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Attorneys for Plaintiffs

ALAN THOMSON, both individually and as the administrator of the Estate of HAYLEY THOMSON, deceased, and DAYNA THOMSON, Plaintiffs, v. NOVARTIS PHARMACEUTICALS, CORPORATION, NOVARTIS CORPORATION, NOVARTIS PHARMA GMBH, and NOVARTIS AG, Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY Docket No. L-17253-06 Civil Action **COMPLAINT AND JURY DEMAND**

Plaintiffs, Alan Thomson, individually and as Administrator of the Estate of Hayley Thomson, and Dayna Thomson, as and for causes of action against the Defendants, allege the following, upon information and belief, except those allegations that pertain to Plaintiffs, which are based on personal knowledge.

BACKGROUND

1. This is an action for damages suffered by Plaintiffs ALAN THOMSON, DAYNA THOMSON, and HAYLEY THOMSON, deceased, as a direct and proximate result of Defendants' wrongful conduct in connection with the designing, manufacturing, distribution, and selling of Defendants' product Elidel.

2. Defendants knew or should have known that Elidel can cause skin irritation, immunosuppressive diseases, and certain forms of cancer, including but not limited to acute myelogenous leukemia (AML); mislead health care professionals and the public into believing that Elidel was safe and effective for use to treat eczema in minors; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to prescribe Elidel even though Defendants knew or should have known that Elidel was unreasonably unsafe; and failed to warn health care professionals and the public about the risks of Elidel use, such as skin diseases, immunosuppressive diseases, and AML.

JURISDICTION AND VENUE

3. This is an action for damages that exceeds the jurisdictional minimum of this Court.

4. This Court has subject matter jurisdiction over the controversy because the damages are within the jurisdictional limits of the Court. The Court has *in personam* jurisdiction over defendants Novartis Pharmaceuticals Corporation and Novartis Corporation because they are New Jersey corporations and have done and continue to do business in Atlantic County, New Jersey.

5. This suit is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 and 2A:58C-2, *et seq.* (or any successor statute) ("Products Liability Act"), the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, *et seq.* (or any successor statute) ("Consumer Fraud Act") the New Jersey Wrongful Death Act, (or any successor statute) N.J.S.A. 2A:15-3, *et seq.* ("Wrongful Death Act"), and the New Jersey Survival Act, N.J.S.A. 2A:14-5, *et seq.* (or any successor statute) ("Survival Act") to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, for the injuries Plaintiffs have sustained as a result

of Defendant's acts and omissions in violation of New Jersey's Product Liability Act, Consumer Fraud Act, Wrongful Death Act, and the Survival Statute.

PARTIES

6. Plaintiff, Alan Thomson, is a resident and citizen of Atlanta, Georgia, and the administrator of the estate of Hayley Thomson.

7. Plaintiff, Dayna Thomson, is a resident and citizen of Atlanta, Georgia.

8. Haley Thomson, deceased, was the daughter of Alan and Dayna Thomson, and prior to her death was a resident and citizen of Atlanta, Georgia.

9. Defendant, Novartis Pharmaceuticals Corporation ("NPC") is a corporation incorporated under the laws of Delaware with its principal place of business located at 59 Route 10, East Hanover, New Jersey, 07936-1080.

10. Defendant, Novartis Corporation ("Novartis Corp.") is a corporation incorporated under the laws of New York with its principal place of business located at 180 Park Avenue, Florham Park, New Jersey, 07932. Novartis Corporation is the North American headquarters of Swiss Novartis.

11. Defendant, Novartis Pharma GmbH (hereinafter "GmbH"), is a German corporation doing business in the United States, and New Jersey specifically, through its agent, subsidiary or alter-ego NPC and/or Novartis Corp.

12. Upon information and belief, Defendant, GmbH, is the ultimate physical manufacturer of the product in question and does so with the intent to sell, provide, distribute, supply or place in the stream of commerce either directly or indirectly through, Novartis Corp. and/or NPC, for ultimate use by consumers throughout the United States, including the states of Georgia and New Jersey. Defendant, GmbH, is listed as the manufacturer on all packaging,

labeling, product inserts, and patient information sheets provided to physicians and consumers in the United States and Georgia.

