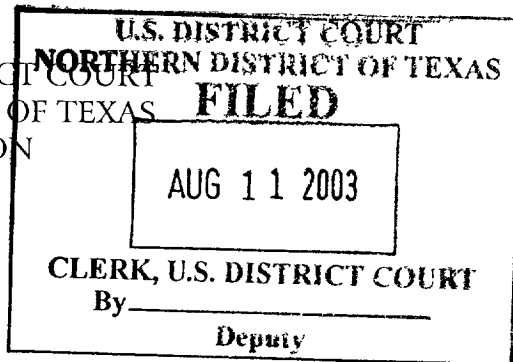


City  
ORIGINAL

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
WICHITA FALLS DIVISION



VICTORIA KLEIN and  
ASHLEY SWADLEY,  
  
Plaintiffs,

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VS.

CA 7-03-CV-102-R

O'NEAL, INC., d/b/a O'NEAL, JONES &  
FELDMAN PHARMACEUTICALS,  
CVS REVCO D.S., INC.; and  
RETRAC, INC.,

Defendants.

**PLAINTIFFS' FIRST AMENDED ORIGINAL COMPLAINT - CLASS ACTION**

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

COME NOW, VICTORIA KLEIN and ASHLEY SWADLEY, Plaintiffs, and those similarly situated, and file this their first amended complaint against Defendants, O'NEAL, INC., d/b/a O'NEAL, JONES & FELDMAN PHARMACEUTICALS, a Delaware Corporation, with it principal place of business in Maryland Height, Missouri; CVS REVCO D.S., INC., a corporation incorporated under the laws of the State of Delaware, with its principal place of business in the State of Delaware; and RETRAC, INC., a corporation incorporated under the laws of the State of Ohio, with it principal place of business in Glendale, Arizona, and for cause of action, would show the Court as follows:

**I.**

**JURISDICTION**

1. Jurisdiction is conferred on this Court by 42 U.S.C. §§ 1332 (diversity) because the

amount in controversy exceeds \$75,000.00 and because there is a complete diversity of citizenship between the Plaintiffs and all Defendants.

2. Plaintiff, Victoria Klein, is a resident and citizen of the State of Texas.
3. Plaintiff, Ashley Swadley, is a resident and citizen of the State of Georgia.
4. Defendant, O'NEAL, INC., d/b/a O'NEAL, JONES & FELDMAN PHARMACEUTICALS (hereinafter referred to as "O'Neal") is a Delaware Corporation, with its principal place of business in Maryland Heights, Missouri, and doing business, at all relevant times, in the State of Texas.
5. Defendant, CVS REVCO D.S., INC. (hereinafter referred to as "Revco") is a corporation incorporated under the laws of the State of Delaware, and doing business, at all relevant times, in the State of Texas.
6. Defendant, RETRAC, INC. (hereinafter referred to as "Carter" or "Carter-Glogau Laboratories") formerly known as Carter-Glogau Laboratories, is a corporation incorporated under the laws of the State of Ohio, with its principal place of business in Glendale, Arizona, and doing business, at all relevant times, in the State of Texas.
7. Plaintiffs, Victoria Klein and Ashley Swadley, each allege an amount in controversy in excess of \$75,000.00 exclusive of any interest and costs.
8. Plaintiff, Victoria Klein, is a resident of the City of Wichita Falls, Texas. Plaintiff was born on March 17, 1984, in Wichita Falls, Texas, and because of her premature condition, transferred to Cook Children's Medical Center in Fort Worth, Texas. The events which give rise to this cause of action occurred when a pharmaceutical product, E-Ferol, was intravenously administered to Plaintiff, Victoria Klein, at Cook Children's

Medical Center, formerly known as Fort Worth Children's Hospital, in Fort Worth, Texas, on March 23, 1984;

9. Plaintiff Ashley Swadley was born on February 18, 1984, at Baylor University Medical Center, Dallas, Texas. Plaintiff was administered E-Ferol intravenously at Baylor University Medical Center, in Dallas, Texas, beginning February 18, 1984.
10. While all of the Defendants are foreign corporations, each did business in the State of Texas, thus, is subject to personal jurisdiction in the State of Texas and in the Northern District of Texas.
11. Since no Defendant filed a responsive pleading, this Amended Complaint is filed as a matter of right pursuant to Fed. R. Civ. P. 15a.

