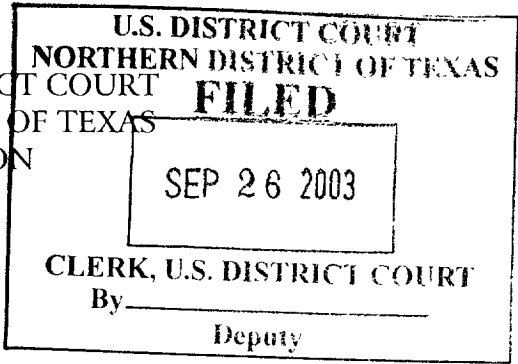


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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION



VICTORIA KLEIN and §
ASHLEY SWADLEY, §
§
Plaintiffs, §

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' MOTION FOR CLASS CERTIFICATION

TO: THE HONORABLE JERRY BUCKMEYER,
UNITED STATES DISTRICT JUDGE:

COME NOW, VICTORIA KLEIN and ASHLEY SWADLEY, Plaintiffs, and move the Court to certify this cause as a class action pursuant to Fed. R. Civ. P. 23 and L.R. 10.2, of the Local Rules of this Court, and, in support of this motion, would show the Court as follows:

1.

The Plaintiffs and the class they seek to represent were all premature infants who, during the time period from November 1, 1983 until April 30, 1984, were administered a pharmaceutical product known as E-Ferol, a toxic substance that was marketed without approval by the Food and Drug Administration ("FDA") as a vitamin supplement suitable for intravenous infusion in premature infants so as to prohibit blindness and other complications that occurred as a result of the need for supplemental oxygen by such infants. When infants soon began to die in the neonatal units at an alarming rate, E-Ferol was recalled by advisement

of the FDA, issued April 12, 1984. In issuing the recall, the FDA advised Defendants that E-Ferol was an unapproved new drug marketed in violation of Sect. 505, of the Federal Food, Drug and Cosmetic Act.

2.

Overview of E-Ferol

In late 1983, Defendant O'Neal, Inc., d/b/a O'Neal, Jones & Feldman Pharmaceuticals ("O'Neal") and Defendant Retrac, Inc, then operating under the name of Carter-Glogau Laboratories, ("Carter"), then a division of Defendant Revco, ("Revco"), developed, manufactured, and 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 alone had heretofore only been administered to premature infants orally or in an intramuscular form. The intramuscular form was difficult to administer to small birthweight infants and the oral form has poor absorption 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; the first marketed Vitamin E preparation for intravenous use in premature infants. 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 not needing the Food and Drug Administration ("FDA") approval. E-Ferol was distributed throughout the country beginning in November, 1983. Soon after E-Ferol was distributed, many hospitals began to experience high infant mortality and morbidity rates,

sufficient to draw the attention of the Federal Center for Disease Control (CDC) and the FDA. On April 9, 1984, the FDA advised Defendants that E-Ferol was an “unapproved new drug” made in violation of the Federal Food, Drug and Cosmetic Act. On April 12, 1984, the FDA classified the recall of E-Ferol on an urgent Class-1 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. *FDA’s Regulation of the Marketing of Unapproved Drugs: The Case of E-Ferol Vitamin E Aqueous Solution, Hearing before a Subcommittee of the Committee on Government Operations, House of Representatives, 98th Cong., 2nd Sess., May 4, 1984. See, App. E, pp. 70-76.* 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) including numerous violations of the Federal Food, Drug and Cosmetic Act 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 for 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) and 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, reviewed and examined 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 nor did they warn of the hazardous and/or potentially long-lasting affects that the receipt of this product could have on the recipients.

3.

Class Definition

The class consists of all persons in the United States, including any estate representatives or heirs of deceased persons, who, during the period from November 1, 1983 until April 30, 1984, were administered E-Ferol. Included in the class are parents, spouses, children, guardians, and legal representatives of such persons with direct or derivative claims.

