IN THE SUPERIOR COURT OF NEW JERSEY
LAW DIVISION, ATLANTIC COUNTY

PLAINTIFF(S)	:	
	:	
v.	:	ACCUTANE LITIGATION
	:	
HOFFMANN-LA ROCHE INC.; ROCHE LABORATORIES INC.; F. HOFFMANN-LA ROCHE LTD.; and ROCHE HOLDING LTD.,	:	Case Code Number 271
	:	**FIRST AMENDED MASTER LONG FORM COMPLAINT**

1. Pursuant to the Order of this Court, this Complaint is a First Amended Master Complaint filed for all plaintiffs, or if applicable, plaintiff's spouse, child, decedent or ward represented by any plaintiff's counsel, and, by operation of such order, all allegations pleaded herein are deemed pleaded in any Short-Form Complaint previously or hereafter filed.

2. As more particularly pleaded below, each plaintiff maintains that the pharmaceutical drug Accutane (also known as Roaccutane and generically as isotretinoin), is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings as to the dangers associated with its use. (Collectively, Accutane and its generic equivalents are referred to herein as "Isotretinoin").

PARTIES -- PLAINTIFF

3. Plaintiff(s) was (were) injured as a result of his or her (or, if applicable, their spouse's, child's, decedents' or ward's) use of Isotretinoin and therefore seek, to the extent denoted on Plaintiff's Short Form Complaint, all such compensatory damages, punitive damages,

all ascertainable economic losses, including, if applicable, survival damages, wrongful death damages, treble damages, attorneys' fees, reimbursement of the cost of obtaining Isotretinoin, reimbursement for all past, present and future health and medical care costs related to Isotretinoin, per quod and derivative damages.

4. Plaintiff(s) is (are) specifically identified in the Short Form Complaint filed with Certification in the Accutane mass tort litigation, designated with Case Code No. 271 in accordance with the Case Management Order Regarding Master and Short Form Complaints.

DEFENDANTS

5. At all times material to this action, Defendant HOFFMANN-La ROCHE INC. was a New Jersey corporation, and Defendant ROCHE LABORATORIES INC., was a Delaware corporation, with their principal place of business located at 340 Kingsland Street, Nutley, New Jersey 07110.

6. Defendant, ROCHE HOLDING LTD., a foreign corporation, is a joint-stock company with its registered office in Basel, Switzerland, whose purpose is to hold shares in companies that manufacture pharmaceutical and other products. Defendant, ROCHE HOLDING LTD., is and was the parent corporation of Defendant, F. HOFFMANN-LA ROCHE LTD., a foreign corporation, which also has its corporate headquarters in Basel, Switzerland. Defendants, HOFFMANN-LA ROCHE INC. and ROCHE LABORATORIES INC., are wholly owned subsidiaries of Defendant, ROCHE HOLDING LTD. and/or F. HOFFMANN-LA ROCHE LTD. Collectively, the Plaintiff refers to the umbrella of companies controlled and owned by Defendants, ROCHE HOLDING LTD. and/or F. HOFFMANN-LA ROCHE LTD., as the "Roche Group."

7. At all times material hereto, Defendants, The Roche Group, were directly or indirectly in the business of designing, creating, manufacturing, assembling, testing, labeling, supplying, packaging, warning, promoting, marketing, developing, selling and/or distributing the pharmaceutical drug Accutane, also known as Roaccutane, and generically known as isotretinoin. The Swiss Defendants are the principals of the United States Defendants and ultimately control the activities of the United States Defendants and are the parent company of the United States Defendants.

8. The Roche Group presents its sales and profits to the public on a unified worldwide basis. The Roche Group present themselves as a highly integrated single entity, releasing one unified set of financial statements and representing itself as one unit in obtaining drug approval and in medical research and development. The Roche Group does not differentiate by entity, but instead refer to internal divisions that cut across entity lines. The Roche Group produces a single Core Data Sheet (also known as the International Standard Prescribing Information), containing the single scientific and medical opinion of all the Roche Group entities with respect to Isotretinoin. Further, Isotretinoin is referred to in publications as a product of the Roche Group and the sole active ingredient for Isotretinoin is distributed to all group affiliates from the Swiss Defendants.

The Roche Group has one global e-mail system, one global standard operating procedures manual, and one global database to which all Isotretinoin adverse effects are reported. The Swiss Defendants have significant input and are actively involved in the labeling of regulatory and scientific matter relating to the sale of Isotretinoin by affiliated U. S. companies and thus are involved in doing business in New Jersey, and subject to jurisdiction in New Jersey.

FACTUAL ALLEGATIONS

9. At all times material hereto, Defendants, HOFFMANN-La ROCHE, INC., and/or ROCHE LABORATORIES, INC. engaged directly or indirectly in the business of designing, developing, creating, manufacturing, assembling, testing, labeling, supplying, packaging, warning, promoting, marketing, developing, selling and/or distributing in interstate commerce, the drug Accutane, also known as Roaccutane, and generically known as isotretinoin. These actions are under the ultimate control and supervision of the Swiss Defendants.

10. Defendants, HOFFMANN-La ROCHE INC. and/or ROCHE LABORATORIES INC. directly or indirectly, negligently and/or defectively developed, made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, marketed, advertised, warned, and/or sold, in this state and throughout the United States, the drug Isotretinoin. These actions are under the ultimate control and supervision of the Swiss Defendants.