13. Defendant, Novartis AG (hereinafter "NAG"), is a Swiss corporation doing business in the United States, specifically including Georgia and New Jersey, through its agent, subsidiary or alter-ego NPC and/or Novartis Corp., GmbH, and is publicly traded on the New York Stock Exchange.

14. NAG, directly and indirectly, owns a 100% interest in NPC, Novartis Corp and GmbH. NAG is ultimately responsible for the organization, administration and direction of NPC and Novartis Corp, and determines the companies' strategies. NAG is also the patent holder of pimecrolimus and trademark holder of the word "ELIDEL" here, in the United States.

15. Upon information and belief, members of the Board of Directors of NPC and/or Novartis Corp., sit on the Novartis Executive Committee which develops and implements strategies for the Novartis Group[1] and procures and allocates the required resources.

16. As used herein, the term "Novartis Defendants" refers collectively to Defendants, Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis Pharma GmbH and Novartis AG.

17. At all times material hereto, Novartis Defendants, either collectively or individually, designed, tested, fabricated, formulated, processed, manufactured, distributed, marketed and sold the drug pimecrolimus, trademarked and marketed as Elidel, in Georgia and New Jersey for purposes of treating various skin diseases.

[1] The "Novartis Group" refers to the ultimate parent company, Novartis AG and its some 360 affiliates in 140 countries.

18. Novartis Defendants have substantial contacts and a presence in New Jersey including, but not limited to the fact that the headquarters of NPC and Novartis Corp. are located in New Jersey.

FACTUAL BACKGROUND

19. NAG holds United States Patent number 5,912,238 for the substance known as pimecrolimus, which was developed as a topical immunosuppressant. In its patent application NAG cited to the patent application for the substance, tacrolimus, as supporting documentation.

20. Pimecrolimus is a macrolide lactone antibiotic, initially developed under the name SDZ ASM 981 by Sandoz[2], and is the ethyl analog of another macrolide, tacrolimus. It was isolated from Streptomyces hygroscopius var. ascomyceticus (Ascomycin) and can also be derived from Streptomyces Tsukubaensis.

21. Pimecrolimus like tacrolimus, binds strongly to macrophilin-12 (FKBP-12) and also inhibits the calcium-dependent phoshatase called calcineurin. This binding results in inhibition of T cell activation by blocking the transcription of early cytokines. Both pimecrolimus and tacrolimus prevent the release of inflammatory cytokines and mediators from mast cells after stimulation by antigen/IgE and inhibit calcineurin. Hence the drugs are also known as calcineurin inhibitors.

22. The United States Adopted Names Council (USAN), which is the national organization that assigns generic names, has assigned both drugs the stem "imus" to their generic names. This indicates that USAN has concluded that these two drugs have similar pharmacological and/or chemical relationship, and thus, are in the same drug classification as

[2] In 1996 Ciba-Geigy, Ltd. merged with Sandoz Pharmaceuticals Corporation, Sandoz AG and Sandoz Pharma AG to form Novartis AG and its progeny. All documents related to the development and testing of SDZ ASM 981 thus were acquired by NAG and its progeny.

each other. When healthcare professionals such as physicians and pharmacists see the same stem "imus", they make the relationship that the two drugs are in the same pharmaceutical class, work in the body similarly, and have similar side effects.

23. On December 13, 2001, Novartis Defendants received Food and Drug Administration ("FDA") approval of its NDA for pimecrolimus, for the treatment of atopic dermatitis. The product had limited prescribing restrictions for its use and application including, for example, that it should not be prescribed for long term use and that it should only be used as a second-line therapy only after first-line treatments were ineffective or could not be used.

24. Eczema is the clinical name for dermatitis, or "[s]uperficial skin inflammation, characterized histologically by epidermal edema and clinically by vesicles (when acute), poorly marginated redness, edema, oozing, crusting, scaling, usually pruritus, and lichenification caused by scratching or rubbing." The Merck Manual of Diagnosis and Therapy 786 (Mark H. Beer, M.D. et al eds., 17th ed. 1999).