Administration of E-Ferol to premature infants caused death and serious immediate injuries in numbers of over 1000 infants that received this illegal substance. Even those infants whose conditions were worsened by E-Ferol, but without immediate and apparent serious consequences, are nevertheless subject to the long term risks and serious health consequences set out in the affidavit of Robert Brown, M.D., a board certified pathologist, now of Geisinger Medical Center, Dansville, Pennsylvania, and formerly of W.I. Cook Fort Worth Children's Medical Center, in Fort Worth, Texas, whose seminal article in *Pediatrics* and research on E-Ferol attests to his status as the acknowledged expert on E-Ferol. Dr. Brown's affidavit is attached to Plaintiffs' Appendix, *see*, App. A, pp. 1-51, and sets out the criteria needed to medically monitor all recipients of E-Ferol, most of whom have never even been told they were administered this illegal substance.

4.

The Claims of the Class are Too Numerous to Join

Following the recall of E-Ferol, the Food & Drug Administration ("FDA") conducted a thorough investigation of Defendants Carter and O'Neal which revealed that over 25,800 vials of E-Ferol were distributed to 159 hospitals nationwide, of which 12,036 vials were administered approximately to a reported 1,008 premature infants. While a few individual

lawsuits have been filed as a result of the administration of E-Ferol, hospitals nationwide did not disclose to the parents and guardians of these premature infants that they had been administered E-Ferol. In Tarrant County, Texas, for example, after a number of years of litigation, the Second Court of Appeals, *In Re Fort Worth Children's Hospital, d/b/a Cook Children's Medical Center*, 100 S.W.3d 582 (Tex. App. -- Fort Worth 2002, *no writ*), that Cook Children's Medical Center could not use legal privileges to block disclosure to the recipients of E-Ferol that they may well have been affected and may continue to be affected by the results of being administered this illegal substance. It is believed that the class will be less than 1,000 since some recipients were ultimately informed of the receipt of this substance and took legal action. A vast majority of those recipients of E-Ferol were never informed of the fact that they received it and hence, may well still be suffering the effects of injuries received as a result of having been infused with this illegal substance and many are in need of medical testing to determine whether or not they have continued effects and risks as a result of having been administered this substance. While those who were administered the substance were minors at the time, their statute of limitation is now running since all will have attained the age of majority and yet, still not having been informed of the fact they received E-Ferol and that they may well be victims of E-Ferol syndrome or continuing and life-long effects from the receipt of this substance may currently have upon them. The Defendants have taken no action whatsoever to inform the victims of E-Ferol of the potential health effects from having received it. Since the victims of E-Ferol are spread throughout the country and because of the numbers of members of the class, they are too numerous to join a single lawsuit. While the identities of the victims are not known to the Plaintiffs at this time, the hospitals, where they received the

substance, and the records indicating that they did, are available and can be notified once their identities are required to be revealed.

5.

Plaintiff's Claim are Typical of Those of the Class

A.

Factual Basis of Plaintiffs' Claims

1. 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 sixth 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. Plaintiffs Ashley Swadley and Victoria Klein and all class members were administered this "drug" that was marketed and distributed in violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 321, 331, 333, 353 and 371.

B.

**E-Ferol Caused Serious Injuries and Has Potential for
Increased Health Risks for All Recipients**

12. 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.

13. 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.
14. 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.
15. Clinical research has demonstrated acute lung toxicity and sudden death, following the intravenous administration of Tween surfactants (Polysorbates 80 and 20).
16. 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.
17. 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.
18. 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.

19. 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.
20. 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.
21. 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.

C.

**Plaintiffs' Claims and Need for Medical Monitoring
and Disclosure are Identical to that of Class Members.**

22. Plaintiffs and all members of the class were administered E-Ferol when the drug was not

approved by the FDA and was misbranded in violation of the FDA Act and thus, each was defrauded by the Defendants; each was misled by the Defendants; each was administered a substance that was not tested for safety by the Defendants; each was and remains subject to the health consequences and risks as set out in the Affidavit of Robert Brown, M.D., *see*, App. A, pp. 1-51; each received in their bodies as a result of fraud, deceit and intentional mislabeling by these Defendants a substance that has been proven medically to cause E-Ferol syndrome which includes a) pulmonary infection; b) liver congestion, inflammation and failure; c) cardiovascular effects ultimately causing a reduction in blood flow creating hypoxic/anoxic compromise; d) compromised immune system resulting in bacteria infection; e) brain damage as a result of (a) through (f); f) blindness; and g) any and all of the risks set out in Dr. Robert Brown's Affidavit (*see*, App. A, pp. 1-51).