## II.

### FACTUAL ALLEGATIONS

#### 12. Overview of E-Ferol Syndrome

In late 1983, Defendant Retrac, Inc, then operating under the name of Carter-Glogau Laboratories, ("Carter"), then a division of Defendant Revco, ("Revco") manufactured, and O'Neal, Inc., d/b/a O'Neal, Jones & Feldman Pharmaceuticals ("O'Neal") marketed a drug called "E-Ferol" as a high potency vitamin E supplement suitable for intravenous infusion in premature infants. Vitamin E was long-known to be beneficial in preventing blindness and respiratory problems in premature infants at risk for these complications because of their need for supplemental oxygen. Vitamin E had heretofore only been administered to premature infants in an intramuscular form. The

intramuscular form was difficult to administer to small birthweight children and hence, pharmaceutical companies were searching for intravenous method of delivering vitamin E. The pharmaceutical product, E-Ferol, was marketed by Defendants to be administered intravenously, an entirely new method of delivery that had not previously been available. Defendant O'Neal attempted to enter this lucrative market ahead of other, more established drug companies, and through its corporate officers, marketed E-Ferol as having (or not needing) the Food and Drug Administration ("FDA") approval and distributed the drug throughout the country beginning in late 1983. Soon after E-Ferol was distributed, it became widely used in neonatal units throughout the country. Many of these hospitals began to experience high infant mortality and morbidity rates, sufficient to draw the attention of the FDA. By April, 1984, after being on the market for approximately four (4) months, the FDA required a recall of E-Ferol on an urgent Class-I Recall due to the unusually high infant mortality and morbidity occurring in premature infants who had been administered E-Ferol. A Subcommittee of the Committee on Government Operations of the U.S. House of Representatives immediately convened an investigation concerning the FDA's regulation of the marketing of these new drugs. Ultimately, the fraudulent practices of O'Neal, "Carter" and others in failing to test the drug and obtain FDA approval and in marketing E-Ferol, resulted in indictments of the corporation and its officers, in United States District Court for the Eastern of Missouri, No. 87-172CR(4), *United States of America v. Carter-Glogau Laboratories, Inc., now known as Retrac, Inc., O'Neal, Jones & Feldman, Ronald Carter, Sr., Larry K. Hiland and James B. Madison*. O'Neal entered a plea of guilty on

November 8, 1988 to a 17 count indictment (the Government agreed to dismiss 25 other counts) and paid a fine sufficient to cover the costs of the investigation by the FDA. James B. Madison, the Vice-President of O'Neal, pled guilty to three counts of the indictment. Carter-Glogau, Inc., Ronald Carter, Sr., CEO of Carter-Glogau, Larry K. Hiland, President of O'Neal, were all convicted following a trial of conspiracy to commit mail and wire fraud and violation of the Federal Food Drug & Cosmetic Act, 18 U.S.C. § 371, including six counts of introducing a new drug not approved by the FDA into interstate commerce with intent to defraud or mislead in violation of 21 U.S.C. §§ 331(d), 333(a)(2) and six counts of introducing a misbranded drug into interstate commerce with intent to defraud or mislead in violation of 21 U.S.C. §§ 331(a), 333(a)(2). Larry Hiland, President of O'Neal, was also convicted of five counts of committing mail fraud in violation of 18 U.S.C. § 1341. The jury verdict was appealed to the United States Court of Appeals for the Eighth Circuit where the verdict was affirmed on all counts on July 19, 1990.

Meanwhile, over one thousand premature babies were administered E-Ferol and thus, affected to some degree by "E-Ferol Syndrome" which resulted in injuries including severe brain injury, blindness and death. Robert Brown, M.D., a Board Certified Pathologist of Fort Worth/Cook Children's Medical Center's Pathology Department, conducted autopsies on babies exposed to E-Ferol during the period from January through April, 1984, when it was administered to neonatal infants at Cook Children's Medical Center and Harris Methodist-Fort Worth Hospital, Fort Worth, Texas. Dr. Brown, together with Solomon Alade, Ph.D., and Andrew Piquet, Ph.D., of Texas

Christian University, Department of Biology, eventually published a seminal study on E-Ferol in the journal *Pediatrics*, attributing the harmful effects of E-Ferol to the polysorbate 80 and polysorbate 20 used as the carrier for the vitamin E. Despite having to report to the FDA the number of babies administered E-Ferol, Cook Children's Medical Center and most other hospitals that administered the drug, did not inform the parents, nor at a later date, the patients themselves, that they had been administered this product or of the hazardous and/or potentially long-lasting affects that the receipt of this product could have on the recipients.

