a drug that is defective and unreasonably dangerous in design, taking into consideration the utility of the product and the risk involved in its use.

37. Because Propulsid is ineffective for its intended use and because use of the drug produces enormous risk of life threatening complications, no reasonable pharmaceutical company exercising due care would have marketed this drug.

38. As a result of the continuing receipt by the Defendants of reports of serious cardiac arrhythmia, heart abnormalities and deaths, the Defendants finally announced on March 23, 2000 that it had decided to stop marketing Cisapride (Propulsid) in the United States, effective as of July 14, 2000.

39. Defendants' wrongful acts complained of herein originated, occurred, emanated from and/or were orchestrated from New Jersey where Defendants Johnson and Janssen maintain their principal places of business. The corporate decisions regarding the aggressive promotion of Propulsid and how it was to occur were made in New Jersey. The sales and marketing materials were developed and approved in New Jersey and emanated from that state. The training materials provided to the sales people or "detail men" were developed, created and approved in New Jersey. The drug's labels and so called warnings were developed and approved in New Jersey. The decisions to maintain this drug on the market in light of the rising death and injury toll were likewise made in New Jersey.

40. In further support of the claims herein, incorporated by reference hereto are the allegations set forth in the following complaints: *Wilson, et al. v. Johnson & Johnson Co., et al.*, No. 00-2403 (E.D. La.); *Williams, et al. v. Johnson & Johnson Co., et al.*, No. 00-2375 (E.D. La.); *Zeno, et al. v. Johnson & Johnson Co., et al.*, No. 00-0282 (E.D.La.); *Ridden, et al. v. Johnson and Johnson Co., et al.*, No. 00-2783 (E.D.La.); *Rice, et al. v. Johnson and Johnson, et al.*, No. 00-2782 (E.D.La.); *Villarreal, et al. v. Johnson & Johnson, et al.*, No. 00-2786 (E.D.La.); *Beardon, et al. v. Johnson and Johnson, et al.*, No. 00-2772 (E.D.La.); *Saucier, et al. v. Johnson & Johnson, et al.*, No. 00-2777 (E.D.La.); *Gallagher v. Johnson & Johnson, et al.*, No. 00-2778 (E.D.La.); *Kirkendall. et al. v. Johnson & Johnson, et al.*, No. 00-2780 (E.D.La.); *Bullock, et al. v. Johnson and Johnson Co.*, No. 00-2781 (E.D.La.); *Fayard, et al. v. Johnson & Johnson, et al*, No. 00-3709 (E.D.La.); *Rutherford, et al. v. Johnson and Johnson, et al.*, No. 00-2417 (E.D.La.); *Haugen, et al. v. Johnson & Johnson Co., et al.*, No. 00-2484 (E.D.La.); *Shields, et al. v. Janssen Pharmaceutical Corp., et al.*, No. 00-2737 (E.D.La.); *Carroll, et al. v. Johnson and Johnson, et al.*, No. 00-2771 (E.D.La.); *Jackson, et al v. Johnson & Johnson, Inc., et al*, No.)1-CV-2539 (E.D.La.); *Boyd, et al. v. Johnson & Johnson Co., et al.*, No. 01-CV-319 (E.D.La.); *Denney, et al. v. Johnson & Johnson Co., et al.*, No. 01-CV-510 (E.D.La.); *Lorio, et al. v. Johnson and Johnson, et al.*, No. 01-CV-315 (E.D.La.); *Lee et al. v. Johnson & Johnson, et al.*, No. 01-CV-1205 (E.D.La.); *Long, et al. v. Johnson & Johnson, et al.*, No. 01-CV-1826 (E.D.La.); *Baust, et al. v. Johnson & Johnson, et al.*, No. 01-CV-506 (E.D.La.); *Fountain, et al. v. Johnson & Johnson, Co., et al.*, No. CV-01-2538 (E.D.La.); *Crane, et al. v. Johnson & Johnson, et al.*, No. 01-CV-1426 (E.D.La.); *Berry, et al. v. Johnson & Johnson, et al.*, No. 01-CV-1750 (E.D.La.); *Kellar, et al. v. Janssen Pharmaceutica, et al.*, No. 01-2506 (E.D.La.).