11. Defendants, HOFFMANN-La ROCHE INC., and/or ROCHE LABORATORIES INC., had control of the design, assembly, packaging, marketing, advertising, manufacturing, labeling, testing, promoting, distribution and/or sale of the drug Isotretinoin. These actions are under the ultimate control and supervision of the Swiss Defendants.

12. At all times material hereto, the Defendants either knew or should have known that the drug Isotretinoin was causally related to severe and life threatening complications and side effects.

13. Although Defendants knew or should have known of the dangers of Isotretinoin use, Defendants proceeded to manufacture, distribute, sell, market, and/or permitted the drug to be advertised, promoted and/or sold without adequate warnings of the serious side effects and dangerous risks.

14. Upon information and belief, at all times relevant hereto, the corporate officers, directors and/or managing agents of the Defendants knew and ratified the acts of the Defendants as alleged herein.

A. The Prescription Drug Isotretinoin and Its Side Effects.

15. In June of 1982, the Roche Group received approval from the Federal Food and Drug Administration ("FDA") to market, distribute and dispense the drug Isotretinoin for use in treating recalcitrant nodular acne throughout the United States.

16. Within a short period of time after Isotretinoin was placed in interstate commerce, users of the drug reported a number of adverse effects from the drug. Patients and physicians began reporting adverse events including: inflammatory bowel disease ("IBD") and gastrointestinal problems, birth defects in children of pregnant women who ingest the drug, and depression or suicide attempts after taking Isotretinoin.

17. The side effect of Isotretinoin use that is central to this case is the propensity of Isotretinoin to cause plaintiffs to suffer from IBD, which is a condition involving the chronic inflammation of the gastrointestinal tract. IBD commonly manifests itself as one of two diseases: Crohn's disease or ulcerative colitis. Symptoms of IBD include but are not limited to diarrhea, gastrointestinal bleeding, rectal bleeding, bloody bowel movements, fatigue, dehydration, anemia, cramping, abdominal pain and bloating. IBD is a permanent condition.

B. Early Warning Signals Suggested That Isotretinoin Causes IBD.

18. Before obtaining FDA approval for Isotretinoin, Roche performed various clinical studies on the drug which, among other things, produced information concerning potential gastrointestinal side effects. In a pre-approval study on 523 patients, 21.6 percent of the patients reported suffering some gastrointestinal problems after using Isotretinoin. Additionally, pre-approval studies of Isotretinoin revealed gastrointestinal injuries in dogs that were administered the drug.

19. The FDA expressed concern over the link between Isotretinoin and gastrointestinal symptoms raised by the pre-approval studies. Nevertheless, Isotretinoin was approved for sale in 1982. The Roche Group did not include any warning regarding the potential risk of IBD on the original 1982 Isotretinoin label.

C. Post-Marketing Adverse Event Reports Further Indicated a Causal Connection Between Isotretinoin and IBD.

20. Although approved by the FDA based on information provided to the agency by the Roche Group, over the ensuing years, additional information not available to the FDA became known to the Roche Group that indicated Isotretinoin posed far greater hazards to patients than previously represented. Numerous Med Watch reports have described adverse gastrointestinal effects among patients taking Isotretinoin. Additionally, internal analyses led to conclusions that Accutane could induce IBD or that it was the possible cause of IBD in some cases.

21. After it began marketing Accutane in 1982, the Roche Group had a duty to monitor side effects reported by Isotretinoin users. The Roche Group received post-marketing reports from numerous patients who developed IBD following their use of Isotretinoin.

22. Based on the information contained in the Roche Group's database of adverse event reports, a Roche physician concluded in 1994 that it was "reasonable" to conclude from the data that Isotretinoin "may induce or aggravate" IBD.

D. The Roche Group Failed to Advise the FDA of Its Conclusion and Failed to Investigate and Warn of Isotretinoin's Dangers.

23. Despite the information contained in its own adverse event database and the conclusions drawn by its own internal scientists, the Roche Group did not share its conclusions that Isotretinoin "may induce or aggravate" IBD, or that IBD was the probably cause of IBD, with the FDA.

24. Despite the information contained in its own adverse event database and the conclusions drawn by its own internal scientists, the Roche Group did not adequately investigate, study, test or research the propensity of Isotretinoin to induce, aggravate or cause IBD.

25. Despite the information contained in its own adverse event database and the conclusion that Isotretinoin may induce IBD drawn by its own physician, the Roche Group, as the manufacturer of Isotretinoin, did not adequately inform physicians or consumers of Isotretinoin's propensity to induce, aggravate or cause IBD.

26. The initial Isotretinoin product label, issued in 1982, did not include any warnings about the potential risks of IBD.

27. Roche's subsequent changes to the Isotretinoin warnings were delayed past the time when they were warranted by reasonably available data and information. In its warnings, Roche never shared its knowledge of the risk of IBD from using Isotretinoin. Rather, the subsequent warnings were worded to downplay the extent and severity of the IBD danger posed by Isotretinoin use, or were contradicted (and thereby marginalized) by information put forth,

directly or indirectly, by the Roche Group that was intended to foster the impression among users and the medical community that Isotretinoin was a safe and effective acne treatment.

E. Generic Equivalents of Brand-Name Accutane.

28. Beginning in 2002, generic manufacturers began marketing generic forms of Accutane under several different brand names. The Generic manufacturers represented the generic isotretinoin product they manufactured and sold as having the same active ingredient as Accutane and as being the bioequivalent and therapeutic equivalent of Accutane. Upon information and belief, the isotretinoin drug product made by the Generic manufacturers did in fact have the same active ingredient as Accutane and was the bioequivalent and therapeutic equivalent of Accutane.