13. Plaintiff Victoria Klein, born at Wichita Falls General Hospital, Wichita Falls, Texas, was initially administered E-Ferol intravenously at Cook Children's Medical Center, formerly known as Fort Worth Children's Hospital, in Fort Worth, Texas, on March 23, 1984, the six-day of her life. Plaintiff was administered sixteen (16) doses from March 23, 1984 through April 9, 1984. Plaintiff Klein received over 500 units of E-Ferol during the above period.
14. At all times herein, Plaintiff Victoria Klein, utilized the E-Ferol product manufactured and distributed by the Defendants as her source of vitamin E prescribed by her physician. As a result, the E-Ferol was the cause of Plaintiff's symptoms acutely experienced at the time of administration and throughout her hospitalization at Fort Worth Children's Hospital and thereafter.
15. Plaintiff Ashley Swadley was initially administered E-Ferol intravenously at Baylor University Medical Center, Dallas, Texas, on February 18, 1984, the first day of her life. Plaintiff Swadley was administered four (4) intravenous doses of E-Ferol, on

February 18, 1984, through February 28, 1984, all together, receiving intravenously thirty (30) units of E-Ferol during that period.

16. At all times herein, Plaintiff Ashley Swadley utilized the E-Ferol product manufactured and distributed by the Defendants as her source of vitamin E prescribed by her physician. As a result, the E-Ferol was the cause of Plaintiff's symptoms, acutely experienced at the time of administration and throughout her hospitalization at Baylor University Medical Center, Dallas, Texas, and thereafter.
17. Defendant O'Neal requested Defendant Carter to develop for Defendant O'Neal, a vitamin E product for use as an intravenous solution to be administered to premature infants. Defendant Carter developed a formula for the product using the ingredients: 25mg/ml vitamin E, dl-alpha, Tocopherol Acetate, polysorbate 80 (Tween 80), polysorbate 20 (Tween 20) and water, to be administered intravenously by injection.
18. E-Ferol was a drug within the meaning of Title 21, U.S.C. § 321(g)(1)(B), in that it was intended for use in the diagnosis, cure, mitigation, treatment and prevention of disease in man pursuant to Title 21, U.S.C. § 321(g)(1)(C), in that it was also intended to affect the structure and function of the body of a man.
19. E-Ferol was a "prescription" drug within the meaning of Title 21, U.S.C. § 353(b)(1)(B), in that, because of its toxicity and other potentiality for harmful effect, and the method of its use, it was not safe for use except under the supervision of a practitioner licensed by law to administer such a drug.
20. E-Ferol was a "new drug" within the meaning of Title 21, U.S.C. § 321(b)(1), in that its composition was not generally recognized among experts qualified by scientific

training and experience to evaluate the safety and effectiveness of the drug, as safe and effective for use under the conditions prescribed, recommended and suggested in the labeling.

21. In the development of E-Ferol, Defendant Carter and Defendant O'Neal did not perform or participate in any of the FDA Regulatory Guidelines for the development of a new drug. Pre-marketing development did not include any animal testing to demonstrate safety and efficacy nor any clinical trials to demonstrate safety and efficacy. Neither Defendant Carter nor Defendant O'Neal obtained FDA approval through the New Drug Application (NDA Process) and/or the paper NDA process at any time, during or after the manufacture and distribution of E-Ferol.
22. During the period from November, 1983 through April 6, 1984, Defendant O'Neal distributed the E-Ferol product to drug wholesalers, hospitals, and doctors with the sole intention to have the product administered to premature infants intravenously.
23. By and through the marketing and distributing efforts of Defendant O'Neal, during the time set forth above, over 25,800 vials of E-Ferol were distributed to 159 hospitals nationwide. Prior to being recalled, 12,036 vials were administered and more than 1,008 premature infants received E-Ferol nationwide. Two young children and one older adult were also administered E-Ferol.
24. In March, 1984, the Center for Disease Control received reports from Good Samaritan Hospital in Cincinnati, Ohio, and the University of Tennessee Hospital, in Knoxville, Tennessee, regarding "clusters of an unusual illness occurring among low-birth weight (less than 1500g), premature infants in neonatal care units . . . affected infants

developed clinically significant ascites, in addition to some or all of the following abnormalities: hepatomegaly, splenomegaly, cholestatic jaundice, azotemia, and thrombocytopenia.” Eight infants from the two hospitals were noted by the CDC to have died from the illness. The common thread between the two hospitals was the E-Ferol drug manufactured and distributed by Defendants which had been administered to them.