IV. CLASS ACTON ALLEGATIONS

41. Plaintiffs bring this class action pursuant to Federal Rules of Civil Procedure Rules 23(a)(1)-(4), 23(b)(2) and 23(b)(3) and 23(c)(4) on behalf of a Class consisting of all persons in the United States who purchased and/or used Cisapride (Propulsid).

42. Also included in the Class are any other persons asserting the right to sue the Defendants independently or derivatively by reason of their personal relationship with persons who used Propulsid, including without limitation, spouses, parents, children, dependents, other relatives or "significant others" ("derivative claimants").

43. Excluded from the Class are the Defendants, including any parent, subsidiary, affiliate or controlled person of the Defendants and their officers, directors, agents or employees and members of their immediate families. Also excluded from the Class is the judicial officer presiding over the litigation and members of his/her immediate family.

44. Plaintiffs are members of the Class they seek to represent. The members of the Class are so numerous that joinder is impracticable and would involve thousands of individual actions.

45. There are questions of law and fact common to the Class including, but not limited to:

a. Whether Defendants designed, manufactured and/or marketed Propulsid with knowledge that it was a dangerously defective product;

b. Whether Defendants acted negligently in marketing and selling Propulsid;

c. Whether Defendants conducted, either directly or

indirectly, adequate testing of Propulsid;

d. Whether Defendants failed to adequately warn consumers of the adverse health hazards caused by using Propulsid;

e. Whether Defendants falsely and fraudulently misrepresented in their advertisements, promotional materials and other materials, among other things, the safety of using Propulsid; and

f. Whether Defendants knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Propulsid from governmental regulators, the medical community and/or the consuming public;

g. Whether Defendants' conduct constituted an unfair, deceptive and/or unconscionable practice within the meaning of the New Jersey Consumer Fraud Act. N.J.S.A. 56:8-2 and/or similar statutes in effect in other states;

h. Whether Defendants' conduct constituted the knowing or intentional concealment, suppression or omission of material information intended to be relied upon by others in connection with the sale of Propulsid within

the meaning of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2 and/or similar statutes in effect in other states;

i. Whether Defendants' actions support a cause of action for medical monitoring pursuant to any or all of the following statutory or common law bases (i) the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq.* and/or similar statutes in effects in other states; (ii) the New Jersey Products Liability Act, New Jersey, N.J.S.A. 2A:58C-1 *et. seq.* and/or similar statutes in effect in other states; (iii) negligence; and/or (iv) medical monitoring.

j. Whether medical monitoring of Plaintiff and the proposed Class who used Propulsid is reasonably necessary.

46. The claims of the named Plaintiffs are typical of the claims of the Class in that the named Plaintiffs and the members of the Class used Propulsid designed, manufactured, supplied, distributed, sold and or placed in the stream of interstate commerce by Defendants Johnson and Janssen, and did suffer or may suffer harm as a result.

47. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class. Plaintiffs have no known interests which are adverse to the interests

of the other members of the Class.

48. Class certification is also appropriate pursuant to Fed.R.Civ.P. 23(b)(2) because Defendants have acted on grounds generally applicable to the Class, making appropriate equitable injunctive relief with respect to Plaintiff and the Class members. Specifically, Plaintiffs seek injunctive relief in the form of court ordered medical monitoring, revised drug warnings to assist Plaintiffs and the Class members in the detection and treatment of consumer patients who used Propulsid, and an emergency notice to the Class regarding the dangers of Propulsid.

49. Class certification is appropriate under Fed.R.Civ.P. Rule 23(b)(3) because common issues of law and fact relative to the design, manufacture and marketing of Propulsid predominate over individual issues. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual joinder of all members of the Class is impracticable.

50. A class action is superior to any other available method for the fair and efficient adjudication of this dispute because common questions of law and fact overwhelming predominate any questions that may affect only individual Class members, and there would be enormous economies to the courts and the parties in litigating the common issues on a classwide instead of repetitive individual basis. A class action approach would serve to consolidate and create a scenario with far fewer management difficulties because it provides the benefits of unity adjudication, judicial economy, economies of scale and comprehensive supervision by a single court. Any person who has been seriously injured and wishes to pursue an individual action outside the remedy sought in this complaint will have the opportunity to opt out.

