

E-Ferol Class Certification

On May 11, 2004 the United States District Court for the Northern District of Texas, Wichita Falls Division (the "Federal District Court"), certified a nationwide class action in *Klein, et al. v. O'Neal, Inc., et al.*, Civil Action No. 7:03-CV-102-D, to pursue claims related to the administration of the drug E-Ferol. *Klein v. O'Neal, Inc.*, 222 F.R.D. 564, 566 (N.D. Tex. 2004) (Buchmeyer, J.).

The class of persons covered by this class action is defined as:

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.

Court Approval of Class Action Settlement

On April 9, 2010, following a fairness hearing, the Federal District Court, by Memorandum Opinion and Order, approved a settlement of the E-Ferol class action. *Klein v. O'Neal, Inc.*, 705 F.Supp.2d 632 (N.D. Tex. 2010) (Fitzwater, C.J.). A copy of the Settlement Agreement is attached and is available via PACER, www.pacer.gov, as document number 306-2 of Civil Action No. 7:03-CV-102-D. Based on medical evidence presented at the fairness hearing, the court found that 328 infants received E-Ferol during the period from November 1, 1983 through April 30, 1984 and are entitled to a monetary recovery.

Additionally, family members, guardians, and/or legal representatives of these E-Ferol recipients ("Non-Recipients") are members of the class and have asserted claims for losses incurred resulting from the recipient's exposure to E-Ferol. The E-Ferol class settlement provides for the class to recover approximately \$90 million from defendants' liability insurers who agreed to fund the Settlement. E-Ferol class members are categorized as follows:

Category 1 claimants consist of Non-Recipients making claims as representatives of deceased infants for whom the receipt of E-Ferol was alleged to be a substantial cause of the infants' death.

Category 2 claimants consist of Non-Recipients making claims as representatives of deceased infants for whom the receipt of E-Ferol was alleged to be a contributing cause of the infant's death.

Category 3 claimants consist of E-Ferol recipients who suffered brain injuries (brain dysfunction and/or cerebral palsy) alleged to be the result of the receipt of E-Ferol, and one class member making a claim as the representative of an E-Ferol recipient. The class members in this category who received E-Ferol were further assessed as having mild, moderate, or severe disability for purposes of assessing a monetary recovery.

Category 4 claimants consist of E-Ferol recipients who, following their initial hospital stay, did not exhibit any permanent E-Ferol-related injury and were symptom-free upon being released from the hospital following their birth, and Non-Recipients making claims as representatives of recipients of E-Ferol who, following their initial hospital stay, did not exhibit any permanent E-Ferol-related injury and whose deaths were not related to E-Ferol.

Category 5 claimants consist of E-Ferol recipients and Non-Recipients making claims as representatives of deceased recipients of E-Ferol. These class members' claims were dismissed based on statute of limitations or statute of repose grounds by the Federal District Court's memorandum opinion and order of May 22, 2008. *See Klein v. O'Neal, Inc.*, 2008 WL 215203, at *10 (N.D. Tex. May 22, 2008) (Fitzwater, C.J.). As a part of this settlement, Category 5 class members will receive a reduced monetary award based upon the category (1-4) to which their

dismissed claim would otherwise have been assigned. Category 5 claims are, for purposes of the remainder of this Notice, included in the discussions of Categories 1 through 4.

A discussion of the medical conditions allegedly caused by E-Ferol is attached as Appendix B.

**Efforts to Determine Whether Class Members
Received Medicare Or Medicaid Assistance**

Class counsel have engaged in an extensive effort to determine whether any class members have a potential obligation of reimbursement under the Medicare Secondary Payer Act of 1980 ("MSP Act") and/or any other Medicare- and/or Medicaid-related federal and state laws and regulations. Class counsel have contacted 43 state agencies that have enforcement authority for third-party reimbursement claims, in each state where an E-Ferol recipient was born as well as in any other state in which a surviving E-Ferol recipient has resided since birth, in an attempt to determine whether any class members were recipients of Medicaid assistance. Class counsel have also obtained the results of CMS Database queries run by defendants' liability insurance carriers, in an attempt to determine whether any class members were recipients of Medicare assistance. In addition, class members completed declarations in which they were asked questions about Medicare and Medicaid assistance; and class counsel have reviewed available medical records for E-Ferol recipients to try to ascertain if their hospital intake forms indicate any Medicare and Medicaid coverage.*

*During the period of approximately six months in 1983 and 1984 when E-Ferol was distributed, social security numbers were not assigned at birth and, consequently, no social security number has been found for most of the deceased E-Ferol infants. Defendants' liability carriers were advised that a social security number was necessary in order to process a "query." Consequently, no query was processed for Category 1 and Category 2 infants.