29. The United States Food and Drug Administration ("FDA") and the medical and pharmaceutical communities, including virtually all physicians, pharmacists, and drug companies, recognize and have recognized that bioequivalent and therapeutically equivalent generic drug products should be expected to produce, and do produce, the same pharmacological and other physiological effects, including side effects, in patients as equivalent doses of their counterpart brand-name drug products.

30. Commercial retail pharmacies will frequently fill prescriptions with generic versions of name brand drugs when a generic version is available. Applicable drug selection laws either require or permit a pharmacist to fill a prescription for a particular drug, whether identified by a brand name (such as "Accutane") or by generic name (such as "Isotretinoin") with the less-expensive generic version of the prescribed drug.

31. All wholesale shipments of prescription drug products, and all samples of such products, are accompanied by "package inserts" which contain information about the product including its active ingredients, phamacokinetics, chemistry, warnings and side effects. The verbatim content of the package insert for a brand-name prescription drug product is typically published, at the instance of the manufacturer, as a so called monograph for the product, in the Physician's Desk Reference (PDR), an annual compilation of such monographs, supplemented periodically. A monograph for any prescription drug product may be published in the PDR at the instance of its manufacturer upon payment of a fee to the publisher.

32. It is reasonable and foreseeable that physicians would rely upon the information contained in the package insert, PDR, monograph or other literature regarding Accutane when considering the properties and effects of the drug Accutane. It is equally reasonable and foreseeable that a physician would rely upon the same information as to the properties and effects of generic drug products that are the bioequivalent and therapeutic equivalent of Accutane.

33. The Generic manufacturers adopted, in substance, as the text of the "package insert" for their generic Isotretinoin drug product, the verbatim content of the package insert for Accutane modified only to reflect therapeutically non-relevant differences among the products, such as color, shape, inactive ingredients, and source of manufacture.

34. The Generic manufacturers relied upon the Roche Group to communicate to physicians adequate information concerning the appropriate uses and risks entailed in the use of Isotretinoin products, including both Accutane and its bioequivalent and therapeutic equivalent generic Isotretinoin products. The Generic manufacturers each expressly and impliedly

adopted, as applicable to their generic Isotretinoin product, such drug information as was disseminated about Accutane by the Roche Group.

35. The package inserts, PDR, monograph and other labeling for Accutane contained false and/or misleading statements and omitted information material to the foreseeable and ordinary contemplated uses of Accutane and its generic equivalents. In particular, the package inserts, PDR, monograph and other labeling for Accutane – as incorporated for use with the generic Isotretinoin drug product ingested by Plaintiff – failed to adequately advise Plaintiff of the risk of IBD.

36. The dangerous propensities of Isotretinoin products, particularly the propensity to cause IBD, were known or scientifically knowable to the defendants through appropriate research and testing at the time that the generic manufacturers distributed, supplied, warned and/or sold the products. Meanwhile, the dangerous propensities of Isotretinoin products were not known to ordinary physicians who could be reasonably expected to prescribe the drug for their patients or to such patients themselves.

E. Plaintiff's Use of Isotretinoin Products and Resulting Injuries.

37. Upon information and belief, the brand-name Accutane pills were made by the Roche Group and accompanied by drug information and warnings prepared by the Roche Group. Upon information and belief, the generic Isotretinoin pills were made by the generic manufacturers and accompanied by drug information and warnings that were substantively identical to the warnings and drug information prepared and put forth by the Roche Group in connection with the drug Accutane.

38. In prescribing Isotretinoin for the Plaintiff, Plaintiff's physicians relied upon the information published in the package inserts and/or the PDR and/or otherwise disseminated by

the manufacturer. In particular, Plaintiff's physicians relied, directly or indirectly, on information put forth by the Roche Group regarding the brand-name Isotretinoin product, Accutane. Plaintiff's physicians believed that generic drug products that were the biological and therapeutic equivalent of brand name Accutane would also present the same risks and side effects as their brand name counterpart. Plaintiff's physicians were not aware of information indicating that the risks or side effect of the generic isotretinoin drug products they prescribed for Plaintiff were different or contrary to the inaccurate, misleading, materially incomplete, false and otherwise inadequate information thus disseminated.

39. As a result of Plaintiff's ingestion of Isotretinoin, Plaintiff experienced several adverse health effects culminating in diagnoses of injuries including one or more of the following conditions and symptoms: ulcerative colitis, Crohn's disease, colitis, IBD, rectal bleeding, diarrhea, abdominal pain or other injury.

40. Had Plaintiff been adequately warned of the true risk of developing IBD with Isotretinoin use, Plaintiff would not have taken the drug.

DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

41. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

42. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, fraudulent concealment, and/or minority tolling.

43. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and

diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

44. Despite diligent investigation by Plaintiff into the cause of Plaintiff's injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to Isotretinoin was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

45. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with taking Isotretinoin. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

46. The running of the statute of limitations in this cause may be tolled due to the pendency of a class action proceeding against one or more of the Defendants herein. Class Action tolling is proper where Plaintiff is a member of an asserted class and the claims asserted in the class action proceeding are the same as the claims asserted in this action.