51. Class certification is appropriate under 23(c)(4) because particular classes or issues, including the common issues identified above, would be best adjudicated on a classwide basis, even

were the court to determine that issues of Class members' injuries and compensatory damages should be adjudicated individually.

COUNT I

(NEGLIGENCE)

52. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

53. The Defendants are the designers, manufacturers, sellers, and suppliers of the drug Propulsid.

54. When placed in the stream of commerce in 1993, Propulsid was not accompanied by any meaningful warnings regarding the significant risk of heart problems associated with the ingestion of Propulsid. The warnings given by the Defendants did not accurately reflect the existence of the risk, let alone the incidence, symptoms, scope, or severity of such injuries.

55. Defendants failed to perform adequate testing concerning the safety of the drug Propulsid in that adequate testing would have shown that Propulsid poses a serious risk of heart problems which would have permitted adequate and appropriate warnings to have been given by Defendants to prescribing physicians and the consuming public.

56. Defendants failed to effectively warn users and physicians that numerous other methods of reducing gastroesophageal reflux disease, including non-drug methods, should be the first or exclusive method of reducing this disease, particularly for certain high risk individuals.

57. Defendants had a duty to exercise reasonable care in the design, manufacture, sale, and distribution of the drug Propulsid, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination

with other drugs.

58. Defendants were negligent in the design, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given, and sale of Propulsid in that, among other things, they:

(a) Failed to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of Propulsid;

(b) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the drug Propulsid;

(c) Failed to provide adequate training and instruction to medical care providers for appropriate use of the drug Propulsid;

(d) Failed to warn Plaintiffs and the Class, prior to actively encouraging the sale of Propulsid, either directly or indirectly, orally or in writing, about the following: 1) the need for a battery of diagnostic tests to be performed on the patient prior to ingesting Propulsid to discover and ensure against potentially fatal side effects; or 2) the need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal side effects;

(e) Failed to warn that the risks associated with the ingestion of Propulsid exceeded the risks of other comparable forms of medication for heartburn;

(f) Failed to effectively warn about the increased danger and potentially fatal relationship in combining use of Propulsid with various other drugs or use with certain identifiable disorders;

(g) Negligently marketed Propulsid for both adult and pediatric use despite the fact that the risks of the drug were so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company, exercising due care, would have done so;

(h) Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of Propulsid from prescribing physicians and the consuming public, and that had prescribing physicians and the consuming public known of such facts, the drug Propulsid would never have been prescribed to, or used by, Plaintiffs or members of the Class;

(i) Remained silent despite their knowledge of the growing public acceptance of misinformation and

misrepresentations regarding both the safety and efficacy of the ingestion of Propulsid, and did so because the prospect of huge profits outweighed health and safety issues, all to the significant detriment of Plaintiffs and the Class;

(j) Failed to perform their post-manufacturing and continuing duty to warn which arose when they knew, or with reasonable certainty should have known, that their drug was being prescribed in a fatal or injurious combination or manner; and

(k) Was otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard for the rights of Plaintiffs and the Class.

59. Despite the fact that the Defendants knew or should have known that Propulsid caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, the Defendants continued to market Propulsid to consumers, including Plaintiffs and the Class, when there were safer alternative methods of reducing heartburn.

60. Defendants knew or should have known that consumers such as Plaintiffs and the Class would forseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

61. Defendants' actions as described herein constitute knowing omissions, suppression, or concealment of material facts, made with the intent that others rely upon such concealment,

suppression, or omissions in connection with the marketing of Propulsid.

62. As the direct and proximate cause and legal result of the Defendants' failure to supply appropriate warnings for the drug Propulsid, and as a direct and legal result of the negligence, carelessness, other wrongdoing and actions of Defendants described herein, the Propulsid recipient Plaintiffs and the Class ingested Propulsid and suffered injury or a significantly increased risk of heart disease and/or related cardio-dysfunctions for which medical monitoring, in the form requested herein, is necessary, appropriate, and beneficial.