The Position of Class Counsel on Reimbursement

In the opinion of class counsel, no Medicare/Medicaid reimbursement is owed by any claimants in Categories 1, (5)1, 2, 5(2), 4, and 5(4). One class counsel testified at the fairness hearing that, despite attempts to obtain medical payment records for E-Ferol recipients, no records were available due to the passage of time. Thus no medical bills were used to obtain settlement proceeds for any E-Ferol recipient. Class counsel's position is that any Medicare or Medicaid assistance received by claimants in these Categories is wholly unrelated to E-Ferol and that there is no evidence or colorable claim to the contrary. Class counsel contend that the awards to Categories 1 and 2—consisting of the parents of the deceased infants—are for loss of consortium with their deceased children and therefore outside the scope of the MSP Act and any applicable Medicaid statute.

Category 1 and 5(1) claimants consist of Non-Recipients making claims as representatives of deceased infants. Only one state Medicaid agency indicated that a payment had been made for a claimant in these categories (\$340.00). Class counsel contend that this agency is in error. No query to Medicare was made for deceased infants in this category for the reasons stated above in footnote *. Two Non-Recipients in Category 5(1), however, returned query results that indicate they may be eligible for Medicare items or services. Based on declaration responses by claimants and a review of hospital intake forms for E-Ferol recipients, approximately five claimants in these categories may have received Medicare assistance, and approximately 20 claimants or deceased infants may have received Medicaid assistance. However, it is the Federal District Court's preliminary finding that any medical expenses incurred by the claimants in these Categories were incurred for conditions not related to the receipt of E-Ferol.

Category 2 and 5(2) claimants consist of Non-Recipients making claims as representatives of deceased infants. According to the information received by class counsel from state Medicaid agencies, no payments were made for any claimants in these categories. No query to Medicare was made for deceased infants in this Category for the reasons stated above in footnote *. CMS query results indicate that one Non-Recipient in Category 2 may be eligible for Medicare items or services. Based on declaration responses by claimants and a review of hospital intake forms for E-Ferol recipients, one claimant in these Categories may have received Medicare assistance, and approximately 11 claimants or deceased infants may have received Medicaid assistance. However, it is the Federal District Court's preliminary finding that any medical expenses incurred by the claimants in these Categories were incurred for conditions not related to the receipt of E-Ferol.

Category 3 and 5(3) claimants consist of E-Ferol recipients for whom E-Ferol was alleged to be a substantial contributing cause to brain dysfunction and/or cerebral palsy and one Non-Recipient making a claim as a representative of an E-Ferol recipient. These infants were evaluated based upon their functional disability and classified as either severe, moderate, or mild. Most, if not all, of these infants had co-morbidities neither caused nor alleged to have been caused by their receipt of E-Ferol but that contributed to their disabilities. Class counsel's investigation, based on the CMS query results submitted by liability insurance carriers, indicates that four E-Ferol recipients in this category are listed as being eligible for or having received medical treatment paid by Medicare. A total of 15 Medicaid recipients (including the four Medicare cases) in this Category may have received some government assistance related to injuries caused by E-Ferol. Five state agencies have either not responded or have failed to provide sufficient data to determine whether there is a potential claim for reimbursement. It is the position of Class Counsel that, although some

payments to E-Ferol recipients in this category may be for injuries caused by the receipt of E-Ferol, in most instances the medical expenses were incurred for conditions not related to the receipt of E-Ferol. Class Counsel further contends that all of these cases were known or should have been known in the exercise of reasonable care by Medicare or Medicaid agencies as a result of the litigation in *United States v. Hiland*, 909 F.2d 1114 (8th Cir. 1990). The Federal District Court is not making any preliminary finding with respect to class members in Category 3 and Category 5(3) regarding medical expenses incurred by these class members.

Category 4 and 5(4) claimants consist of E-Ferol recipients who have not suffered (or have not alleged that they have suffered) any permanent E-Ferol injury and were symptom-free upon being released from the hospital following their birth, and Non-Recipients making claims as representatives of deceased E-Ferol recipients who did not suffer (or who were not alleged to have suffered) any permanent E-Ferol injury and were symptom-free upon being released from the hospital following their birth. Eight E-ferol recipients in Category 4, plus one E-ferol recipient in Category 5(4) returned CMS query results that indicate they may be eligible for Medicare items or services, and twelve Non-Recipients in Category 4 also have query results indicating they may be eligible for Medicare items or services. Based on declaration responses by claimants and a review of hospital intake forms for E-Ferol recipients, approximately 35 claimants in these Categories may have received Medicare assistance, and approximately 94 claimants may have received Medicaid assistance. However, it is the Federal District Court's preliminary finding that any medical expenses incurred by the claimants in these Categories were incurred for conditions not related to the receipt of E-Ferol.