25. On or about April 2, 1984, the CDC contacted the Food & Drug Administration (FDA) and by April 11, 1984, the FDA requested and Defendants agreed to voluntarily recall E-Ferol in a “Class 1” Recall action.
26. Despite having performed no testing and having initiated no procedures under the FDA rules for marketing E-Ferol, Defendants Carter and O'Neal developed labeling and marketed E-Ferol for intravenous use, representing that the drug product was safe and effective for use in all humans, including premature infants.
27. Extensive research following the recall of E-Ferol has established that the Defendants' E-Ferol preparation is responsible for the suppression of human lymphocytes to phytohemagglutinin (PHA), with a decrease in the percentage of T11 lymphocytes, resulting in a compromised immunity, resulting in increased susceptibility and inability to resist the hostilities of bacteria causing infections. Clinical research has demonstrated the prolonged exposure to the Defendants' E-Ferol was associated with progressive intralobular cholestasis, inflammation of the hepatic (liver) venules, and extensive sinusoidal veno-occlusion by fibrosis.
28. Clinical research of affected cases (E-Ferol syndrome), note the hepatic (liver) histology

in these cases indicated a progressive injury characterized by Kupffer cell exfoliation, central lobular accumulation of cellular debris, and centrally accentuated panlobular congestion.

29. Clinical research on the cardiovascular affects of Polysorbate 80 (Tween 80) noted reductions of cardiac dimensions, hypotension effects and tachycardia, ultimately causing a reduction in organ blood flow, creating a hypoxic/anoxic physiologic compromise.
30. Clinical research has demonstrated acute lung toxicity and sudden death, following the intravenous administration of Tween surfactants (Polysorbates 80 and 20).
31. Clinical Research has demonstrated that the probable cause of the E-Ferol associated toxic reactions are the polysorbates. Further, it is the polysorbates that cause sinusoidal dilatation and congestion of the liver.
32. Clinical research has demonstrated that neonatal exposure to polysorbates has a profound effect on the female reproductive development, with a potential for a lifetime risk of clear-cell cervico-vaginal cancer; alterations in the menstrual cycle; potential for infertility and reproductive mishaps, and the potential for dysmorphogenesis and abnormal vascularity of the uterus.
33. Plaintiffs Victoria Klein and Ashley Swadley and other female class members were exposed to polysorbates during their neonatal period of development, with a probable effect on their reproductive development, and a concurrent lifetime risk for clear-cell cervico-vaginal cancer; alterations in their menstrual cycle; potential for infertility and reproductive mishaps, and the potential for dysmorphogenesis and abnormal vascularity

of their uteruses.

34. The exposure to the toxic drug E-Ferol during the neonatal period for the male infant, places the male class members at risk for the long term consequences of xenoestrogen exposure during testicular and prostrate development, exposing him to the risk of germ-cell cancer during his adolescent and adult years.
35. The exposure to the toxic drug E-Ferol during the neonatal period and concurrently experienced direct hyperbilirubinemia, put the male class members at risk for long-term hepatotoxicity and for the consequences of xenoestrogen exposure during testicular and prostrate development, exposing them to the risk of germ-cell cancer during their adolescent and adult years.
36. Plaintiffs, Victoria Klein and Ashley Swadley, were exposed to the toxic drug E-Ferol during their neonatal periods and concurrently experienced direct hyperbilirubinemia, putting each at risk for long-term hepatotoxicity and chronic liver diseases throughout their lifetimes.
37. Prior to the "Class 1" recall of the toxic drug, E-Ferol, initiated on April 11, 1984, Defendants continued to manufacture, distribute and market their product despite complaints to the distributor of illnesses and deaths to premature infants from user hospitals in December, 1983, and again, in January, 1984. (The deaths and illnesses described were of like causation and characteristic of the deaths and illnesses reported to the CDC in March, 1984).
38. Defendants' conduct, as described in the preceding paragraphs, amount to conduct purposefully committed, which Defendants knew or reasonably should have known, was

dangerous, done wantonly and recklessly, without regard to consequences of the rights and safety of the Plaintiffs, Defendants acted in conscious disregard of Plaintiffs' rights.

### III.

#### LEGAL ALLEGATIONS

##### A. First Claim for Relief - Negligence/Negligence Per Se

39. Plaintiffs and members of the class incorporate by reference the allegations contained in paragraphs 1 through 37 above.
40. Plaintiffs would show that Defendants owed a duty of ordinary care to Plaintiffs and members of the class and that the Defendants failed to use ordinary reasonable care in the manufacture, marketing and preparation of this toxic product, and thus, breached their duty of ordinary care to Plaintiffs and members of the class.
41. Defendants had a duty, among others, to Plaintiffs and members of the class, to provide a safe, non-toxic product in design and manufacture; to notify the FDA, the Plaintiffs and members of the class of the design and manufacturing flaws, if any; and to warn the FDA, the Plaintiffs and members of the class, of the defective and toxic nature of the Defendants' E-Ferol and the source of the toxic product. This, the Defendants failed to do.
42. Defendants had a duty to submit this product for approval to the Food and Drug Administration (FDA) pursuant to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 300, *et seq.*, and failed to do so: Defendants failed to advise the Plaintiffs and the members of the class, as well as their physicians, pharmacists and other providers of

their failure to submit this product to the FDA, as required by federal law and of their failure to obtain approval for the use of the drug. Thus, Defendants are guilty of negligence per se.