23. The claims of these Plaintiffs are typical claims of the members of the class and that each member of the class, including the Plaintiffs, were prescribed and administered E-Ferol and it was illegal under the Food and Drug Administration Act, Title XXI, U.S.C. §§ 321b1, 353b1b, and other sections of the Act to distribute and to put into commerce this substance which was a drug within the meaning of the Act and thus, required to be tested and approved by the FDA before distribution. The drug was distributed for infusion of the body of premature infants who were legally minors and who have now reached the age of majority. Since this substance was marketed illegally and since the illegality was not revealed to the hospitals and the physicians to which it was administered and in fact, the Defendants intentionally misrepresented the fact that it was not approved by the FDA and the substance was illegally injected into the bodies of each and every one of the recipients and thus, entitling them to

damages as a matter of law under the laws of each and every state and due to the violation of the FDA Act and based upon the common law of negligence and assault applicable to each and every state in the union. Furthermore, those receiving E-Ferol may well have suffered very serious consequences of E-Ferol syndrome which includes hepatomegaly, cholestatic jaundice, ascites, splenomegaly, renal failure, azotemia, and thrombocytopenia. These conditions in severe cases have 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. In addition, a prominent expert in the field, Robert E. Brown, M.D., who co-authored the seminal article on E-Ferol, published in *Pediatrics*, has outlined the need for medical monitoring for each and every patient exposed to E-Ferol because of the effect on reproductive and gynecological and genitourinary implications, as well as hepatic cirrhosis and hepatocellular carcinoma, necessitating the need for monitoring and vigilance for early detection of these problems have been thoroughly outlined in App. A, pp. 1-51. Dr. Brown's research further indicates not only that all recipients of E-Ferol are in need of this monitoring in light of the risk to their health from the exposure, but also the fact that a class action is necessary in order to inform these victims of the need for a medical examination and continued vigilance to detect early signs of these diseases.

24. Each case of E-Ferol exposure satisfies any jurisdictional amount required and the medical monitoring and injunctive relief also satisfy the jurisdictional requirement of the Fed. R. Civ. P. 23.

6.

Common Questions of Law and Fact Exists as to All Member of the Class

These questions are predominant over any questions affecting only individual members of the class such as what amount of damage did each individual person suffer as a result of E-Ferol exposure. The common legal and factual questions are as follows:

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 alleviate and/or 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?

In addition, the Plaintiffs would show that Defendants have entered pleas of guilty to violations of the Food and Drug Administration Act and that such violations are the basis for legal liability in each and every state in the union.

Each of the exposed patients was infused with the substance which was illegal to place in their body and thus, liability on these grounds alone is common to each and every member of

the class. Likewise, the defenses as to each would be common as to each. Each of the victims were not only a minor, but were less than a few months old, and there are no individual questions concerning consent, knowledge or other factors that are sometimes used by defendants in order to avoid class action treatment in mass tort cases. Furthermore, the victims are manageable given the number of cases. Likewise, a misrepresentation was made equally to each and every hospital and physician who were led to believe that the FDA had approved this substance or that approval was not necessary, and thus, are common grounds of liability and of damages, since the mere act of infusing into the body of a minor an illegal substance is illegal under the federal law and the laws of every state and the common law of every state and damages are thus, caused by the very act of infusing the illegal substance into the bodies of these infants.

7.