63. Defendants' negligence was a proximate cause of the injury and/or increased risk of harm suffered by the Propulsid recipient Plaintiffs and the Class as previously set forth herein.

64. As a direct and proximate cause and legal result of the Defendants' negligence, carelessness, and the other wrongdoing and actions of the Defendants as described herein, the Derivative Claimants have suffered a loss of consortium, services, love and affection, and have incurred financial expenses and have suffered economic losses.

COUNT II

(FRAUD)

65. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

66. Defendants either knew or should have known that Propulsid was dangerous and not as effective for its purpose as represented, and posed greater risks than disclosed, and otherwise not as represented to be as alleged above.

67. Defendants were under a duty to disclose this information to the Plaintiffs and the Class under the common law as well as laws requiring it not to engage in false and deceptive trade

practices, and as otherwise alleged in this complaint, because Defendants made representations and partial disclosures concerning the nature and quality of their product which they had a duty to correct, because Defendants were in a superior position to know the true state of the facts about the dangerous and defective nature of Propulsid and its known risks to the Plaintiffs and the Class. These deliberate and/or intentional omissions of material facts and misrepresentations include but are not limited to:

1. suppressing, failing to disclose and mischaracterizing the known risks of ingesting Propulsid;
2. omitting material information showing that Propulsid was no more effective than other drugs on the market available to treat GERD;
3. failure to timely and fully disclose the actual results of clinical tests and studies related to Propulsid;
4. failing to issue adequate warnings concerning the risks and dangers of ingesting Propulsid which would disclose the nature and extent of the side effects of Propulsid;
5. failing to disclose that adequate and/or standard and/or generally accepted standards for pre-clinical and clinical testing had not been done;
6. failing to disclose that adequate and/or standard and/or generally accepted standards for post-

marketing testing had not been done;

7. making the representations concerning the safety, efficacy and benefits of Propulsid as detailed in this complaint without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

68. Plaintiffs and Class members did not know, and could not learn, the material facts and important information Defendants omitted and suppressed. The facts and information suppressed and concealed by Defendants is material, and of such a nature that it can be reasonably informed or presumed that the suppression and concealment of such facts caused, contributed to, and/or was a substantial factor in causing harm to Plaintiff and the Plaintiff Class.

69. As a result of Defendants' fraud, suppression and omission of material facts, the Plaintiffs and the Class acted to their detriment in purchasing and ingesting Propulsid, which they would not have purchased or ingested had they been told the truth, and should be reimbursed what they spent.

70. As a result of Defendants' practices, Plaintiffs and Class members have suffered actual damages in that they have purchased and ingested Propulsid which is dangerous and defective that has caused damage and will continue to cause Plaintiffs and Class members expenses for medical testing, health monitoring and/or treatment, which they incurred in the past and which continues.

COUNT III

VIOLATION OF NEW JERSEY PRODUCTS LIABILITY ACT,

N.J.S.A. 2A:58C-1 et seq.

(Failure to Warn)

71. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

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

73. Defendants are manufacturers and/or suppliers and/or distributors of Propulsid.

74. The Propulsid manufactured and/or supplied by Defendants was and is unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects.

75. Defendants failed to warn the FDA of material facts regarding the safety and efficacy of Propulsid, such that this drug would likely never have been approved, and no physician would have been able to prescribe this drug, for use in the United States.

76. Defendants failed to perform adequate testing in that adequate testing would have shown that Propulsid possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made with respect to the use of Propulsid.

77. The Propulsid manufactured and/or distributed and/or supplied by Defendants was

defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risk of injury from Propulsid, they failed to provide adequate warnings to physicians, users or consumers of Propulsid and continued to aggressively promote Propulsid.

78. As the proximate cause and legal result of the defective condition of Propulsid as manufactured and/or supplied and/or distributed by Defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein, Plaintiffs and Class members have been damaged.

COUNT IV

STRICT PRODUCT LIABILITY

(Failure to Warn)

79. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

80. The Propulsid manufactured and/or supplied by Defendants was and is unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. Defendants failed to perform adequate testing in that adequate testing would have shown that Propulsid possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made with respect to the use of Propulsid. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely

identified the risks and dangers of the drug.