43. Defendants were negligent in failing to advise the Plaintiffs, the members of the class, and their physicians, that E-Ferol had not been properly approved by the FDA.
44. Defendants were negligent and breached their duty of reasonable care to the Plaintiffs and members of the class by falsely claiming that E-Ferol was approved by the FDA.
45. Defendants breached their duty of reasonable care to the Plaintiffs and members of the class by failing to withdraw the product from the market in December, 1983, following notification from Kapiolani Women's and Children's Medical Center in Honolulu, Hawaii on or about December 15, 1983, that premature infants receiving the drug had become seriously ill.
46. Defendants breached their duty of reasonable care to the Plaintiffs and members of the class by failing to withdraw that product permanently in January, 1984, following notification from Sacred Heart Hospital in Spokane, Washington, that premature infants receiving the drug had become seriously ill and died after receiving the E-Ferol product.
47. Defendants breached their duty of reasonable care to Plaintiffs and members of the class by failing to remove from the stream of commerce the E-Ferol product Defendants knew was toxic, but instead, continued to manufacture, market and/or distribute their product until April 6, 1984.
48. Defendants breached their duty of reasonable care to the Plaintiffs and the members of

the class by otherwise failing to exercise due care in that Defendants failed to test E-Ferol in any clinical trials.

49. Defendants supplied E-Ferol and had a duty to see that the product might be dangerous if negligently made and thus, had an obligation to exercise reasonable care in the design, processing, testing, manufacturing, and inspecting of the product and the testing and/or inspection of any components made by another before selling it; at all times relevant Defendants breached that duty, failing to test or inspect the product and represent that E-Ferol was safe when it was defective and toxic, and sold to the Plaintiffs and the members of the class.
50. Defendants which sold a product manufactured, processed, and/or provided by another as their own, had the same duty of care as that of the manufacturer and/or provider.
51. As a direct, proximate, producing and/or legal result of Defendants' negligence and carelessness, Plaintiffs, and members of the class, have been injured and damaged as set forth herein.

**B. Second Claim for Relief - Breach of Expressed Warranties**

52. The Plaintiffs and the members of the class incorporate by reference the allegations contained in paragraphs 1 through 50 above.
53. The Defendants, as manufacturers, marketers, sellers and middlemen, sold to the Plaintiffs and to the members of the class, the pharmaceutical product, E-Ferol, and in doing so, made expressed, affirmative representations concerning certain characteristics of the pharmaceutical product, including the fact that the product had been approved

by the FDA, that it was non-toxic, not defective and safe for its intended use.

54. The Plaintiffs and the members of the class and their physicians who prescribed E-Ferol to them, relied upon them for these expressed warranties and misstatements of fact.
55. The Defendants have breached their expressed warranties by offering for sale and selling a safe, non-toxic product, approved by the FDA, the pharmaceutical product, "E-Ferol," when, in fact, that product was defective in design, manufacture, processing and/or warning and it was unmerchantable and unfit for its intended use.
56. As a direct, proximate and/or producing or legal result of this breach, the Plaintiffs and members of the class have been injured in damages set forth herein.

**C. Third Claim - Breach of Implied Warranty**

57. The Plaintiffs and members of the class incorporate by reference the allegations made in paragraphs 1 through 55 above.
58. The Plaintiffs and members of the class intended to use E-Ferol as their vitamin E supplement prescribed for them by their physician for their delicate condition as premature infants due to the need they had in their vulnerable condition for vitamin E to prevent respiratory problems, blindness and other problems associated with the use of supplemental oxygen in premature infants.
59. The Plaintiffs and members of the class used E-Ferol for a particular purpose in conjunction with the treatment for their condition.
60. The Defendants implied warranted that E-Ferol was designed, manufactured, processed and promoted and sold to the Plaintiffs and members of their class as merchantable and

fit and safe for ordinary and intended use, that is, as a vitamin E supplement in premature infants. The Defendants knew at the time they placed E-Ferol in the stream of commerce that the Plaintiffs and members of the class were relying upon the Defendants to supply them with a simple, safe, non-toxic vitamin E supplement.

61. Defendants impliedly warranted to the Plaintiffs and members of the class that E-Ferol was fit for its use as a vitamin E supplement.
62. Defendants' E-Ferol pharmaceutical product was in fact defective, unmerchantable, unfit for use when sold and not fit for the ordinary, foreseeable purposes of providing a safe, effective vitamin E supplement for premature infants. Defendants subjected Plaintiffs and members of the class to severe and permanent injuries as set forth herein. Thus, Defendants breached the implied warranty of merchantability and fitness for use of the E-Ferol pharmaceutical product.
63. As a direct, proximate, producing and/or legal result of Defendants' breach of the implied warranties of merchantability and fitness for use, Plaintiffs and members of the class had been injured and damaged as set forth herein.