Class Action Superior to Other Available Methods

for Fair and Efficient Adjudication of this Case, FRCP 23(b)(3)

- A. This class consists of less than one thousand recipients of E-Ferol who, at the time they received this drug, were only a few months old. Although recall notices were sent to the hospitals, Plaintiffs would show that most hospitals, such as Cook Children's Medical Center, f/k/a Fort Worth Children's Hospital, in Fort Worth, Texas, where Plaintiff Victoria Klein received E-Ferol, and Baylor University Medical Center, in Dallas, Texas, where Plaintiff Swadley received E-Ferol, as well as Harris Hospital, in Fort Worth, Texas, where other known recipients received E-Ferol, never advised the parents of these

children, nor did they advise the children themselves, even after these children reached the age of majority, that they had received this illegal drug. The Second Court of Appeals, in Fort Worth, Texas, held *In Re Fort Worth Children's Hospital, supra*, that Cook Children's Medical Center could not use patient privileges to deny disclosure of those who received E-Ferol, *see, App. B*, pp. 52-61. Upon information and belief, the Plaintiffs would show that the hospitals simply did not disclose to parents or to their patients even after they attained the age of majority that they received this substance. Consequently, most recipients of E-Ferol are not aware of the fact that they received this substance. Since E-Ferol was distributed between November 1, 1983 and April 12, 1984, when it was recalled from the market by advisement of the FDA, the premature infants who received this drug are now eighteen and nineteen years-old and thus, subject, in certain circumstances the running of state statutes of limitation, while although the Plaintiffs would show the Court that equitable doctrines may well estop these Defendants from invoking such a defense. More importantly, as displayed by the sworn Affidavit of Robert Brown, M.D., *see, App. A*, pp. 1-51, the recipients of E-Ferol may well have medical conditions that need testing and monitoring. Thus, the interests of the members of the class in being informed of their receipt of this drug and the medical risks and medical monitoring necessary in order to deal with the potential health risks that each of them may encounter, prevails over the interest any individual class member has in controlling the prosecution or defense of separate actions. While certain individual actions have been prosecuted against these Defendants, with the failure to disclose to most of the recipients that they even received this substance and

since at the age at which they received it were far too young to have any knowledge of this fact themselves, it was only in fortuitous circumstances that victims of E-Ferol were informed that this substance had caused their injuries. Thus, a class action is desirable so as to concentrate all claims in one court for purposes of informing those who received E-Ferol of the potential health risks that need to be monitored through their lifetime so as to detect early signs of the diseases and/or medical conditions set forth in Dr. Brown's Affidavit, *see*, App. A, pp. 1-51. A class action is desirable so as to concentrate the litigation of these claims as to liability in a particular form so that appropriate medical monitoring can be accomplished as part of the relief sought by the Plaintiffs. Any difficulties encountered in the management of the class action of this type would be minimal, as this class is notably smaller than classes certified concerning asbestos, breast implants, diet drugs, Albuterol and agent orange. The exposure time of this drug was short and the doses administered will be contained in the medical records of the recipients. Since the Defendants were required to notify the FDA of the hospitals that received E-Ferol and since those hospitals were required to notify the FDA of the number of doses that were administered, records exist whereby class members can be located and notified that they are recipients and their medical records obtained, and an appropriate analysis done on whether or not they suffered the severe effects of E-Ferol syndrome. The FDA itself advised physicians to "closely monitor infants who received E-Ferol Aqueous Solution because of the possibility of delayed onset of symptoms." (*See*, Brown Affidavit, *see*, App. A, pp. 1-51) There was no subsequent follow-up to see if in fact this occurred. Since the long-term effects are documented by extensive medical research set