The funds distributed to the class members in this category are based on the alleged cost of future medical monitoring, or, in the case of deceased E-Ferol recipients in this Category, for damages due to tortious invasion of their bodies as infants, and not for the payment for any past, present, or future medical expense related to any injury from the receipt of E-Ferol. According to Class Counsel, the monetary awards payable to surviving Category 4 claimants are for medical monitoring alone and not for the payment for any past medical expense that, according to the medical evidence, could not be attributed to the effects of E-Ferol. Likewise, there will be no subsequent payment for future claims. The complications from the early receipt of E-Ferol are neither discussed in the medical literature nor can they be predicted based upon reasonable medical probability. Because no complication of E-Ferol can be proven by the required legal standard, there is no provision in the class action settlement for any future compensation. Class medical experts recommend that Category 4 class members obtain an initial baseline examination and radiographic study of the liver, followed by annual blood tests, in order to provide the earliest possible notice of any cirrhosis or carcinoma. Class members are not required to use their recovery for this purpose, however. Class counsel are also of the opinion that the medical monitoring suggested, but not required, of claimants in this category would not be covered by Medicare and/or Medicaid, and thus not subject to any reimbursement obligation by the MSP Act or any Medicaid third party recovery statute.

Preliminary Finding

On March 30, 2011, based on the record before the court, the Federal District Court issued the attached order (the "Order") that includes a preliminary finding that members of Categories 1, 5(1), 2, 5(2), 4, and 5(4) of the E-Ferol Class do not have any actual or potential reimbursement

obligations under the MSP Act and/or any other Medicare- and Medicaid-related federal and state laws and regulations. At this time, the court has made no preliminary finding regarding reimbursement obligations for E-Ferol class members in Categories 3 and 5(3).

Claims Covered by this Notice

For E-Ferol class members in Categories 1, 2, and 4 (and related Category 5 claimants), claims covered by this Notice are claims for expenses paid to (or on behalf of) such class members at any time. For class members in Categories 3 and 5(3), claims covered by this Notice are claims for expenses paid to (or on behalf of) such class members through January 20, 2011.

Notice of Hearing and Deadline to Assert Reimbursement Claims

This Notice is being given to the agencies listed in Appendix A to entitle them to protect their interests, if any, should they determine any medical expense subject to reimbursement and covered by this Notice has been paid for an E-Ferol class member. A hearing will be conducted on June 10, 2011 at 2:00 p.m. before the Honorable Sidney A. Fitzwater, Chief Judge, U.S. District Court for the Northern District of Texas, at the U.S. Courthouse, 1100 Commerce, Courtroom 1525, Dallas, Texas, to determine whether the preliminary finding as set out above shall become a final adjudication of reimbursement liabilities for class members in Categories 1, 5(1), 2, 5(2), 4, 5(4), and to further consider whether any reimbursement liabilities covered by this Notice exist for class members in Categories 3 and 5(3) and, if so, what additional procedures may be necessary to resolve them. ALL CLAIMS COVERED BY THIS NOTICE MUST BE FILED IN THE ABOVE-STYLED CAUSE NO LATER THAN May 31, 2011, with a copy of said claim served on lead class counsel, Art Brender, Law Office of Art Brender, 600 8th Ave., Fort Worth, Texas 76102, and lead defense counsel, Barry

Chasnoff, of Akin Gump Strauss Hauer & Feld, LLP, 300 Convent Street, Suite 1600, San Antonio, Texas 78205.

Effect of Failure to File Claim

The time given above for filing claims and the hearing constitute the agencies' sole opportunity to assert claims and present evidence, if any, to rebut the Federal District Court's preliminary findings with respect to the claimants in Categories 1, 2, and 4 (and related Category 5 claimants). In addition, this filing period and hearing constitute the agencies' sole opportunity to assert reimbursement claims against class members in Categories 3 and 5(3) for expenses through January 20, 2011, as well as to provide evidence in support of such claims.

To provide sufficient notice and to permit class action proceeds to be timely distributed, the court requires that, by the deadline stated above, any claim for reimbursement against E-Ferol class members must be filed with the Clerk of the U.S. District Court for the Northern District of Texas, Wichita Falls Division, 1000 Lamar St., Room 203, Wichita Falls, Texas 76301, in the above-styled cause, specifically identifying the member of the E-Ferol Class, the amount of the claim, the specific billing upon which the claim is based, and the evidence upon which the claim for reimbursement resulting from the receipt of E-Ferol is based.