**D. Fourth Claim for Relief - Misrepresentation**

64. Plaintiffs and members of the class incorporate by reference those allegations contained in paragraphs 1 through 62 above.
65. At all relevant times herein, Defendants owed to Plaintiffs and members of the class a duty of care which required, among other things that Defendants be truthful, accurate in representations to Plaintiffs and members of the class concerning E-Ferol vitamin E

supplement that was provided to them by prescription from their physicians to assist them in their fragile and vulnerable position following their premature birth.

66. Defendants represented to Plaintiffs and members of the class by and through the physicians who treated, prescribed E-Ferol for them, that E-Ferol was approved by the FDA and thus, reassured Plaintiffs and members of the class that the product was safe and non-toxic to be used as a vitamin E supplement.
67. The fact that the Defendants had neither sought nor obtained FDA approval for their product and, in fact, had not clinically tested their product at all or performed any type of testing necessary to secure such approval, and thus, knowingly made false, misleading and deceptive representations concerning FDA approval of E-Ferol.
68. As a direct, proximate, producing and/or legal result of Defendants' conduct as described above, Plaintiffs and members of the class have been injured and damaged as set forth herein.

**E. Fifth Claim - Product Liability**

69. The Plaintiffs and members of the class incorporate by reference the allegations contained in paragraphs 1 through 67 above.
70. The Plaintiffs and the members of the class would show that E-Ferol is a product that was placed in the stream of commerce by the Defendants for use as a pharmaceutical product to be intravenously injected into the bodies of premature infants as a vitamin E supplement. The Defendants knew at the time throughout their possession that the product was unreasonably dangerous, that is, dangerous to an extent beyond that which

would be contemplated by the ordinary users of the product with ordinary knowledge common to the community as to the product's characteristics. Furthermore, the Defendants knew that the product was defectively designed, thus, rendering it unreasonably dangerous, taken into account the utility of the product and the risk involved in its use.

71. The Defendants knew that E-Ferol was defectively marketed in that the Defendant failed to give adequate warnings of the products dangers that were known or by the application of reasonable testing should have been known, and the Defendants failed to give adequate instructions to avoid such dangers. Defendants continuously misrepresented that E-Ferol had FDA approval, when it did not, such that the marketing of the product rendered it unreasonably dangerous in that the Defendants failed to give adequate warnings and instructions concerning the use of the product and failed to disclose that it had not been tested and did not have FDA approval.
72. Thus, the Defendants designed, manufactured, and marketed an unreasonably dangerous product, placed it in the stream of commerce where it was transferred and sold by Defendants to the ultimate users or consumers, the Plaintiffs and the class they represent.
73. The Plaintiffs and the members of the class would show that in its direct, proximate and/or producing or legal cause of their receiving intravenously as premature infants, this defectively manufactured, designed, and marketed product, they were caused to suffer injuries and damages as set forth herein.

F. Sixth Claim - Punitive Damage

74. Plaintiffs and members of the class incorporate by reference allegations contained in paragraphs 1 through 72 above.
75. The Plaintiffs would show that as a result of conduct alleged in paragraphs 1 through 73 herein, that Defendants were guilty of gross negligence in that Defendants' actions were more than merely momentary thoughtlessness, inadvertence or error of a judgment, but rather, indicated a course of conduct such that Defendants displayed an entire wanton of care so as to establish that the act or omissions in connection with the manufacture, design, distribution, lack of testing, misrepresentation and marketing of E-Ferol, were the result of actual conscious indifference as to the rights, welfare and safety to the Plaintiffs and the members of the class.
76. The Defendants engaged in intentional malice with regard to the misrepresentations and marketing of E-Ferol and thus, intentionally caused harm to the Plaintiffs and members of the class such that they should be entitled to exemplary damages.
77. As a result of the gross negligence and malice of the Defendants, Plaintiffs and members of the class are entitled to exemplary or punitive damages.

IV.