forth in the Affidavit of Dr. Brown, *see*, App. A, pp. 1-51, which indicates that the female reproductive and gynecological physiological health may be imperiled, medical attention is necessary in order to provide for early detection of cervico-vaginal cancer, alterations in the menstrual cycle, potential for infertility and reproductive mishaps, and the determination of abnormal vasculature of the uterus. The female members of the class need to be informed of these risks and proper information given to them and their physicians for medical monitoring and continued vigilance. Likewise, male members of the class may have male reproductive and/or genitourinary health risks, including alterations and increase in size of the adult prostate and increase in prostatitis, as well as the risk of testicular germ cell cancer. Both males and females are at increased risks for hepatic cirrhosis and hepatocellular carcinoma and consequently, they need both the information and medical monitoring to allow for early detection of the treatment of these diseases. Both males and females are at the risk of chronic renal failure, once again, on the expert advice of Dr. Brown, necessitating both baseline studies to determine renal status and continued vigilance, necessary for early detection and treatment of these diseases. A class action is superior to individual actions for the reason that individual actions have been sporadic since there was no unified nor uniform attempt to notify and inform the recipients of E-Ferol that they had been so exposed. Furthermore, if E-Ferol caused damage in the past, the recipients are entitled to know the cause of their medical condition before state statutes of limitation may intervene to prevent their going forward in order to receive compensation for their injuries. While questions concerning causation of any of these diseases may arise among

class members, the desirability of informing members of the class that they are recipients of E-Ferol and permitting them to pursue baseline studies and medical monitoring to best monitor and preserve their health, far exceeds the fact that they have also been injured in some form or fashion by having been administered an illegal drug that has caused and can potentially cause such harm. The fact that each individual class member may have a different quantum manifestation of damages, depending upon the harm done, it is no reason for finding the class action is not superior to individual actions. The fact that after so many years there have been so few individual actions brought by victims of E-Ferol attest to the defacto conspiracy of silence between the medical community and the Defendant manufacturers of this drug to lessen any potential liability that may come from informing the members of the class of what happened to them many years ago. The fact that issues of causation and the amount of damages may require individual adjudication are not difficulties that overcome the overall desirability and potential for protection of innocent victims that the class action will provide to members of this class, the vast majority of whom are unaware that they even received this substance. By use of many trials or through potential for class settlement with structure monetary awards according to injuries received by members of the class are both manageable and increasingly useful devices used by courts to deal with far larger classes of victims of pharmaceutical malfeasance.

The Plaintiffs would show that the Defendants have settled all of the individual claims brought by class members (which Plaintiffs believe are fewer than two hundred claims) and given the criminal convictions of the corporation and its principals for violation of the Food

Drug and Cosmetic Act, it would appear that the contesting liability would not be a strategy pursued by these Defendants. The usefulness of the class action to establish both liability and medical monitoring has been frequently cited as a reason for certifying a class even if many trials are required to assess damages among the individual class members.

The Plaintiffs would show that simply providing an illegal substance to a minor is violative of every state's tort laws, entitling even a victim with no lingering or permanent injury damages for such an outrageous act in and of itself. There is no question that liability against these Defendants is overwhelming and there is responsibility for some damage in each and every case a foregoing conclusion. Thus, the use of the class action device has been repeatedly invoked for far larger classes involving mass tort actions with far greater issues concerning causation than presented here. Likewise, the need for medical monitoring, given the toxicity of E-Ferol, which, according to the FDA, caused at least thirty-eight (38) deaths among premature infants in the five months it was on the market, makes the desirability of both informing the recipients and providing some compensation and medical monitoring, is the type of social good which our civil tort system is supposed to engage.

8.

Plaintiff Would Adequately Represent the Class

The Plaintiffs would show that the Plaintiffs will adequately and fairly represent the member of the class and that each of them was a victim of E-Ferol exposure and desire to have the medical monitoring and examination as set forth by Dr. Brown in this motion.

The Plaintiffs propose that their attorneys, Art Brender, Dwain Dent and Fred L. Streck, III, be attorneys for the class. All three attorneys are Board Certified in Personal Injury

Trial Law by the Texas Board of Legal Specialization. All have extensive experience in trying complex product liability litigation. All have been involved in class action litigation. Plaintiffs' attorney, Art Brender, has been lead counsel in a number of class actions lawsuits, including *Ladd v. Dairyland*, CA4-77-28-E, in the United States District Court for the Northern District of Texas, Fort Worth Division, 96 F.R.D. 335 (N.D. Tex. 1982); *Coble v. TDC*, CAH-77-707, in the United States District Court for the Southern District of Texas, Houston Division, 568 F.Supp. 410 (S.D. Tex. 1983); *Jackson v. Fort Worth National Bank*, CA4-77-276-K, in the United States District Court for the Northern District of Texas, Fort Worth Division, (June 8, 1983); *Watson v. Fort Worth Bank & Trust*, 789 F.2d 791 (5th Cir. 1986), cert. granted ; 487 U.S. 977, 108 S.Ct. 2777, 101 L.Ed.2d 827 (1988); and *Halkias v. General Dynamics*, No. 4-92-CV-860-A ; 825 F.Supp. 123 (1993).