47. The statute of limitations is tolled due to the minority of the Plaintiff. Plaintiff was a minor at the time Plaintiff ingested Isotretinoin. This action was filed within the applicable statutory period after Plaintiff achieved the age of majority.

48. The statute of limitations is tolled due to the disability of Plaintiff. Plaintiff was under one or more of the following recognized disabilities: mental illness, insanity, inability to comprehend the nature of legal proceedings, imprisonment, absence from the state due to government service, or other legal disability recognized by the applicable state law.

49. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and Defendants' tortious conduct.

COUNT I
PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 *et seq.* and/or the analogous law of plaintiff's state(s) of ingestion and/or prescription.)

50. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

51. At all times material hereto, Defendants, HOFFMANN-LA ROCHE INC. and/or ROCHE LABORATORIES INC., engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting the drug Isotretinoin, which is defective and unreasonably dangerous to consumers, including the Plaintiff(s). These actions are under the ultimate control and supervision of the Swiss Defendants.

52. At all times material hereto, the drug Isotretinoin was sold, distributed, supplied, manufactured, marketed and/or promoted by Defendants, HOFFMANN-La ROCHE INC. and/or ROCHE LABORATORIES INC. These actions are under the ultimate control and supervision of the Swiss Defendants.

53. At all times material hereto, the drug Isotretinoin, was expected to reach, and did reach, consumers in this state and throughout the United States, including the Plaintiff(s),

without substantial change in the condition in which it was sold. These actions are under the ultimate control and supervision of the Swiss Defendants.

54. At all times material hereto, Isotretinoin was sold, marketed, distributed, supplied, manufactured and/or promoted by the Defendants, in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff(s) to risks that exceeded the benefits of the drug;

(b) When placed in the stream of commerce, it was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of acne;

(c) The drug was insufficiently tested;

(d) The drug caused harmful side effects that outweighed any potential utility;

(e) The drug was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including the Plaintiff(s), of the full nature and extent of the risks and side effects associated with their use, thereby rendering the Defendants, liable to the Plaintiff(s), individually and collectively.

(f) Defendants also failed to adequately instruct on the length of time an individual should be allowed to continue using Isotretinoin.

55. In the alternative, Plaintiff pleads the analogous statute and/or common law of plaintiffs' state(s) of ingestion and/or prescription.

56. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiff(s) have suffered and continue to suffer serious and permanent physical and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-2 *et seq.* and/or the analogous law of plaintiff's state(s) of ingestion and/or prescription)

57. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

58. The drug Isotretinoin was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff(s) herein, to the dangerous risks and reactions associated with the drug, including, but not limited to severe damage to the internal organs, IBD, vascular problems, liver toxicity, musculoskeletal problems, including premature epiphyseal closure, skeletal hyperostosis, calcification of tendons and ligaments, arthralgia, transient chest pain, pseudotumor cerebri, dizziness, drowsiness, headaches, seizures, stroke, pancreatitis, suicidal ideations, suicide,

depression, psychosis, emotional instability, elevated triglycerides, and elevated cholesterol, and other serious and life-threatening side effects.

59. The Plaintiff(s) could not have discovered any defect in the drug through the exercise of care.

60. Defendants, as manufacturers and/or distributors of a prescription drug, are held to the level of knowledge of an expert in the field.

61. The warnings that were given by the Defendants were not accurate, clear, and/or were ambiguous.

62. Defendants had a continuing duty to warn the Plaintiff(s) of the dangers of its drug.

63. In the alternative, Plaintiff(s) pleads the analogous statute and/or common law cause of plaintiff(s)'s state(s) of ingestion and/or prescription.

64. As direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff(s) have suffered and continue to suffer serious and permanent physical and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
NEW JERSEY CONSUMER FRAUD ACT (N.J.S.A. 56:8-2 *et seq.* and/or the analogous law of plaintiff's state(s) of ingestion or prescription.)

65. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

66. Prescription drugs, such as Isotretinoin, are "merchandise" as that term is defined by N.J.S.A. 56:8-1(c).

67. Defendants are manufacturers, promoters, marketers, developers, sellers and/or distributors of Isotretinoin.

68. Defendants knew, or should have known, that the use of Isotretinoin caused serious and potentially life-threatening side effects.

69. Defendants' practice of promoting Isotretinoin (a) created or reinforced a false impression as to the safety of taking Isotretinoin for the treatment of acne and (b) places all consumers of Accutane at risk for serious and potentially lethal side effects.

70. Defendants' statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including the Plaintiff(s), would rely on the Defendant's statements and/or omissions.

71. Plaintiff(s)' physician prescribed and/or otherwise provided Plaintiff(s) with Isotretinoin, and Plaintiff(s) consumed Isotretinoin, primarily for personal and family reasons and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

72. The aforesaid promotion and release of Isotretinoin into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission in connection with the sale or

advertisement of merchandise or services by Defendants, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq. and/or other applicable state law.

73. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

74. In the alternative, Plaintiff(s) pleads the analogous statute and/or common law of plaintiffs' state(s) of ingestion and/or prescription.

75. As a proximate result of the acts of consumer fraud set forth above, Plaintiff(s) have purchased an unsafe product and incurred economic loss that includes the purchase price of Accutane and other out-of pocket healthcare related costs, for which Defendants are liable to Plaintiff(s) for treble damages.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

76. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

77. Defendants placed Isotretinoin into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including the Plaintiff(s), of the risks associated with the use of Accutane.