81. The Propulsid manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because Defendants failed to provide adequate warnings to users or consumers of Propulsid and continued to aggressively promote Propulsid.

82. As the proximate cause and legal result of the defective condition of Propulsid as manufactured and/or supplied and/or distributed by Defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein, Plaintiffs and Class members have been damaged.

COUNT V

VIOLATION OF NEW JERSEY PRODUCTS LIABILITY ACT,

N.J.S.A. 2A:58C-1 et seq.

(Defective Design)

83. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

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

85. The Propulsid manufactured 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.

86. Alternatively, the Propulsid manufactured and/or supplied by Defendants was defective in design or formulation, in that, when it left the hands of the manufacturer and/or

suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other indigestion medications.

87. As the proximate cause and legal result of the defective condition of Propulsid as manufactured and/or supplied and/or distributed by Defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein, Plaintiffs and Class members have been damaged.

COUNT VI

STRICT PRODUCT LIABILITY

(Pursuant to Restatement Second of Torts 402a (1965))

88. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

89. The Propulsid manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

90. Alternatively, the Propulsid manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than drugs for the treatment of GERD.

91. There existed, at all times material hereto, safer alternative medications.

92. Defendants did not perform adequate testing on Propulsid. Adequate testing would

have shown that Propulsid caused serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

93. The Propulsid manufactured, designed, marketed, distributed and/or sold by defendant was unaccompanied by proper and adequate warnings regarding adverse effects associated with the use of Propulsid, and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

94. Defendants did not warn the FDA of material facts regarding the safety and efficacy of Propulsid, which facts defendant knew or should have known.

95. The Propulsid manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risk of injury from Propulsid, they failed to provide adequate warnings to users or consumers of Propulsid and continued to promote Propulsid.

96. As a result of the defective condition of Propulsid, Plaintiffs and Class members have been damaged.

COUNT VII

BREACH OF EXPRESS WARRANTY

97. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

98. Defendants expressly warranted that Propulsid was safe and well accepted by clinical studies.

99. Propulsid does not conform to these express representations because Propulsid is not

safe and has high levels of serious, life-threatening side effects.

100. As a direct and proximate result of the breach of said warranties, Plaintiffs and Class members have been damaged.

COUNT VIII

BREACH OF IMPLIED WARRANTY

101. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

102. At the time Defendants marketed, sold and distributed Propulsid for use by Plaintiffs and Class members, Defendants knew of the use for which Propulsid was intended (especially as it pertained to use by pediatric Class members) and impliedly warranted Propulsid to be of merchantable quality and safe and fit for such use.

103. Plaintiffs and the Class members reasonably relied upon the skill and judgment of Defendants as to whether Propulsid was of merchantable quality and safe and fit for its intended use.

104. Contrary to such implied warranty, Propulsid was not of merchantable quality or safe or fit for its intended use, because Propulsid was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used as described above.

105. As a direct and proximate result of the breach of implied warranty, Plaintiffs and Class members have been damaged.

COUNT IX

VIOLATION OF NEW JERSEY CONSUMER FRAUD ACT

N.J.S.A. 56:8-1 *et seq.*

(Knowing Concealment, Suppression, or Omission of Material Facts)

106. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

107. Plaintiffs bring this cause of action pursuant to the New Jersey Consumer Fraud Act (the "Act"), N.J.S.A. §56:8-1, *et seq.*, in that Plaintiffs and the Class purchased and used Propulsid primarily for their personal medical use and thereby suffered ascertainable loss as a result of Defendants' actions in violation of the Act.

108. Prescription drugs are "merchandise" as that term is defined in N.J.S.A. 56:8-1(c).

109. Defendants are manufacturers and/or distributors of Propulsid.

110. Unfair methods of competitive and unfair or deceptive acts or practices are defined and declared unlawful in N.J.S.A. §56:8-1, *et seq.*:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

111. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Propulsid, including but not limited to the risks of heart disease and cardiovascular injury. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with Propulsid use in order to increase the sales of Propulsid.

112. In their interaction with the FDA regarding the safety and efficacy of Propulsid, Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality that, had the FDA known of such facts, the drug would never have been

approved and no physician would have been able to prescribe this drug to Plaintiff and to members of the Class.