25. Prior to the approval of topical preparations of theses drugs, calcineurin inhibitors had been approved for use as systemic immunosuppressants in organ transplant recipients. In these patients, systemic treatment has long been known to increase the risk of malignancies and have carried appropriate Black Box Warnings.

26. No later then December 2001, the Novartis Defendants were aware of the potential for pediatric patients to develop systemic malignancies with intermittent use of pimecrolimus. Indeed, the FDA expressed such a concern to the Novartis Defendants in December 2001.

27. Because of these various concerns, the approval of pimecrolimus for treatment of atopic dermatitis in children included a post-marketing commitment from Novartis Defendants to

conduct a registry study to asses the risk for developing cutaneous or systemic malignancies among pediatric patients who undergo intermittent treatment with these drugs.

28. On October 30, 2003, an open meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee was held to discuss how to approach long-term monitoring for malignancy occurrence, among patients treated for atopic dermatitis with pimecrolimus and tacrolimus.

29. The subcommittee noted that the preclinical and clinical studies of both pimecrolimus and tacrolimus suggested these drugs may increase the risk of malignancies in the pediatric population.

30. The subcommittee further stated that for children under 2, because of immune system development issues and lack of understanding regarding the development of other systems in the very young, a Black Box Warning was recommended. The Novartis Defendants, however, provided no such warning.

31. Following the close of the October 2003 subcommittee meeting, the adverse events relating to pimecrolimus and tacrolimus continued to increase. Specifically, there were additional malignancy cases that had been reported to the FDA.

32. Based on this concern the Pediatric Advisory Committee of the FDA convened, on February 14 & 15, 2005 again to discuss the potential malignancy risk from the use of pimecrolimus and tacrolimus.

33. In March 2005, after accumulating scientific evidence of deaths, malignancies and other serious adverse events the FDA required Novartis Defendants to require a Black Box Warning of malignancy risks on pimecrolimus.

34. In January 2006, the language to be included in the above mentioned Black Box

was finally agreed to by and between the Novartis defendants and the FDA, and thereafter the Black Box Warning was affixed to the pimecrolimus label.

THE NOVARTIS DEFENDANTS

35. From 2001 through the date of this complaint, the Novartis defendants generally, GmbH and NPC specifically, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel to the sale and distribution of a pharmaceutical, and by said activities, caused pimecrolimus to be placed into the stream of commerce throughout the United States, including New Jersey.

36. The Novartis Defendants, made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for pimecrolimus in the United States. As part of said activities, the Novartis defendants also engaged in "negotiations" with the FDA with respect to the approval of the labeling, (also known as the "package insert" or "direction circular" to be approved for use with pimecrolimus).

37. Upon information and belief, the Novartis Defendants, individually and collectively, were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to pimecrolimus.

38. Pimecrolimus has been widely advertised, marketed and represented by the defendants as a safe and effective treatment for atopic dermatitis or eczema.

39. The Novartis Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other after market activities that pertain to all pharmaceuticals, including pimecrolimus.

40. By virtue of its mechanism of action, pimecrolimus increases the risk of skin irritation, immunosuppressive diseases, malignancies, and other serious health problems.

41. To promote pimecrolimus and to increase the total market and sales of the drug, the Novartis Defendants hired public relations, marketing, and advertising firms, provided promotional materials to sales forces, sponsored studies, hired ghost writers to publish papers in medical journals that supported the use of pimecrolimus, provided media contacts with promotional material, and in essence engaged in a widespread plan to market the use of pimecrolimus, thereby increasing sales and enlarging the market potential for pimecrolimus.

42. In part due to the promotional efforts of the Novartis Defendants, pimecrolimus was so pervasively prescribed throughout the United States that, by 2005, the number of prescriptions in the United States totaled in the millions.

43. As early as 2001, and up through and including 2005, the package insert for pimecrolimus failed to provide any WARNINGS for malignancies in association with the use of pimecrolimus.

44. As early as 2001, and up through and including 2005, absolutely no information regarding malignancies had ever been included in the WARNINGS section of the product labeling for pimecrolimus. In fact no information regarding malignancies whatsoever was provided in the PRECAUTIONS section of the product labeling either.