78. Defendants had a duty to exercise reasonable care in the research, development, design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of Isotretinoin, including a duty to:

(a) Ensure that the product did not cause the user unreasonably dangerous side effects;

(b) Warn of dangerous and potentially fatal side effects; and

(c) Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiff(s).

79. When Plaintiff(s)' physicians(s) prescribed Isotretinoin and Plaintiff(s) made the decision to use Isotretinoin, both Plaintiff(s) and their physicians reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers and side effects of Accutane.

80. Plaintiff(s)' physician(s), the FDA and/or Plaintiff(s) had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning Isotretinoin when Plaintiff(s)' physician prescribed and/or otherwise provided Isotretinoin and Plaintiff(s) purchased and used Isotretinoin as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendants. Plaintiff(s) justifiably and detrimentally relied on the warranties and representations of Defendants in the purchase and use of Isotretinoin.

81. Defendants were under a duty to disclose the defective and unsafe nature of Isotretinoin to physicians, the FDA, consumers and users, such as Plaintiff(s). Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the FDA and users, such as Plaintiff(s), could not have reasonably discovered such defects.

82. By the conduct alleged, Defendants, their agents and employees expressly warranted to Plaintiff(s) and Plaintiff(s)' physician(s) that the products were merchantable and fit for the purpose intended, in violation of N.J.S.A. 12A:2-313 *et seq*.

83. This warranty was breached because Isotretinoin was not safe and effective as a medication for acne, as Defendants had represented, and Plaintiff(s) were injured.

84. In the alternative, Plaintiff(s) pleads the analogous statute and/or common law of plaintiffs' state(s) of ingestion and/or prescription.

85. As a direct result of Defendants' conduct as aforesaid, Plaintiff(s) have suffered and continue to suffer serious and permanent physical and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
PUNITIVE DAMAGES

86. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

87. Although Defendants knew or recklessly disregarded the fact that Isotretinoin causes debilitating and potentially lethal side effects, Defendants continued to market Isotretinoin to consumers, including Plaintiff(s), without disclosing the true risk of side effects when there were safer alternative methods for treating acne.

88. Defendants knew of Isotretinoin's defective nature, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff(s) in conscious and/or negligent disregard of the foreseeable harm caused by Isotretinoin.

89. Defendants intentionally concealed or recklessly failed to disclose to the public, including Plaintiff(s), the potentially life-threatening side effects of Isotretinoin to ensure their continued and increased sales. Defendant failed to provide warnings that would have dissuaded physicians from prescribing Isotretinoin and consumers from purchasing and consuming Isotretinoin, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming.

90. The aforementioned conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff(s), thereby entitling Plaintiff(s) to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

91. In the alternative, Plaintiff(s) pleads the analogous statute and/or common law of plaintiffs' state(s) of ingestion and/or prescription.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT VI
WRONGFUL DEATH

92. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

93. As a result of the acts and/or omissions of the Defendants as set forth herein, Decedent suffered serious emotional and bodily injuries resulting in his/her death on (date).

94. Plaintiff(s) (as Decedent's surviving relative (wife, husband, father, mother, etc.), are entitled to recover damages as Decedent would have if he/she were living, as a result of the acts and/or omissions of the Defendants as specifically pled herein pursuant to N.J.S.A. 2A:15-3.

95. Plaintiff(s) are entitled to recover punitive damages and damages for the pain and suffering caused to Decedent from the acts and omissions of the Defendant as specifically pled herein, including, without limitation, punitive damages pursuant to N.J.S.A. 2A:15-3.

96. In the alternative, Plaintiff(s) pleads the analogous statute and/or common law of plaintiffs' state(s) of ingestion and/or prescription.

WHEREFORE, Plaintiff(s) demand Judgment on this Count against Defendant and in the alternative for the damages resulting from the death of the (wife, husband father, mother, etc.)'s death including, without limitation, Decedent's pecuniary injury, together with all hospital, medical and funeral expenses as specifically provided for under the applicable state law, as well as compensatory damages, treble damages, exemplary damages, attorneys' fees, interest and costs of suit, including without limitation, punitive damages as provided for under the applicable state law, and all such other relief as the Court deems just.

COUNT VII
SURVIVAL ACTION

97. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

98. As a result of the actions and inactions of the Defendants, Decedent was caused to suffer before his/her death.

99. Plaintiff(s), on behalf of the Decedent's estate, seeks damages compensable under the Survival Act, N.J.S.A. 2A:15-3 (or any successor statute and/or the analogous law of plaintiff's state(s) of ingestion and/or prescription) against the Defendants. Plaintiff(s), in his/her/their own right, seek damages compensable under the Survival Act, N.J.S.A. 2A:15-3 (or any successor statute and/or the analogous law of plaintiff's state(s) of ingestion and/or prescription) against the Defendants.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT VIII
LOSS OF CONSORTIUM/PER QUOD CLAIM

100. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

101. By reason of the foregoing, Plaintiff's (mother, father, child) has (have) necessarily paid and has (have) become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

102. By reason of the foregoing, Plaintiff's (mother, father, child) further has (have) been caused presently and in the future the loss of his/her (wife, husband, child)'s companionship, services, and society.

103. In the alternative, Plaintiff(s) pleads the analogous statute and/or common law of plaintiffs' state(s) of ingestion and/or prescription.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT IX
NEGLIGENCE AS AGAINST THE ROCHE GROUP WITH REGARD TO BRAND NAME ACCUTANE

104. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

105. At all times relevant to this Complaint, the Roche Group had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare Accutane for use.