Class Action Allegations

78. The Plaintiffs and members of the class incorporate by reference Paragraphs 1 through 76 as set forth above.
79. The Plaintiff brings this action pursuant to Fed. R. Civ. P. 23 on behalf of a class of all persons in the United States who were administered E-Ferol as premature infants during the time period of December, 1983 until E-Ferol was removed from the market in April, 1984.
80. The Plaintiff, Victoria Klein, is a member of the class.
81. The Plaintiff, Ashley Swadley, is a member of the class.
82. The members of the class are so numerous that joinder of all its members is impractical. Defendants manufactured and distributed to hospitals throughout the country over 28,000 vials of E-Ferol that were administered to over 1,000 premature infants. Two young children and one adult were also known to have received doses of E-Ferol. While the identity of all class members are unknown at this time, upon information and belief, the Plaintiff would show that over 1,000 premature infants received E-Ferol and virtually all were not informed of that fact by their physicians or hospitals. Cook Children's Medical Center, formerly known as Fort Worth Children's Hospital, where Plaintiff Klein received E-Ferol has admitted in other litigation that it did not inform the parents of these premature infants or the infants themselves after they attained the age of majority that they had received E-Ferol and upon information and belief, Plaintiffs would show virtually all hospitals throughout the United States that had

administered E-Ferol had a similar policy of not disclosing this fact either to the parents or to the patients once they were old enough to understand the significance of the information or once they attained their majority. The Second Court of Appeals in the State of Texas, located in Fort Worth, Texas, has ruled in Cause No. 236-181122-99, that a hospital, such as Cook Children's Medical Center, is not allowed to claim privileges in order to prevent disclosure to the recipients of E-Ferol. The Plaintiffs believe that numerous other medical centers had similar policies and had prevented recipients of E-Ferol from being aware that their symptoms, disabilities and injuries were caused by E-Ferol syndrome. Upon information and belief, well over one thousand, premature infants were victims of E-Ferol syndrome as a result of being administered E-Ferol solution during the first few days of their lives. Most of these victims have not been informed that they are victims of E-Ferol Syndrome with its potentially catastrophic, and sometimes fatal, symptoms. E-Ferol Syndrome is recognized and documented in medical literature. After the removal of E-Ferol from the market, hospitals and medical providers did not notify victims that they had received this toxic substance. Defendants have taken no action to attempt to inform these victims of E-Ferol of the potential health effects of having received it.

83. The Plaintiffs' claims are typical claims of the class in that each member of the class, including the Plaintiffs, was prescribed and administered E-Ferol and suffered the physical, mental and/or emotional injuries and economic damages, including loss of income that resulted from the development of the recognized symptoms of E-Ferol syndrome, including pulmonary deterioration, hepatomegaly, cholestatic jaundice,

ascites, splenomegaly, renal failure, azotemia, and thrombocytopenia. These conditions in severe cases led to severe brain damage, blindness and even death, and even in non-severe cases, the infants frequently experienced prolonged hospitalization stays and permanent organ damage.

84. Because of the latency period and the potentially concealed nature of the complications from the failure of the Defendants and the medical providers to advise each member of the class that they were a recipient of E-Ferol, medical monitoring, testing or treatment is necessary for each member of the class.
85. The class consists of not only of the remaining infant recipients, now of legal age, but also the parents of those children who died after receiving E-Ferol and were denied legal representation and access to the judicial system as a result of the failure of the Defendants or of the medical providers to advise the parents that their infant received E-Ferol.
86. While the identities of the class members are not known at this time, their identity can be discovered by the production of the drug recipient's name from each hospital to which E-Ferol was distributed, the hospitals have previously identified E-Ferol recipients as a result of the FDA inquiry and congressional hearing in 1984.
87. The Plaintiffs will fairly and accurately represent the class and to protect the interests of the members of the class. The Plaintiffs have retained attorneys, experienced in the prosecution of complex class action litigation to assist them.
88. Common questions of law and fact exist as to all members of the class. These questions predominate over any questions affecting only individual members of the class. These

common legal and factual questions include the following:

- (a) Was the E-Ferol, as developed, manufactured, distributed, fabricated, advertised, promoted and/or sold by Defendants, a toxic and defective product?
- (b) Did Defendants conduct adequate testing of E-Ferol to determine its safety prior to selling and distributing it and did it accurately report the results of this testing?
- (c) When did Defendants learn of the defects or toxicity of its E-Ferol?
- (d) What steps, if any, did Defendants take to cure the defects that had harmed or may harm those who were infused with E-Ferol?
- (e) Did Defendants continue to sell and distribute E-Ferol after they knew of the defects and of the injuries and risks associated with its use?
- (f) Did Defendants fail to give adequate and timely warning of the dangers associated with the use of E-Ferol?
- (g) Did the Defendants misrepresent E-Ferol by claiming that it had FDA approval when it did not?
- (h) Are the Defendants strictly liable for sale of a defective product?
- (i) Did the Defendants violate the Food, Drug and Cosmetic Act in marketing E-Ferol as being safe?
- (j) Were the Defendants negligent?
- (k) Did the Defendants breach both expressed and implied warranties of merchantability and fitness for a particular purpose?
- (l) Are the Defendants guilty of misrepresentation?
- (m) Have the members of the class sustained injuries and damages, and if so, what is

the proper measure of damages?

