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IN THE UNITED STATES DIS
FOR THE NORTHERN DISTRI
WICHITA FALLS DIV

VICTORIA KLEIN and ASHLEY SWADLEY,	§	
	§	
Plaintiffs,	§	
	§	CA 7-03CV-102-R
VS.	§	
	§	
O'NEAL, INC., d/b/a O'NEAL, JONES & FELDMAN PHARMACEUTICALS, and CVS REVCO D.S., INC.;	§	
	§	
Defendants.	§	

DEFENDANTS' OPPOSITION TO PLAINTIFFS MOTION FOR CLASS CERTIFICATION

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INTRODUCTION

E-Ferol first become available in late 1983, and was never used after its recall in April of 1984. For the past twenty years, almost 150 lawsuits – all individual claims – have been filed on behalf of infants who were administered E-Ferol. All of these prior lawsuit were filed in the states in which the plaintiffs were treated, using the best claims available under those states' laws. All of these prior lawsuits presented distinctly individualized claims, attempting to prove that E-Ferol caused the particular injuries suffered by the plaintiff. Experts were hired, witnesses deposed and medical records were analyzed, all in support of plaintiffs' attempts to show that, based on the specific facts of their case, E-Ferol was the cause of some particular injury or injuries an infant suffered.

Now, twenty years later, plaintiffs shift gears and argue for the first time that these claims should proceed as a class action, because common issues purportedly outweigh the many individual issues involved in these cases. The past twenty years of litigation, involving almost 150 individual claims, refute this new tactic more strongly than any argument defendants might make. The dominant issue in every E-Ferol case is causation. E-Ferol was administered to premature infants, who were given different doses, for different amounts of time, at different stages of prematurity. Even when provided perfect treatment, premature infants suffer many medical problems. Twenty years ago, the mortality rate for premature infants, as well as the risk of serious complications, was dramatically higher than it is today. Sifting out whether E-Ferol cause a particular problem suffered by a premature infant is the quintessential individual issue that cannot be litigated on a class basis.

Plaintiffs' change in tactics does not reflect a recent insight that, after twenty years of individual litigation, this case is actually appropriate for class action treatment. Rather,

plaintiffs' counsel have seemingly filed all the individual cases they could find, including one just months ago in April 2003 in state court. Now, with the statute of limitations possibly running on any future claims, plaintiffs' counsel seeks class action status in an attempt to pursue the claims of those individuals who have not chosen to file individual claims over the past twenty years. This change of tactics, however, cannot overcome that fact that E-Ferol claims are and always will raise highly individualized issues of causation that are utterly inappropriate for a class action.

Perhaps recognizing that class treatment of a damages claim is unlikely to succeed, plaintiffs argue that two other forms of relief merit class treatment, albeit still under the aegis of the money damages class provision in Rule 23 (b)(3). First, plaintiffs claim that there may be E-Ferol recipients who were never told they had been administered E-Ferol, and therefore a class should be certified so that notice can be sent to all recipients of E-Ferol. The implication here is that the use of E-Ferol was some darkly guarded secret. Quite to the contrary, the unfortunate deaths of infants who received E-Ferol drew nationwide attention, and E-Ferol was the subject of extensive television and newspaper coverage at the national level, plus a widely publicized congressional inquiry. In addition, every doctor who prescribed E-Ferol was told of the recall and could have, if they deemed it appropriate, told the patients' parents about the use of E-Ferol. There is simply no evidence, nor any reason to believe, that E-Ferol recipients who might want to bring a claim are unaware of their potential claims, and the filing of 150 prior lawsuits is ample proof of this.

Plaintiffs' other claim is a request for money to pay for medical monitoring. Plaintiffs assert that E-Ferol may cause latent injuries such as cancer that do not appear until the infant that received E-Ferol reaches adulthood. There is, however, absolutely no scientific basis for this

claim. There has not been a single recorded case of E-Ferol causing such an injury. There is not a single journal article, textbook or scientific study stating that E-Ferol can cause such latent injuries. Plaintiffs base this entire claim on the theory of one person, their expert Dr. Brown, but the courts have never sustained such a claim based on the untested speculation of one doctor. Furthermore, defendants will show that, even if there was a medical basis for this claim, it would continue to present individual issues, not the kind of common issues that support class certification.