106. The Roche Group directly or indirectly, negligently and/or defectively, made, created, designed, developed, manufactured, assembled, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned and/or sold in interstate commerce, and in the State of New Jersey, the drug Accutane.

107. The Roche Group knew or should have known that the use of Accutane created an unreasonable risk of injury – including an unreasonable risk of IBD - as a result of its design, testing, manufacturing, marketing and inadequate warnings.

108. The Roche Group was negligent, and breached duties owed to Plaintiff with respect to Accutane in the following regards:

a. Despite knowledge of injurious side effects, failing to accompany Accutane with adequate warnings and instructions regarding the adverse effects caused by the product's foreseeable use by Plaintiff;

b. Failing to adequately and properly test the drug before placing the drug on the market and after the drug was on the market. Specifically, the Roche Group failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to inflammatory bowel disease, vascular problems, liver toxicity, musculoskeletal problems including premature epiphyseal closure, skeletal hyperostosis, calcification of tendons and ligaments, arthralgia, transient chest pain, pseudotumor cerebri, dizziness, drowsiness, headaches, seizures, stroke, pancreatitis, suicidal ideations, suicide, depression, psychosis, emotional

instability, elevated triglycerides, elevated cholesterol, and other serious and life-threatening side effects;

c. Failing to conduct adequate post-marketing surveillance and testing to determine the safety of the product. This is so even after numerous reports of adverse events of IBD were reported and logged in the Roche Group's own database;

d. Failing to provide adequate post-marketing warnings or instructions after the Roche Group knew or should have known of the significant risks associated with the use of the drug;

e. Despite knowledge of the danger, failing to adequately warn Plaintiff and/or Plaintiff's physician that Accutane causes IBD and other injurious conditions.

f. Despite the fact that they knew or should have known of Accutane's dangers, the Roche Group willfully and deliberately failed to adequately disclose the known or knowable risks of Accutane use in conscious disregard for Plaintiffs' safety or welfare;

g. Encouraging misuse, overuse and off-label of the drug by doctors and consumers while downplaying the side effects of the drug to doctors and consumers in order to increase their profits from Accutane sales.

h. Failing to warn about the dangers of prolonged use of Accutane;

i. Failing to adequately provide labeling to draw attention to the adverse effects of the dug Accutane.

j. Failing to make a full disclosure of the adverse effects of the drug Accutane.

k. Continuing to manufacture, inadequately label and market for profit the drug Accutane when the adverse health effects of the drug were known to create a substantial risk to the health of persons ingesting the drug.

l. Failing to withdraw Accutane from the market when the adverse health effects of the drug were known to create a substantial risk to the health of persons ingesting the drug.

m. Failing to exercise the degree of care and caution that a reasonable, prudent manufacture would exercise in the same or similar circumstances.

109. As a result of the Roche Group's negligence and their willful and wanton misconduct, Accutane was prescribed and used by Plaintiff thereby causing Plaintiff to sustain

reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint. The negligence of the Roche Group was a proximate cause of Plaintiff's harm and injuries.

110. The Roche Group' conduct fell below the required standard of care in that it failed to comply with the minimal standards of conduct adhered to by reasonably prudent manufacturers of pharmaceutical products, and the minimal standards of conduct adhered to by a reasonably manufacturer when preparing consumer warnings and information in connection with pharmaceutical products.

111. The negligence described above directly and proximately caused Plaintiff's injuries. Had the Roche Group properly designed, adequately tested, properly responded to safety signals, and provided full, complete, clear, truthful, and accurate warnings, Plaintiff would not have ingested Accutane.

112. As a direct and legal consequence of the Roche Group's negligence, Plaintiff has sustained serious and permanent injuries including but not limited to: IBD, gastrointestinal problems, inflammatory bowel diseases including but not limited to colitis, ulcerative colitis, Crohn's Disease, rectal bleeding, diarrhea, anemia, abdominal pain, edema of the colon and other bodily injury. As a result of the injuries suffered due to the use of the drug, Plaintiff has endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT X
NEGLIGENCE AS AGAINST THE ROCHE GROUP WITH REGARD TO GENERIC ISOTRETINOIN PRODUCTS

113. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

114. Based on public policy, legislative enactments, and customary practices among physicians and manufacturers of generic drug products, the Roche Group knew or should have known that physicians, in weighing the potential benefits and potential risks of using Isotretinoin products, whether name brand or generic, and in writing prescriptions for either "Accutane" or "Isotretinoin", would rely upon information disseminated to them by the manufacturer of the brand-name drug product regardless of whether the prescription might be filled with either the name-brand product or with one of the generic isotretinoin products. The Roche Group also knew, or should have known, that many patients, in accordance with prescriptions for either "Accutane" or "Isotretinoin" written in reliance upon information put forth regarding Accutane, were likely to ingest a generic isotretinoin product.

115. At all times relevant to this Complaint, the Roche Group had a duty to properly test, package, label, and provide proper warnings regarding Accutane, knowing that manufacturers and distributors of generic drug products are required to copy the substance of the brand name package insert verbatim for use with their generic drug products. Further, manufacturers of generic products typically rely upon the marketing efforts of the name brand

manufacturer to generate sales of their own products. The Roche Group knew or should have known that their marketing efforts were relied upon to generate sales of generic isotretinoin.