113. Defendants knew or should have known (or would have known had appropriate testing been done) that use of Propulsid caused serious and potentially life-threatening side effects of cardiovascular injury.

114. Defendants engaged in calculated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of Propulsid, and did so because the prospect of significant future profits caused them to ignore concerns regarding health and safety issues, all to the significant detriment of the public, including the Plaintiffs and members of the Class.

115. Many safer and less expensive indigestion agents were available to patients being treated with Propulsid.

116. Defendants purposefully downplayed the side effects or provided misinformation about adverse reactions and potential harms from Propulsid, and succeeded in persuading large segments of the relevant consumer market to request, i.e., the average consumer, and large segments of the medical community to prescribe Propulsid, despite both the lack of efficacy and the presence of significant dangers, as set forth herein.

117. Defendants had a post-manufacturing and continuing duty to warn, which arose when they knew, or with reasonable care should have known, that Propulsid was injurious or fatal.

118. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Propulsid, including but not limited to the risks of death, severe heart disease and other health problems associated with the use of Propulsid. Defendants have

purposely downplayed and/or understated the serious nature of the risks associated with the use of Propulsid and have implicitly encouraged the use of this drug despite knowledge of the dangerous side effects that this drug presents to the patient population.

119. Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed or concealed facts of such materiality regarding the safety and efficacy of Propulsid to or from the FDA such that, had the FDA known of such facts, the drug would never have been approved and no physician would have been able to prescribe this drug to Plaintiffs and/or to other members of the Class.

120. The Defendants knew or should have known, and would have known had appropriate testing been done, that the use of Propulsid caused the serious and potentially life threatening side effects of heart disease, other health related problems or death.

121. 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 Propulsid, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, *et seq*.

122. Defendants' actions as described above evidence lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2.

123. Such unconscionable commercial practices make Defendants liable to the Plaintiffs and the Class under N.J.S.A. 56:8-2, which provides that: "Any person violating the provisions of the within act shall be liable for a refund of all moneys acquired by means of any practice declared herein to be unlawful."

124. As a proximate result of these violations of the New Jersey Fraud Act, Plaintiffs and members of the Class have suffered ascertainable loss -- economic losses that include the purchase price of the drug, the out-of-pocket cost of interim medical tests and services and other costs incidental to their ingestion of a harmful and defective produce - - for which Defendants, jointly and severally, are liable to Plaintiffs and the members of the Class in an amount treble their actual damages. N.J.S.A. §56:8-13, 19.

125. N.J.S.A. §56:8-13, 19 provides Plaintiffs with standing to commence this action, recover treble damages, attorneys' fees and costs:

> **56:8-19. Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice.**
>
> Any person who suffers any ascertainable loss of moneys or property, real or personal, as a result of the use or employment by another person of any method, act, or practice declared unlawful under this act or the act hereby amended and supplemented may bring an action or assert a counterclaim therefor in any court of competent jurisdiction. In any action under this section the court shall, in addition to any other appropriate legal or equitable relief, award threefold the damages sustained by any person in interest. In all actions under this section the court shall also award reasonable attorneys' fees, filing fees and reasonable costs of suit.

126. As a proximate result of consuming Propulsid, Plaintiffs and the members of the Class have been significantly exposed to toxic chemicals and thereby have suffered an increased risk of heart disease and/or cardiovascular injury, making the periodic examination of such persons both reasonable and medically necessary.

127. There currently exists a means to detect the onset of heart disease and/or cardiovascular injury, as well as the other adverse health problems caused by the use of Propulsid, at an early stage, which includes the use of electrocardiograms, holter monitors, and other medical techniques, such that subsequent treatment would have a higher chance of success at prolonging life

and reducing suffering than would exist without such monitoring and treatment.

128. The prescribed monitoring regime is different from that normally recommended in the absence of the exposure to this drug, and is reasonably necessary according to contemporary scientific principles.