This litigation has run its course. Lawyers across the country have filed and vigorously pursued approximately 150 E-Ferol claims in eight different states. What is left, in all likelihood, are people who were not injured, or people who have no desire for litigation. Plaintiffs are seeking to use the class action to elevate this remnant into a legal claim. As the Fifth Circuit cautioned in *Castano v. The American Tobacco Co.*, 84 F.3d 734, 744 (5th Cir. 1996), "Class certification magnifies and strengthens the number of unmeritorious claims." This is precisely what plaintiffs seek here.

Some of the infants who received E-Ferol became ill, and some even died. If an infant's illnesses or death was caused by E-Ferol, it was a terrible tragedy, and has probably been the subject of a lawsuit. The severity of the tragedy, however, does not supply the necessary ingredients for a class action under Federal Rule 23, and there is no need entirely new round of litigation concerning this issue at this late date.

STATEMENT OF FACTS

A. A Brief History Of E-Ferol Use

Like most allegedly defective products, E-Ferol began with the best of intentions.[1] The primary ingredient in E-Ferol is vitamin E, which for many years before E-Ferol's development was given to premature infants for a variety of reasons, but particularly for the prevention of retinal problems. [Pediatrics Vol. 83 No. 2 February 1989] Prior to the introduction of E-Ferol, vitamin E for premature infants was only available in oral or intramuscular forms. There were problems, however, in administering vitamin E in this manner to premature infants. E-Ferol was the first intravenous form of vitamin E that could be administered to premature infants. *Id.*

E-Ferol was first introduced to the market in November 1983. In the months that followed, some infants who received E-Ferol developed a set of symptoms that became known as E-Ferol syndrome. Shortly thereafter, in April 1984, the manufacturer voluntarily recalled E-Ferol. *Id.*

This is neither the time nor place to debate whether E-Ferol was the cause of this syndrome, or whether the defendants are liable, if E-Ferol was the cause. That is a matter for trial. What is critical here is the fact that, in the short time it was in use, the vast majority of infants who received E-Ferol never manifested E-Ferol syndrome. An Editorial in the journal Pediatrics reported the experience as follows:

> The product was stocked in 150 hospitals according to an early survey; 62 of these hospitals never used E-Ferol and 62 reported "no problem" associated with its use. However, 35 hospitals reported side effects in a total of 81 cases. There were 38 deaths reported from 11 states and 43 other infants sustained serious effects. (Vol. 78 No. 3 September 3 1986)

The death of 38 premature infants is, of course, an enormous tragedy. The overwhelming majority of infants who received E-Ferol, however, never developed the syndrome. These infants

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[1] There have actually been several forms of E-Ferol. E-Ferol in this brief will always refer to the one that has been at issue in all the litigation, E-Ferol Aqueous Solution.

may have even received the intended benefit from the vitamin E. As another article in the Journal of the American Medical Association reported:

> In fact, most babies who received E-Ferol had little or no evidence to suggest a toxic reaction, and, in them, the E-Ferol may well have served it intended protective purpose. (JAMA, Nov. 1 1985 – Vol. 254, no. 17)

The class plaintiffs seek to have certified, therefore, will consist almost entirely of 19 to 20 year old individuals who never showed any signs of E-Ferol syndrome when they received E-Ferol, nor have they since manifested any E-Ferol related health problems since. This, in fact, is exactly the status of the two proposed class representatives, neither of whom claims to have suffered any specific health-related problem due to the ingestion of E-Ferol. [cite to their depositions]

B. <u>A Brief History Of E-Ferol Litigation</u>

E-Ferol cases have, for the past twenty years, been litigated as individual claims. Interestingly, on two prior occasions plaintiffs alleged the existence of a class in their complaint. [cite exhibit that has complaints] In one of those cases, a Texas state court action in which plaintiffs were represented by the Dent Law Firm, the same counsel appearing in this case, plaintiffs actually went so far as to file a Motion for Class Certification. [cite] In both of these prior instances, however, plaintiffs never pursued class certification, preferring instead to litigate the claims of their clients on an individual basis.