116. Despite knowing that the false, inadequate and incomplete information it put forth would be relied upon by physicians and patients when prescribing and ingesting both Accutane and generic isotretinoin products, the Roche Group directly or indirectly, negligently and/or defectively, made, created, designed, developed, tested, labeled, supplied, promoted, marketed, advertised, warned and sold or provided deficient Accutane warnings and labeling information.

117. The Roche Group knew or should have known that the inadequate Accutane label created an unreasonable risk of injury – including an unreasonable risk of IBD.

118. The Roche Group was negligent, and breached duties owed to Plaintiff with respect to Isotretinoin in the following regards:

a. Despite knowledge of the drug's injurious side effects, failing to accompany Accutane with adequate warnings and instructions regarding the adverse effects, including the risk of IBD, associated with Isotretinoin's foreseeable use by Plaintiff;

b. Failing to adequately and properly test the drug before placing the drug on the market and after the drug was on the market. Specifically, the Roche Group failed to conduct sufficient testing on the drug which, if properly performed would have shown that Isotretinoin had serious side effects, including, but not limited to IBD;

c. Failing to conduct adequate post-marketing surveillance and testing to determine the safety of the product. This is so even after numerous reports of adverse events of IBD were reported and logged in the Roche Group's own database;

d. Failing to provide adequate post-marketing warnings or instructions to Plaintiff and/or Plaintiff's physician regarding Accutane after the Roche Group knew or should have known of the significant risks associated with the use of the drug;

e. Despite knowledge of the danger, failing to adequately warn Plaintiff and/or Plaintiff's physician that the use of Accutane could result in IBD and other injurious conditions;

f. Encouraging misuse, overuse and off-label use of the drug by doctors and consumers while downplaying the side effects of the drug to doctors and consumers in order to increase their profits from Accutane sales;

g. Failing to adequately provide labeling to draw attention to the adverse effects of the drug Accutane;

h. Failing to make a full disclosure of the adverse effects of the drug Accutane;

i. Continuing to market Accutane when the adverse health effects of the drug were known to create a substantial risk to the health of persons ingesting the drug;

j. Failing to exercise the degree of care and caution that a reasonable, prudent manufacture would exercise in the same or similar circumstances.

119. As a result of the Roche Group's negligence and their willful and wanton misconduct in connection with Accutane labeling, warnings and information that the Roche Group knew would be incorporated into, and become a component of, generic isotretinoin products. Plaintiff was also caused to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint. The negligence of the Roche Group was a proximate cause of Plaintiff's harm and injuries.

120. The Roche Group's conduct fell below the required standard of care in that it failed to comply with the minimal standards of conduct adhered to by reasonably prudent manufacturers of pharmaceutical products, and the minimal standards of conduct adhered to by a reasonably manufacturer when preparing consumer warnings and information in connection with pharmaceutical products.

121. As a direct and legal consequence of the Roche Group's negligence, Plaintiff has sustained serious and permanent injuries including but not limited to: IBD, gastrointestinal problems, inflammatory bowel diseases including but not limited to colitis, ulcerative colitis,

Crohn's Disease, rectal bleeding, diarrhea, anemia, abdominal pain, edema of the colon and other bodily injury. As a result of the injuries suffered due to the use of the drug, Plaintiff has endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT XI
NEGLIGENT MISREPRESENTATION AS AGAINST THE ROCHE GROUP WITH REGARD TO GENERIC ISOTRETINOIN PRODUCTS

122. Plaintiff(s) incorporate by reference all other paragraphs of this First Amended Master Complaint as if fully set forth herein and further alleges as follows:

123. Based on public policy, legislative enactments, and customary practices among physicians and manufacturers of generic drug products, the Roche Group knew or should have known that physicians, in weighing the potential benefits and potential risks of using Isotretinoin products, whether name brand or generic, and in writing prescriptions for either "Accutane" or "Isotretinoin", would rely upon information disseminated to them by the manufacturer of the brand-name drug product regardless of whether the prescription might be filled with either the name-brand product or with one of the generic isotretinoin products. The Roche Group also knew, or should have known, that many patients, in accordance with prescriptions for either

"Accutane" or "Isotretinoin" written in reliance upon information put forth regarding Accutane, were likely to ingest a generic isotretinoin product.

124. To obtain basic information about the properties and effects of a drug or group of drug products that is available in both name-brand and generic formulations, physicians have commonly and typically consulted the information disseminated by the manufacturer and distributor of the name brand product, in PDR monographs or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients, whether by brand name or generic name. To that end, the Roche Group disseminated to physicians, through package inserts, the publication of a PDR monograph, and otherwise, information concerning the properties and effects of Isotretinoin. The Roche Group took such action with the intent that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients. The Roche Group knew that physicians relied on the information the Roche Group put forth regarding Accutane when prescribing generic Isotretinoin products, such as the ones prescribed for Plaintiff, that are therapeutically equivalent to the name brand product.

125. The Roche Group also knew or should have known that the misinformation it disseminated regarding Accutane would be provided to generic isotretinoin users. The manufacturers and distributors of generic drug products are required to copy the substance of the brand name package insert verbatim for use with their generic drug products. Further, manufacturers of generic products typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

126. The information disseminated by the Roche Group misrepresented to the public and to Plaintiffs' physicians that isotretinoin was safe and effective. More specifically, the Roche Group misrepresented, concealed, suppressed, or omitted that:

a. There had been insufficient studies regarding the safety and efficacy of the drug Accutane.

b. Despite evidence of a causal connection between Accutane and IBD, the Roche Group did not adequately warn of the risk of IBD that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

c. Despite knowing that there had been insufficient or inadequate testing of the drug, Accutane was marketed, promoted, and/or sold the drug as if it had been fully and adequately tested;

d. There had been prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious adverse reactions, and

e. The Roche Group knew or should have known of reports of severe adverse reactions with use of the drug.

f. Adverse drug information was strategically minimized, understated, or omitted in order to create the overall impression that the dangers were insignificant and infrequent.