45. The Novartis Defendants also knew that because both pimecrolimus and tacrolimus belonged to the same class of drugs, *i.e.*, calcineurin inhibitors, that any adverse event applicable to one would be applicable to the other.

46. Despite their knowledge of the potentially life threatening diseases associated with increased use of their pimecrolimus, the Novartis Defendants engaged in a marketing and

advertising program, which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of pimecrolimus was safe for human use, had fewer side effects and adverse reactions than other methods of treating eczema, and would not result in a side effect that was potentially fatal.

47. The Novartis Defendants falsely and deceptively kept relevant information from prescribing physicians and potential pimecrolimus users in order to minimize user and prescriber concern regarding the safety of the drug.

48. The Novartis Defendants, individually and collectively, downplayed and understated the health hazards and risks associated with the use of pimecrolimus, and, through promotional literature as well as sales visits to prescribing physicians, deceived prescribing physicians and potential users of pimecrolimus by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

49. The information produced and disseminated by and on behalf of the Novartis Defendants, falsely and deceptively misrepresented a number of facts regarding pimecrolimus, including, but not limited to, the existence of adequate testing of pimecrolimus, and the nature, severity, and frequency of side effects and adverse health effects caused by pimecrolimus.

50. Prior to January 19, 2006, no WARNINGS were listed for pimecrolimus in the various package inserts and product labels to alert prescribing physicians as well as consumer patients of the actual risks associated with this drug, including the risk of potentially fatal malignancies, and the extent or actual risk thereof, notwithstanding the fact that the Novartis Defendants, individually and collectively, knew that reasonable evidence of an association between the use of pimecrolimus and such conditions existed.

51. The Novartis Defendants, individually and collectively, notwithstanding access to

information establishing the aforementioned dangers associated with the use of pimecrolimus specifically and, immunosuppressants generally, promoted the use of pimecrolimus as an effective treatment for eczema without offering timely supplements to their warnings and product information to adequately advise prescribing physicians and potential consumers of the very real risks and side effects, especially that of malignancies.

52. The Novartis Defendants failed to timely and appropriately amend, change, alter, or otherwise update the product labeling, package insert, or to otherwise advise physicians, patients, pharmacists, or other health care providers of the risks of Elidel, including the risk of developing malignancies, and otherwise omitted such data and information regarding the aforementioned dangers associated with the use of pimecrolimus in the information shared with the medical community and the consumer public.

53. Nevertheless, the Novartis Defendants negligently failed to adequately warn and apprize prescribing physicians, as well as the consumer public, including Plaintiffs and Plaintiffs' decedent, Hayley Thomson, and her physicians, that there was any risk of developing malignancies or AML.

54. In addition, the Novartis defendants failed to adequately warn the prescribing physicians and the consumer public, including Plaintiffs and Plaintiffs' decedent, Hayley Thomson, about the special risks of developing malignancies and AML associated with pimecrolimus, of which use the said defendants, individually and collectively, were well aware.

55. Furthermore, the Novartis Defendants were aware of the cancer risks associated with immunosuppressants such as pimecrolimus *even before* they did the first test on a rat for their investigational new drug application to the FDA, by virtue of their experience with similar drugs in organ transplant patients, and similar topical immunosuppressants/calcineurin inhibitors

already on the worldwide market.

56. As a direct and proximate result of the failures of the Novartis Defendants to adequately disclose the aforesaid information to prescribing physicians in the United States, including the states of Georgia and New Jersey, physicians had been prescribing and over-prescribing pimecrolimus to patients, and both prescribing physicians and the consumer public, including the decedent, Hayley Thomson, had been grossly under-informed regarding the risks of serious health effects, including skin diseases, immunosuppressive diseases, and certain forms of cancer, including AML, that were reported and/or known to be associated with immunosuppressant drugs.

57. Despite knowing of an increased incidence of cancer beyond what was reported to physicians in product labeling, and the Novartis defendants enjoying markedly increased sales of pimecrolimus, the said defendants deprived the general public and physicians of such knowledge. In fact, the Novartis Defendants, through a complete lack of action decided not to include Warnings of an increased risk of cancer, or to send physicians any "Dear Doctor" letters, or to otherwise alert the health care profession of the risks seen with the drug.

