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
	:	**MASTER LONG FORM COMPLAINT**

1. Pursuant to the Order of this Court, this Complaint is a 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 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.

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 Accutane 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 Accutane, reimbursement for all past, present and future health and medical care costs related to Accutane, 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 in the business of manufacturing, 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, containing the single scientific and medical opinion of all the Roche Group entities with respect to Accutane. Further, Accutane (or Roaccutane) is referred to in publications as a product of the Roche Group and the sole active ingredient for Accutane is distributed to all group affiliates from the Swiss Defendants.

9. The Roche Group has one global e-mail system, one global standard operating procedures manual, and one global database to which all Accutane 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 Accutane by affiliated U. S. companies and thus are involved in doing business in New Jersey, and subject to jurisdiction in New Jersey.

FACTS COMMON TO ALL COUNTS

10. At all times material hereto, Defendants, HOFFMANN-La ROCHE, INC., and/or ROCHE LABORATORIES, INC. engaged in business in this state and throughout the United States, and developed, manufactured, distributed, promoted, marketed, and/or sold 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.

11. Defendants, HOFFMANN-La ROCHE INC. and/or ROCHE LABORATORIES INC. directly or indirectly, negligently and/or defectively 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 Accutane. These actions are under the ultimate control and supervision of the Swiss Defendants.

12. 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 Accutane. These actions are under the ultimate control and supervision of the Swiss Defendants.

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

14. Although Defendants knew or should have known that dangerous risks were associated with the use of Accutane, 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.

COUNT I
PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 *et seq.*)

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

16. 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 Accutane, 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.

17. At all times material hereto, the drug Accutane 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.

18. At all times material hereto, the drug Accutane, 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.

19. At all times material hereto, Accutane 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 apprize the 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, are 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 Accutane.

20. 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.*)

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

22. The drug Accutane 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, 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, and elevated cholesterol, and other serious and life-threatening side effects.

23. The Plaintiff was administered the drug for its intended purposes.

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

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

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

27. Defendants had a continuing duty to warn the Plaintiff(s) of the dangers associated with the drug.

28. 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.*)

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

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

31. Defendants are manufacturers, promoters, marketers, developers, sellers and/or distributors of Accutane.

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

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

34. 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.

35. Plaintiff(s)' physician prescribed and/or otherwise provided Plaintiff(s) with Accutane, and Plaintiff(s) consumed Accutane, 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.

36. The aforesaid promotion and release of Accutane 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.

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

38. 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

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

40. Defendants placed Accutane 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.

41. Defendants had a duty to exercise reasonable care in the research, development, design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of Accutane, 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).

42. When Plaintiff(s)' physicians(s) prescribed Accutane and Plaintiff(s) made the decision to use Accutane, 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.

43. 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 Accutane when Plaintiff(s)' physician prescribed and/or otherwise provided Accutane and Plaintiff(s) purchased and used Accutane 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 Accutane.

44. Defendants were under a duty to disclose the defective and unsafe nature of Accutane 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.

45. 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*.

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

47. 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 UNDER THE PRODUCTS LIABILITY ACT (N.J.S.A.2A:58C-1)

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

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

50. Defendants knew of Accutane'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 Accutane.

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

52. 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.

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

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

54. 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).

55. 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.

56. 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.

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 New Jersey Wrongful Death Act, N.J.S.A. 31-1 *et seq.* , 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 New Jersey Survivor's Act, N.J.S.A. 2A:15-3 *et seq.*, and all such other relief as the Court deems just.

COUNT VII
SURVIVAL ACTION

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

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

59. 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) 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) 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

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

61. 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.

62. 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.

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;

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)