The litigation has been geographically widespread. FDA records indicate that E-Ferol was administered in at least 67 hospitals in 26 states and the District of Columbia. To date, E-Ferol claims have been made in eight of those states: Texas, Ohio, S. Carolina, Tennessee, Washington (state), Hawaii, Louisiana, and Oklahoma. [cite to exhibit]

The E-Ferol lawsuits have been fairly typical product liability cases. They have been filed in the states in which the plaintiffs were treated, and they allege various state law tort claims. The legal claims typically include negligence, product liability and breach of warranty claims. In Mr. Dent's Texas state court cases, plaintiffs also assert a DTPA cause of action. (See Affidavit of David Taylor)

Individual causation has always been ***the*** dominant issue in these cases. Regardless of what the evidence might show about E-Ferol in general, and regardless of what the defendants' did or did not do in marketing E-Ferol, the key question in each case has been whether E-Ferol injured that particular infant. Plaintiffs have claimed that E-Ferol caused a wide variety of injuries, including death, cerebral palsy, pulmonary deterioration, hepatomegaly, cholestatic jaundice, ascites, splenomegaly, renal failure, azotemia, thrombocytopenia, blindness, and learning disabilities. [cite] The central issue in most of these claims has been a battle of the experts on which injuries, if any, were caused by E-Ferol. [cite to Taylor affidavit, even if he speaks only of Texas]

C. CAUSATION IS A FUNDAMENTALLY INDIVIDUAL ISSUE

E-Ferol was administered to premature infants. As defendants' expert Dr. Kramer explains, now, and even more so in 1983-84 when E-Ferol was administered, premature infants are fragile creatures who suffer many problems and have a high mortality rate. Determining the cause of any injury in a premature infant is a difficult matter that requires an intensively individual examination of all the facts and circumstances concerning that infant's medical history.

[short summary or quotes from Kramer's opinion]

Dr. Kramer's comments are borne out by the technical literature on E-Ferol. One study, for example, noted the wide variance in E-Ferol dosage and found that "the development of the syndrome was related to the total dose, duration of therapy, and body weight." JAMA, Nov. 1, 1985-Vol 254, NO. 17 at 2424. Another study noted that "increasing total days of E-Ferol and increasing birth weight were found to be associated with a decreasing risk for illness" and "exposed infants were at increased risk for illness only during the first one to 14 days of exposure." Pediatrics Vol. 83 NO. 2 February 1989.

Without question, however, the most powerful evidence that causation is an individual issue is the way in which plaintiffs have presented their claims in the past twenty years of E-Ferol litigation. Plaintiffs have consistently argued that the complex and particular facts of their unique situations demonstrated that E-Ferol caused their alleged injuries. A good and very typical example of this is a Pathologic Summary submitted in one E-Ferol lawsuit by plaintiffs' current expert, Dr. Robert Brown, in which Dr. Brown concluded that a particular infant suffered E-Ferol syndrome based upon...because of the following facts:

This analysis, moreover, was just for the question of whether the infant suffered E-Ferol syndrome. Dr. Brown also provided a separate factual analysis... opined on the possibility of E-Ferol causing certain other injuries (See App):

Dr. Brown employed yet another complex individual analysis when opining whether a plaintiff was at risk of suffering a future injury because of E-Ferol. Contrary to the current case, where Dr. Brown argues that all female E-Ferol recipients suffer the potential for reproductive and gynecological problems, he previously opined that an infant was at risk for these future problems based on the particular circumstances.... (See App)