129. The increased susceptibility to injuries and irreparable threat to the health of Plaintiffs and other Class members resulting from their exposure to this hazardous substance can only be mitigated or redressed by the creation of a court-supervised medical monitoring fund to provide for a medical monitoring program, that would include:

1. Locating persons who use or used Propulsid and notifying them of the potential harm from the use of this drug;
2. An epidemiological or data analysis component to detect trends of adverse health effects related to the Class members' use of Propulsid, including population-based studies of and for the benefit of the Class and the establishment of an adverse health effects registry;
3. Gathering and forwarding to treating physicians information related to the diagnosis and treatment of injuries that may result from the use of Propulsid; and
4. Aiding in the early diagnosis and treatment of resulting injuries through ongoing testing and

monitoring of Propulsid users.

130. As a result of Defendants' marketing of Propulsid and Plaintiffs' consumption thereof, Plaintiffs and members of the Class are entitled to medical monitoring services funded by Defendants, including but not limited to, testing, preventative screening, care and treatment of the resultant medical conditions of heart disease and other latent adverse cardiovascular health problems associated with the use of Propulsid in addition to costs and reasonable attorneys' fees.

131. Propulsid users have no adequate remedy at law in that monetary damages alone do not compensate for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injury and aids in their treatment can prevent the greater harms which may not occur immediately, or for which there may be no noticeable symptoms, and which may be treatable if proper investigation is conducted and the health risks are diagnosed and treated before they occur or become worse.

132. As a further result of Defendants' violations of the New Jersey Consumer Fraud Act, Defendants are liable, jointly and severally to Plaintiffs and members of the Class for their reasonable attorney's fees, filing fees and costs. N.J.S.A. 56:8-19.

COUNT X

VIOLATION OF STATUTORY CONSUMER PROTECTION ACTS

133. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

134. Defendants' wrongful acts occurred in or emanated from New Jersey thereby rendering New Jersey's Consumer Fraud Act applicable to govern Defendants' conduct. In the alternative, Defendants' wrongful acts violated the consumer fraud and consumer protection statutes

of the various states.

COUNT XI

MEDICAL MONITORING, INJUNCTIVE AND EQUITABLE RELIEF

135. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if fully set forth herein.

136. The foregoing wrongful and negligent acts, omissions and conduct by Defendants constitute actionable negligence under the common law and/or constitute actionable conduct under the New Jersey Products Liability Act, N.J.S.A. 2A:58C *et seq.* (failure to warn and/or defective design) or under similar statutes in effect in other states, and/or actionable conduct under the common law of products liability and/or actionable conduct under the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1, *et seq.*, or under similar statutes in other states.

137. Defendants' negligent and wrongful acts are a proximate cause of the Plaintiffs' and Class members' suffering an increased risk of serious injury and disease, which they will continue to suffer. Plaintiffs and Class members have been exposed to a hazardous product and suffer a significantly increased risk of contracting serious injury including heart disease and/or cardiovascular injury. This increased risk makes periodic diagnostic and medical examinations reasonable and necessary.

138. Medical monitoring is particularly appropriate, and, indeed, imperative, with respect to this action due to the following:

1. Propulsid has been found to cause prolongation of the QT interval, heart disease and/or cardiovascular injury.

2. It has been discovered, both through scientific research and through review of Adverse Event Reports made to the FDA, that the injury and damage caused by Propulsid is often latent, asymptomatic and/or undiscovered.

139. Early detection and diagnosis of these diseases is clinically invaluable since it can prevent, reduce and/or significantly delay resulting discomfort, suffering and/or death and since these conditions can be often asymptomatic absent proper testing.

140. Easily administered, cost-effective monitoring and testing procedures exist which make the early detection and treatment of such injuries or disease possible and beneficial. For example, administration of the several readily available non-invasive tests readily diagnose the presence of prolongation of the QT interval, heart disease and/or cardiovascular injury, even in asymptomatic individuals. Early diagnosis of these diseases and conditions will allow prompt and effective treatment which will reduce the risk of morbidity and mortality which these patients would suffer if treatment were delayed until their condition became overly symptomatic.

141. The recommended testing procedures will be subject to expert testimony at the time of Class certification and/or trial. Appropriate testing regimes will likely include non-invasive, readily administrate able initial tests and procedures.

142. Many individuals at risk for heart disease and cardiovascular injury cannot afford to get appropriate testing and/or have not been advised, and do not otherwise know, of the need to undergo testing. Class members also need to be advised of the availability of non-invasive testing as a diagnostic tool and treatment which will prevent even more grave injury.