127. By misrepresenting or omitting important information regarding the safety and efficacy of Isotretinoin in the promotional materials, advertising, product inserts, PDR monograph and other materials distributed to Plaintiff's prescribing physician, the Roche Group intended to cause Accutane to be prescribed for Plaintiff. The Roche Group either knew or should have known that the misrepresentations they were making, directly and indirectly, regarding Isotretinoin's safety would also lead physicians' to authorize or prescribe generic Isotretinoin products to patients like Plaintiff.

128. The Roche Group knew or should have known that patients receiving prescriptions for Isotretinoin written in reliance upon information they disseminated as the

manufacturers of Accutane, the name-brand Isotretinoin product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading or otherwise false.

129. The Roche Group owed a duty in all of its undertakings, including the dissemination of information concerning Isotretinoin and Accutane, to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others. Nevertheless, the Roche Group failed to exercise reasonable care to ensure that the information it disseminated to physicians concerning the properties and effects of Isotretinoin was accurate and not misleading. As a result, the information it disseminated to physicians and patients was negligently and materially inaccurate, misleading, and false.

130. If Plaintiff and Plaintiff's physicians had known the true facts concerning the risks of the use of Isotretinoin, in particular the risk of IBD, Plaintiff would not have ingested a generic Isotretinoin drug product.

131. The reliance of Plaintiff and Plaintiff's physicians upon the misrepresentations of the Roche Group was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Isotretinoin while Plaintiff and Plaintiffs' physicians were not in a position to know the true facts, and because the Roche Group, overstated the benefits and safety of Isotretinoin, encouraged the misuse, overuse and off-label use of Isotretinoin, and concomitantly downplayed the risks in their use, thereby inducing Plaintiff's physician to prescribe Isotretinoin.

132. The misrepresentations of and/or active concealment, suppression, and omissions by the Roche Group constitute a continuing tort.

133. As a direct and legal consequence of the defective condition of the drug, Plaintiff has sustained serious and permanent injuries including but not limited to: IBD, gastrointestinal problems, inflammatory bowel diseases including but not limited to colitis, ulcerative colitis, Crohn's Disease, rectal bleeding, diarrhea, anemia, abdominal pain, edema of the colon and other bodily injury. As a result of the injuries suffered due to the use of the drug, Plaintiff has endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT XII
COMPONENT PART STRICT PRODUCT LIABILITY - FAILURE TO WARN AS AGAINST THE ROCHE GROUP WITH REGARD TO GENERIC ISOTRETINOIN PRODUCTS

134. Plaintiff incorporates by reference all other allegations as if fully set forth herein.

135. At all material times, the Roche Group was engaged in the business of preparing, selling and/or otherwise distributing Isotretinoin drug information. The Roche Group manufactures, prepares, sells and distributes warnings and information regarding the isotretinoin product Accutane that the Roche Group knew or should have known would be integrated into generic isotretinoin products such as the ones ingested by Plaintiff.

136. The Isotretinoin drug information prepared, sold and/or distributed by the Roche Group was integrated into the Generic Isotretinoin drug products. The drug information supplied

by the Roche Group was an integral component of the generic isotretinoin drug products without which those products would not have been permitted on the market.

137. The drug information and warning component provided by the Roche Group was defective in itself, in that it failed to adequately inform Isotretinoin users of the risk of IBD.

138. As the manufacturer, supplier, seller and distributor of the information and warning component of generic isotretinoin drug products, the Roche Group had the same duty to warn Plaintiffs and physicians as the final product manufacturer.

139. As a foreseeable and proximate result of the defective condition of the Isotretinoin information and warning component, Plaintiff has sustained serious and permanent injuries including but not limited to: IBD, gastrointestinal problems, inflammatory bowel diseases including but not limited to colitis, ulcerative colitis, Crohn's Disease, rectal bleeding, diarrhea, anemia, abdominal pain, edema of the colon and other bodily injury. As a result of the injuries suffered due to the use of the drug, Plaintiff has endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff(s) demand judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

RELIEF REQUESTED

WHEREFORE, Plaintiff(s) demand judgment against Defendants as follows:

A. Awarding Plaintiff(s) compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiff(s) for all damages;

B. Awarding Plaintiff(s) treble damages against Defendants so to fairly and completely compensate Plaintiff(s) for all damages, and to deter similar wrongful conduct in the future;

C. Awarding Plaintiff(s) punitive damages against Defendants in an amount sufficient to punish Defendants for its wrongful conduct and to deter similar wrongful conduct in the future;

D. Awarding Plaintiff(s) costs and disbursements, costs of investigations, attorneys' fees and all such other relief available under New Jersey law and/or the law of plaintiff's state(s) of ingestion and/or prescription;

E. Awarding that the costs of this action be taxed to Defendants; and

F. Awarding such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff(s) demand a trial by jury.

Dated: _____
Respectfully submitted,

_____
(Attorney name)
(Firm name and address)