FACTUAL ALLEGATIONS – HAYLEY THOMSON'S CASE

58. Prior to May 2003, the treating physician for Plaintiffs' decedent, as well as the Plaintiffs, were exposed to the aforementioned advertising and marketing campaign directly by the defendants.

59. Plaintiffs and Haley Thomson's physician, either through direct promotional contact with Sales Representative Defendants, through word of mouth from other health care providers, and/or through promotional materials, received the information the Defendants intended that they receive, to-wit: that Elidel was "steroid-free," safer then corticosteroids, had

very little side effects and could be used as first-line therapy.

60. In 2003, Plaintiffs presented their child, Hayley Thomson, to a physician for the purposes of treating Haley's dermatitis. At that time, the physician performed a physical examination which found the decedent, Hayley Thomson, to be suffering from dermatitis on her scalp. Hayley Thomson was prescribed Elidel, and Plaintiffs were directed to apply the topical medication to Hayley Thomson as indicated. Plaintiffs applied Elidel in accordance with the recommendations Hayley Thomson's physician.

61. As a direct and proximate result of the use and application of pimecrolimus, Hayley Thomson suffered serious bodily injury and harm, including being diagnosed with a form of cancer, more specifically AML, on February 25, 2004.

62. On December 19, 2004, Hayley Thomson died from complications resulting from her AML caused by her exposure to Elidel.

63. At no time material to the use of pimecrolimus on Hayley Thomson, were Plaintiffs, their daughter, or their daughter's physicians told, warned, or given information about the risks of developing cancer or AML from the use of pimecrolimus.

Count I
(Products Liability Act - Failure to Warn)

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

65. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the drug Elidel and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and

therefore had a duty to warn of the risks associated with the use of Elidel.

66. Defendants failed to adequately warn health care professionals and the public, including Plaintiffs, Hayley Thomson, and her prescribing physician, of the true risks of Elidel, including that Elidel increased the risk of skin diseases, immunosuppressive diseases, and certain forms of cancer, such as AML.

67. Elidel was under the exclusive control of the Defendant as aforesaid, but was unaccompanied by appropriate warnings of Elidel's risks, including that Elidel increased the risk of skin diseases, immunosuppressive diseases, and cancer such as AML.

68. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Elidel. Had they done so, a proper warning would have been heeded and no health care professional would have prescribed, including Hayley's physician, or no consumer, and Plaintiffs and Haley respectively, would have purchased and/or used, Elidel.

69. Elidel, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendant knew or should have known that there was reasonable evidence of an association between Elidel use and an increased the risk of skin diseases, immunosuppressive diseases, and cancer, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Hayley, and continued to aggressively promote Elidel.

70. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

71. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiffs and Plaintiffs' Decedent suffered serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiffs 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 II
Breach of Express Warranty

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

73. Defendants advertised, labeled, marketed and promoted its product, Elidel, representing the quality to health care professionals, the FDA, Hayley, Plaintiff and the public in such a way as to induce its purchase or use, thereby making an express warranty that Elidel would conform to the representations. More specifically, Defendants represented that Elidel was safe and effective, that it was safe and effective for use by minors, such as Hayley, and/or that it was safe and effective to treat Hayley's condition.

74. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

75. Elidel did not conform to the representations made by Defendants in that Elidel was not safe and effective, was not safe and effective for use by minors, such as Hayley, and/or

was not safe and effective to treat eczema in minors, such as Hayley.

76. Elidel, in fact, increased the risk of skin diseases, immunosuppressive diseases, and cancer, including AML.

77. At all relevant times, Hayley used Elidel for the purpose and in the manner intended by Defendants.

78. Hayley, Plaintiffs and Hayley's physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

79. The breach of the warranty was a substantial factor in bringing about Hayley's injuries and death, and Plaintiffs' injuries.