Regarding Category 1, 5(1), 2, 5(2), 4, and 5(4) class members, a failure to file a claim that includes the information required by this Notice, failure to appear in this court at the scheduled hearing, or failure to submit evidence sufficient to rebut the preliminary determination described above will result in the court's preliminary determination's becoming final and further bar any claim for reimbursement arising from the receipt of E-Ferol with

respect to that E-Ferol class member. Any failure to file a claim covered by this Notice against any class member in any category, including any Category 3 or 5(3) class member, or, if filed, failure to provide adequate evidence, as required by this Notice, will result in a waiver of such claim by the state or federal agency for reimbursement from any E-Ferol class member and said agency will be enjoined from making a claim covered by this Notice against that E-Ferol class member or against class counsel, defendant, defense counsel, and participating insurer, or related parties, as those terms are defined in the Settlement Agreement and Release on file in this cause on account of that class member. All rulings by the court entered in accordance with these procedures will be binding on any potentially affected federal or state agency. E-Ferol class members, class counsel, defendants, defense counsel, and all participating insurers shall be entitled to rely on this court's findings with respect to any claimed reimbursement obligation of an E-Ferol class member as a defense to any action by any government agency to recoup any costs or expense related to E-Ferol on account of that E-Ferol class member.

Means to Protect Confidentiality of Disclosed Information

In order to protect the personal identification information of E-Ferol Class Members and recipients, the list of E-Ferol recipients and Non-Recipients, arranged according to categories set out above, together with the dates and locations of birth; dates of death, if applicable; dates of receipt of E-Ferol; Social Security number, if the person has one; relationship to E-Ferol recipient; the percentage of settlement proceeds allocated to the claim(s) made by or through each E-Ferol recipient (before any reduction for attorney's fees and litigation expenses); and information regarding whether a class member has been identified through CMS query results as a Medicare or

Medicaid recipient are included in a password-protected spreadsheet provided to each agency. Instructions for opening the spreadsheet will be provided.

Any party accessing information contained in such a spreadsheet is obligated to treat the information as confidential and to comply with applicable laws regarding the non-disclosure of such information.

Questions about this Notice

Any governmental entity or individual who has questions about this Notice or the E-Ferol class action may direct such questions to E-Ferol Class Counsel.

**DO NOT CONTACT THE COURT OR COURT CLERK
WITH QUESTIONS ABOUT THESE MATTERS**

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SIGNED March 30, 2011.



SIDNEY A. FITZWATER
CHIEF JUDGE

Appendix A

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APPENDIX B

Medical Conditions Caused by E-Ferol

E-Ferol was an altered form of vitamin E delivered intravenously (IV) and claimed by the distributor to be a "safe intravenous form of vitamin E" for use in preventing retrolental fibroplasia. Now known as the retinopathy of prematurity, this condition causes visual impairment and blindness in premature children. E-Ferol was administered almost exclusively to premature children to prevent visual impairment resulting from the oxygen therapy needed by pre-term neonates. Plaintiffs provided evidence that E-Ferol was dose-specific and, if given in a sufficient quantity relative to infant weight, could cause clinical deterioration in premature infants, including unexplained thrombocytopenia, hepatic and/or renal failure, hepatomegaly, splenomegaly, cholestatic jaundice, azotemia, respiratory distress, cardiopulmonary deterioration, ascites, and distinct findings on autopsy of progressive veno-occlusive hepatic disease. Because the receipt of E-Ferol was a unique experience in pharmaceutical history, the long-term effects, if any, of the receipt of the E-Ferol, whether an infant experienced some or no symptoms prior to his or her release from the hospital, are unknown. Class counsel introduced medical evidence that, in unrelated instances, early insult to the liver could possibly lead to latent cirrhosis or carcinoma. However, no living E-Ferol recipients in the E-Ferol class have reported these problems.

In the spring of 1984, the Center for Disease Control dispatched a team of epidemiologists, led by William Martone, M.D., to investigate the phenomenon being observed in hospitals throughout the country. This investigation resulted in the recall of E-Ferol on April 12, 1984. Dr. Martone published his findings in *Pediatrics*, Martone, et al., "Illnesses with Fatalities in Premature Infants: The Association with Vitamin E Preparation, E-Ferol," 78 *Pediatrics* 591 (1986).

Pathologist Kevin Bove, M.D., together with neonatologist Carl Bodenstein, M.D., and pediatric liver specialist William Balistreri, M.D., compared autopsy slides and medical records from several nurseries that administered E-Ferol to those in the same town (Cincinnati) that had not distributed E-Ferol and confirmed the constellation of symptoms that they designated as E-Ferol Syndrome. Bove, et al., "Vascular-Pathic Hepatotoxicity Associated with E-Ferol Syndrome in Low Birthweight Infants," 254 *JAMA* 2422 (1985). The corporations involved in formulating and distributing E-Ferol and their principles were convicted of numerous violations of the FDA Act. See *United States v. Hiland*, 909 F.2d 1114 (8th Cir. 1990).

Appendix C

Appendix C pertains to matters that are confidential and consequently, not being reproduced on the E-Ferol website.

Appendix D

Appendix D is the Settlement Agreement and Release which is already contained on the E-Ferol website and thus, it is not being reproduced here.