As noted earlier, the complexity of the causation question in prior cases is amplified by the fact that plaintiffs have attempted to attribute a wide spectrum of injuries to the ingestion of E-Ferol. Each different alleged injury requires a different analysis of the medical history for that infant. A good example of this is another(?) report issued by Dr. Brown (Manuela Coronada). After first opining why, based on many individual factors, this infant suffered E-Ferol syndrome, Dr. Brown proceeds to opine that E-Ferol caused this infant's blindness: (see app) Note that for the blindness issue, Dr. Brown was able to conclude only that it is "highly probable" that E-Ferol "***contributed***" to the blindness. Thus, even after this detailed analysis of that plaintiff's specific facts, Dr. Brown acknowledged that there were other causes of the blindness. The evaluation of causation issues in these personal injury claims involves, as these reports by Plaintiffs' expert powerfully illustrate, a detailed analysis of each separate alleged injury, based on the unique facts and circumstances of each case.

Only by closely scrutinizing all the evidence of what happened to a particular infant can a medical expert begin to formulate a reasoned, scientific judgment about whether E-Ferol was the likely cause of any injury. The difficulty in making this determination, moreover, is exacerbated by the nearly unlimited variety of conditions plaintiffs have attempted to attribute to E-Ferol, including death, cerebral palsy, pulmonary deterioration, hepatomegaly, cholestatic jaundice, ascites, splenomegaly, renal failure, azotemia, thrombocytopenia, blindness, and learning disabilities. Each of these conditions requires a different medical analysis to see if there is any link to the administration of E-Ferol, especially in light of the fact that premature infants in 1983-1984 faced such high risk for developing these types of conditions regardless of their care or treatment or receipt of E-Ferol.

If a class were to be certified in this action, medical experts would have to conduct this kind of intensive, individual inquiry for each of the allegedly 1,000 class members, and the experts would have to be deposed on their opinions in each of these cases. The Court would then would have to conduct trials for each of those 1,000 cases to permit the jury to determine whether E-Ferol injured each infant, and if so, what injury or injuries it caused, and finally, what compensation might be due.

D. <u>The Alleged Lack Of Notice To E-Ferol Recipients</u>

Plaintiffs assert that some families may not know that E-Ferol was administered to their child as an infant. There is, as a threshold matter, essentially no evidence supporting this assertion. The sole cited source is an appellate court decision relating to one hospital, in Texas, in which the trial court stated that it was concerned that "some child" may not know they received E-Ferol. *In re Fort Worth Children's Hospital*, 100 S.W.2d 582 (Tex.App. 2002). In addition to this complete lack of supporting evidence, the Court should have the benefit of some additional facts on this issue.

The entire E-Ferol matter was the subject of enormous publicity. There were numerous television stories as well as articles in newspapers across the country, including the New York Times and the Wall Street Journal. [cite] It was also the subject of a congressional hearing, with all the publicity that follows that kind of proceeding. [cite]

> More significantly, plaintiffs' own motion shows that the FDA sent a letter to all doctors advising them of the E-Ferol situation. (Brown Affidavit Ex. F) Thus, ***every potential class member's doctor knew about the problems associated with E-Ferol.*** There is no reason to assume that these doctors failed to tell their patients (actually, their patients' parents) everything they should have told them about E-Ferol. Furthermore, to the extent some doctors did not tell their patients they had been administered E-Ferol, it was likely they did this because, in their medical judgment, there was no need for such a disclosure. (See App ____)

Unless there has been a massive conspiracy of silence among the nation's pediatricians, there is every reason to assume that patients who received E-Ferol were told exactly what their treating physicians thought they should be told. Plaintiffs, however, are not satisfied with this, not because there is any evidence these physicians did not exercise proper medial judgment, but undoubtedly because notice will create the potential for continued litigation.