- (n) Are the Defendants liable for punitive damages, and if so, in what amount?
- (o) Are the Plaintiffs and the class members entitled to the establishment of a medical monitoring program designed to identify and, where possible, reduce the risk of future harm from E-Ferol?

89. A class action is superior to other available methods for the fair and efficient adjudication of this litigation. An individual joinder of all members of the class is impractical. Further, the burden to the courts of handling hundreds, if not thousands, of individual cases arising from the same nucleus of operative fact would be excessive. Individual litigation would also increase the expense of litigation to all parties and to the court systems. Many class members are unaware of their plight and require identification, screening and education.
90. Class certification under Fed. R. Civ. P. 23 is appropriate as the Plaintiffs seek declaratory and equitable relief in the form of the notification and medical monitoring, and examination program so that each victim of E-Ferol would be advised of the fact that they were administered E-Ferol and be examined and monitored for potential, long-term adverse effects. Separate actions would create a risk of incompatible standards of conduct being imposed upon the Defendants. It is appropriate because the Plaintiffs seek the return of all medical, hospital, and surgical costs incurred as a result of the injuries suffered as a result of receiving E-Ferol, as well as hospital, pharmacological, and incidental expenses for past and future care and economic damages for loss of income and future loss of income on behalf of all members of the class.

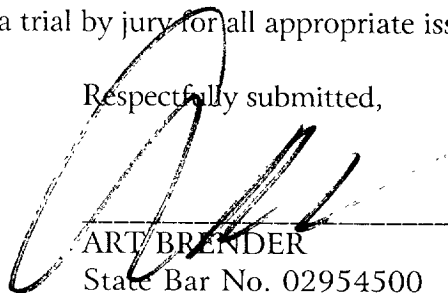
WHEREFORE PREMISES CONSIDERED, the Plaintiffs and class pray for judgment against the Defendants as follows:

- A. Declaring and certifying this as a class action, appointing the Plaintiffs as a class representatives, and Plaintiffs' attorneys as class counsel;
- B. Entering an order requiring the Defendants and any distributors, hospitals or medical providers to make full and accurate disclosure to the Court of those premature infants who received E-Ferol prior to it being removed from the market;
- C. Entering an order requiring the Defendants make full and accurate disclosure with all risks associated with the use of E-Ferol;
- D. Establishing and funding a medical monitoring program, at Defendants' expense, and to notify those persons who have been recipients of E-Ferol, the dangers associated with the product and to monitor and test the health of each and every person who received E-Ferol and in the process to gather information and use it to assist in the diagnosis and treatment of any effect of E-Ferol syndrome;
- E. Enter an order requiring the Defendants to provide funds for research, diagnosis and treatment of E-Ferol syndrome;
- F. Enter an order appointing a trustee to supervise relief if necessary;
- G. Establishing a common fund on behalf of the Plaintiffs and the class so as to distribute any and all funds necessary to reimburse Plaintiffs and members of the class for their medical expenses, treatment and other losses;
- H. Enter a judgment against the Defendants in an amount in excess of

\$75,000.00, exclusive of interests and costs of suit for each of the Plaintiffs and for each class member;

- I. To award punitive damages against Defendants in an amount in excess of \$75,000.00, exclusive of interest and costs of suit for each of the Plaintiffs and each class member;
- J. To enjoin the prosecution of any other action which may be instituted in the future in this or other court cases involving the same class members and/or issues;
- K. To awarding reasonable attorneys' fees and costs of court, including the costs of notification of the class;
- L. Awarding any and all relief to which the Plaintiff and class may be entitled to, either in equity or at law; and
- M. The Plaintiffs demand a trial by jury for all appropriate issues.

Respectfully submitted,



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ART BRENDER  
State Bar No. 02954500

LAW OFFICES OF ART BRENDER  
Pennsylvania at Eighth Avenue  
600 Eighth Avenue  
Fort Worth, Texas 76104  
(817) 334-0171, telephone  
(817) 334-0274, telecopier

DWAIN DENT  
State Bar No. 05760550

FRED L. STRECK  
State Bar No. 19374350

THE DENT LAW FIRM  
1120 Penn Street  
Fort Worth, Texas 76102  
(817) 332-2889, telephone  
(817) 332-5809, telephone

ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing document was served upon the attorneys of record of all parties to the above cause in accordance with the Federal Rules of Civil Procedure, on this the 7<sup>th</sup> day of August, 2003.

  
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ART BENDER