Plaintiffs' counsel have the financial resources and office staff to manage a class of this size.

9.

The Plaintiffs propose that notice be made individually to each and every member of the class whose identity will be determined by a court order which orders each and every hospital to which E-Ferol was marketed to prepare and forward to the Plaintiffs the list of recipients of E-Ferol and their last known address, date of birth, Social Security number and any other information about the parents or guardians so as to facilitate location of these victims. The Plaintiffs will then research the addresses and then notify each member of the class pursuant to a notice approved by this Court giving each member of the class an opportunity to opt-out of the class during a time period specified by the Court. The

approximate costs of such mailing would not exceed \$5,000.00 and the Plaintiffs will be responsible for the costs of providing such notice.

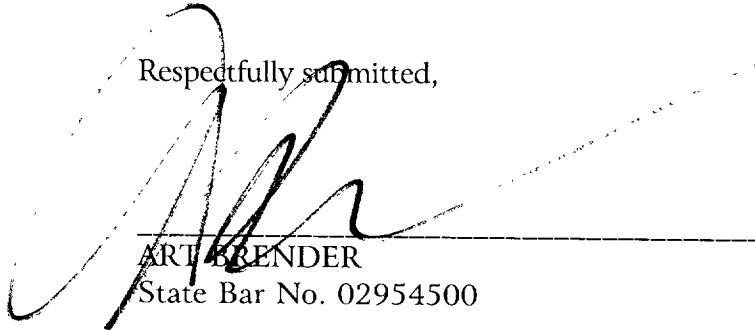
10.

A copy of the Order to require disclosure of the names of the recipients of E-Ferol from the hospitals known through Defendants' records to have been shipped E-Ferol is attached to Plaintiffs' Appendix, *see*, App. C, pp. 62-63.

A copy of the class action notice is attached to Plaintiffs' Appendix, *see*, App. D, pp. 64-69.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that the Court grant their motion to certify this as a class action pursuant to Fed. R. Civ. P. 23.

Respectfully submitted,



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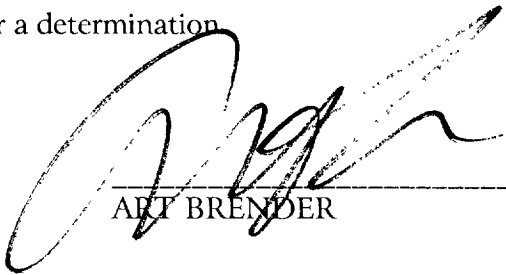
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CERTIFICATE OF CONFERENCE

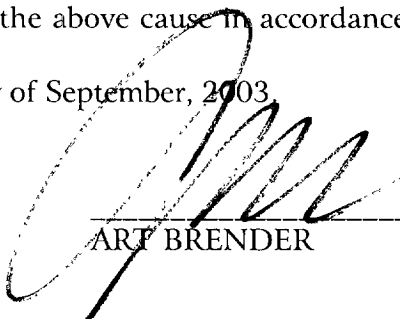
A conference was attempted on the 26th day of September, 2003, with David McFarland and Brad Burdette, attorneys for Defendants, on the merits of this motion. Defendants have advised in Defendants' Original Answer, that they oppose class certification in this matter and, further, pursuant to the Order granting Defendant O'Neal's Agreed Motion for Extension of Time to File Responsive Pleadings and Motion for Class Certification, this motion is presented to the Court for a determination



ART BENDER

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 26th day of September, 2003.



ART BENDER