80. As a direct result of Defendants' conduct as aforesaid, Plaintiffs and Plaintiffs' Decedent suffered and continue to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiffs 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 III
New Jersey Consumer Fraud Act

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

82. Prescription drugs such as Elidel are "merchandise," as that term is defined by N.J.S.A. 56:8-1 *et seq.*

83. Defendants are the researcher, tester, manufacturer, inspector, labeler, distributor, marketer, promoter, seller and/or otherwise released Elidel into the stream of commerce.

84. Defendants knew or should have known that the use of Elidel causes serious and life threatening injuries but failed to warn the public, including Plaintiffs and Plaintiffs' Decedent of same.

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

> 56:8-2. Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice.
> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, 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.

86. Defendants knew or should have known that the use of Elidel causes serious and potentially life-threatening side effects.

87. Defendant's statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including the Plaintiff and Plaintiff's Decedent, would rely on such statements and/or omissions.

88. Defendants knew that their representations were false or misleading when they were made; the representations were made under a pretense of knowledge when there was none or there was no basis for the pretense; the representations were made recklessly without knowledge of a genuine belief in their accuracy.

89. Hayley's physician prescribed and/or otherwise provided Hayley with Elidel, and Hayley used Elidel as directed. Hayley and Plaintiffs suffered ascertainable losses of money as a result of Defendants' use or employment of the methods, acts, or practices alleged herein.

90. The aforesaid promotion and release of Elidel into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connection with the sale or advertisement of such merchandise or services by Defendants, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq*.

91. Defendants knew of the growing public acceptance of the misinformation, or incomplete information, and misrepresentations regarding the safety and efficacy of Elidel, but remained silent due to the large profits being earned.

92. As a direct and proximate cause of Defendants' acts of consumer fraud, Plaintiffs have suffered ascertainable loss -- economic loss that includes the purchase price of Elidel and other out-of-pocket healthcare related costs –for which Defendants are liable to Plaintiffs for treble their actual damages.

WHEREFORE, Plaintiffs 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
Products Liability Act - Breach of Implied Warranty

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

94. Elidel was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was Elidel minimally safe for its

expected purpose.

95. Elidel, in fact, increased the risk of skin diseases, immunosuppressive diseases, and cancer, including AML, in children and adolescents.d

96. At all relevant times, Hayley used Elidel for the purpose and in the manner intended by Defendants.

97. Hayley, Plaintiffs and Hayley's physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

98. The breach of the warranty was a substantial factor in bringing about Hayley's injuries and death and Plaintiffs' injuries.

99. As a direct result of Defendant's conduct as aforesaid, Plaintiffs and Hayley have suffered and continue to suffer serious and permanent non-economic and economic injuries.

WHEREFORE, Plaintiffs demands 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 VI
Products Liability Act – Defective Design

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

101. Defendants are the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of Elidel, which is defective and unreasonably dangerous to consumers.

102. Elidel is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated

with its design and formulation. Elidel is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other eczema medicines and similar drugs on the market and is more dangerous than ordinary consumers can reasonably foresee.

103. If the design defect were known at the time of manufacture, a reasonable person would have concluded that the utility of Elidel did not outweigh the risk of marketing a product designed in that manner.

104. The defective condition of Elidel rendered it unreasonably dangerous and/or not reasonably safe, and Elidel was in this defective condition at the time it left the hands of the Defendant. Elidel was expected to and did reach consumers, including Hayley and Plaintiff, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

105. Plaintiffs and Hayley were unaware of the significant hazards and defects in Elidel. Elidel was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Hayley took Elidel, the medication was being utilized in a manner that was intended by Defendants. At the time Hayley received and consumed Elidel, it was represented to be safe and free from latent defects.

106. Defendants are strictly liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

107. Defendants knew or should have known of the danger associated with the use of

Elidel, as well as the defective nature of Elidel, but has continued to design, manufacture, sell, distribute, market, promote and/or supply Elidel so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Elidel.

108. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiffs and Plaintiffs' decedent have suffered and continue to suffer serious and permanent non-economic and economic injuries.

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

COUNT VII
Punitive Damages Under Common Law and the Products Liability Act

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

110. Plaintiffs are entitled to punitive damages because the Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. The Defendants misled both the medical community and the public at large, including Hayley and the Plaintiffs herein, by making false representations about the safety and efficacy of Elidel. Defendants downplayed, understated, and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Elidel despite available information demonstrating that Elidel was likely to cause serious and even fatal side effects to users. Defendants actively concealed knowledge of the serious and permanent side effects and risks associated with the use of Elidel.