143. The increased susceptibility to injuries and irreparable threat to the health of Plaintiffs and the Class members resulting from their exposure to Propulsid can only be mitigated or addressed by the creation of a comprehensive medical monitoring program:

1. Notifying individuals who use or used Propulsid of the potential harm from Propulsid either alone or in combination with other drugs;
2. Funding further studies of the long term effects of Propulsid either alone or in combination with other drugs;
3. Aiding in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of the users of Propulsid;
4. Providing for medical examinations for all members of the Class;
5. Providing for accumulation and analysis of relevant medical and demographic information from Class members including, but not limited to the results of tests performed on Class members;
6. Providing for the creation, maintenance, and operation of a registry in which relevant demographic and medical information concerning all Class members is gathered, maintained and analyzed;

7. Providing for medical research concerning the incidence, prevalence, natural course and history, diagnosis and treatment of Propulsid induced diseases; and

8. Publishing and otherwise disseminating all such information to members of the Class and their physicians.

144. Plaintiffs and members of the Class have no adequate remedy at law in that monetary damages alone do not compensate for the continuing nature of harm to them. A monitoring program will enable Class members to ascertain the presence of injury and/or disease which are presently asymptomatic or only slightly symptomatic. Early detection and warnings aids in Class members' treatment and may prevent the greater harms if the adverse conditions caused by Propulsid are treated before they become worse.

145. Without a court-approved medical monitoring program, the users of Propulsid will not receive prompt medical care which could prolong their productive lives, increase prospects for improvement and minimize disability. The Class does not have an adequate remedy at law.

146. By reason of the foregoing, Defendants are liable, jointly and/or severally to Plaintiffs and every Class member for injunctive and equitable relief including periodic medical monitoring, as well as the other relief set forth herein.

COUNT XII

UNJUST ENRICHMENT

147. Plaintiffs repeat and reallege the allegations set forth in the paragraphs above as if

fully set forth herein.

148. Defendants have been unjustly enriched in the amount of the profits they have earned as a result of the Defendants' conduct as alleged herein.

149. The Defendants have been unjustly enriched at the expense of and to the detriment of the Plaintiffs and each member of the Class.

150. Defendants should be ordered to disgorge the profits they made from their wrongful sale of Propulsid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs on behalf of themselves and the Class members they seek to represent, request the following relief:

1. an Order declaring this action to be proper class action pursuant to Federal Rule of Civil Procedure 23, establishing an appropriate Class or Classes, and finding that Plaintiffs are proper representatives of the Class;

2. creation of a court-supervised trust fund, paid for by Defendants, to finance a medical monitoring program to deliver services, including, but not limited to, testing, preventative screening and surveillance for conditions resulting from, or potentially resulting from consumption of Propulsid, as well as establishment or a medical research and education fund and a medical/legal registry;

3. ordering that Defendants refund and make restitution of all monies acquired from the sale of Propulsid to Plaintiffs and members of the Class;

4. awarding Plaintiffs and Class members compensatory and punitive damages in an amount to be proven at trial for the wrongful acts complained of;

5. awarding Plaintiffs and Class members statutory damages as permitted, including any applicable exemplary damages;

6. awarding Plaintiffs and Class members punitive damages to deter Defendants' outrageous and wanton conduct and flagrant disregard for the lives and health of the Class members;

7. awarding Plaintiffs and the Class pre-judgment and post-judgment interest;

8. awarding Plaintiffs and the Class their costs and expenses in this litigation, including, but not limited to, expert fees and reasonable attorneys' fees; and

9. awarding Plaintiffs and the Class such other and further relief as may be just and proper.

Respectfully submitted:

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PLAINTIFFS' STEERING COMMITTEE

CERTIFICATE OF SERVICE

I hereby certify that the above and foregoing Master Class Action Complaint has been served on Liaison Counsel, James Irwin, by U. S. Mail and e-mail or by hand delivery and e-mail and upon all parties electronically by uploading the same to Verilaw in accordance with Pre-Trial Order No. 4, on this 5th day of October, 2001.