111. Defendants were or should have been in possession of evidence demonstrating that Elidel caused serious side effects, such as increased risk of skin diseases, immunosuppressive diseases, and cancer, including AML. Nevertheless, Defendants continued to market Elidel by providing false and misleading information with regard to safety and efficacy.

112. Defendants failed to provide warnings that would have dissuaded health care professionals from prescribing Elidel and consumers from purchasing and consuming Elidel, thus preventing health care professionals and consumers, including Hayley and Plaintiffs, from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Elidel.

WHEREFORE, Plaintiffs demands 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
Wrongful Death

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

114. As a result of the wrongful acts and/or omissions of the Defendants as set forth herein, Hayley died on December 19, 2004. As a result thereof, Plaintiffs suffered injuries to the fullest extent allowable pursuant to N.J.S.A. 2A:15-3.

115. Had Hayley survived, she could have maintained a cause of action at the moment of her death pursuant to N.J.S.A. 2A:15-3.

116. Hayley is survived by distributees, including her parents Alan and Dayna

Thomson, who have suffered, and will continue to suffer, pecuniary loss by reason of Hayley's death.

117. Alan Thomson has been duly appointed as Administrator of Hayley's estate by a court of competent jurisdiction.

118. By reason of the foregoing wrongful acts and/or omissions on the part of Defendants, the aforementioned distributees were further obliged to expend diverse sums of money for funeral and burial expenses occasioned by Hayley's death.

119. Plaintiffs are entitled to recover punitive damages and damages for the pain and suffering caused to Hayley from the acts and omissions of the Defendants as specifically pled herein, including, without limitation, punitive damages pursuant to N.J.S.A. 2A:15-3.

WHEREFORE, Plaintiffs demand judgment against Defendants for all damages permitted 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 cost of suit, including without limitation, punitive damages as provided for under the together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT IX
Survival Action

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

121. As a result of the wrongful acts and/or omissions of the Defendants as set forth herein, Hayley suffered substantial conscious pain and suffering prior to her death.

122. Plaintiff, on behalf of Hayley's estate, seeks damages compensable under the Survival Act, N.J.S.A.2A; 14-5 (or any successor statute) against Defendants. Plaintiff, in his

own right, seeks damages compensable under the Survival Act, N.J.S.A. 2A:15-3 (or any successor statute) against Defendants.

WHEREFORE, Plaintiffs 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, Plaintiffs demand judgment against Defendants as follows:

A. Awarding Plaintiffs compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;

B. Awarding Plaintiffs treble damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiffs for all damages

C. Awarding Plaintiffs 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 Plaintiffs all damages recoverable under N.J.S.A. 2A:58:C-2 *et seq.* against Defendants;

E. Awarding Plaintiffs costs and disbursements, costs of investigations, attorneys' fees and all such other relief available under New Jersey law; and

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

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

JURY TRIAL DEMANDED

The Plaintiffs demand a trial by jury on all issues.

Dated: December 19, 2006

Respectfully submitted,

SEEGER WEISS LLP

By: _____

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Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO R. 4:5-1

Plaintiffs, by their attorneys, hereby certifies that the matter in controversy is not the subject of any other pending or contemplated judicial or arbitration proceedings. Plaintiffs are not currently aware of any other parties that should be joined in this particular action. In addition, Plaintiffs recognize their continuing obligation to file and serve on all parties and the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: December 19, 2006

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Attorneys for Plaintiffs

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, David R. Buchanan is hereby designated as trial counsel in this matter.

Dated: December 19, 2006

SEEGER WEISS LLP

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Attorneys for Plaintiffs

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A. 56:8-20, Plaintiffs are mailing a copy of this Complaint and Jury Demand to the Office of the Attorney General, CN-006, Trenton, New Jersey, within ten (10) days of the filing of this Complaint and Jury Demand.

Dated: December 19, 2006

SEEGER WEISS LLP

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