Finally, there is no allegation, nor could there be, that the defendants in this action, the manufacturers and marketers of E-Ferol, failed to make some disclosure to the recipients of E-Ferol. Plaintiffs in previous E-Ferol litigation, represented by the same counsel representing plaintiffs in this action, submitted the opinion of Edward Feldman, Ph.D., an expert in health and drug safety issues, who opined that the defendants in this action fulfilled their duty of disclosure:

> A drug manufacturer can identify (either as a result of its records or direct shipments or through the records of intermediate distributors, such as wholesale suppliers) the hospitals, clinics, pharmacies, or other purchasers authorized to obtain prescription drugs, to which its drug has been distributed. However, the manufacturer has no way of readily identifying individual patients to whom the drug has been given.
>
> ***In the case of E-Ferol distribution, the manufacturer***, the FDA, and the CDC, all ***did widely publicize to hospital administrators, hospital pharmacists, and pediatricians the facts that [there were problems alleged in connection with E-Ferol use.]***

[cite to exhibit; emphasis added]

E. Medical Monitoring

Plaintiffs seek, as one aspect of their damages, amounts to pay for individual Plaintiffs and class members' medical monitoring, purportedly to monitor E-Ferol recipients for any latent effects E-Ferol might cause. Defendants will show in the Argument section that, even if there was a scientific basis for this claim, it would not support the certification of a class because it raises individual issues that predominate over any common issues.

That said, defendants can demonstrate that there is no scientific basis for the proposed medical monitoring. Plaintiffs rely on the affidavit of their expert, Dr. Robert Brown, as the sole support for the medical monitoring claim. Defendants have submitted the Affidavits of Dr. Robert Kramer, Dr. Thomas Kurt and Dr. Jack Snyder, each of which show the overwhelming flaws in Dr. Brown's opinions.

Defendants can, however, show the court the inescapable flaw in Dr. Brown's opinions even without the assistance of experts. It comes down to this: Dr. Brown does not and cannot cite a single piece of medical literature stating that E-Ferol has the potential to cause latent injuries. Indeed, there has not been a single recorded case of an E-Ferol recipient actually experiencing the latent injuries suggested by Dr. Brown. While there was much literature about whether E-Ferol caused the injuries to infants at the time it was administered, there is not a single published study concerning E-Ferol's potential to cause latent injuries such as those suggested by Dr. Brown.

Dr. Brown is, so far as defendants can tell, the sole doctor to conclude that E-Ferol has the potential to cause latent injuries that require medical monitoring. Whatever one may make of Dr. Brown's theories, therefore, they cannot under any standard be considered established science, and those courts that accept medical monitoring claims all required established, proven science to back up such a claim.

ARGUMENT

> The skeptical attitude towards mass tort class actions dates back to 1966 revision of Rule 23, in which..... not only of damages but of liability and defenses of liability, would be present, affecting the individuals in different ways. In these circumstances an action conducted nominally as a class action would degenerate in practice into multiple lawsuits separately tried.

Since that time, courts have denied certification in all but a small handful of tort cases,

including numerous denials of class certification in product liability cases involving drugs. As the Fifth Circuit stated in its seminal decision on this point:

> It is no surprise the, that historically, certification of mass tort litigation classes has been disfavored.

Castano v. The American Tobacco Co., 84 F.3d 734, 745 (5th Cir. 1996);

As disfavored as mass tort class actions in general, the case before this Court is even less appropriate for class certification than the typical mass tort case. Plaintiffs generally seek class certification at the beginning of product liability dispute, arguing that a class action is the only feasible way to efficiently litigate an issue that will involve large numbers of claims. Here, the plaintiffs' lawyers who have pursued E-Ferol claims for the past twenty years, in eight different states, and they seem to have done just fine litigating this issue without the "benefit" of a class action.

Plaintiffs attempt to sidestep this massive and unfavorable body of law concerning mass tort class actions by relying heavily on the Fifth Circuit's decision in *Jenkins v. Raymark Industries, Inc.*, 782 F.2d 468 (5th Cir. 1986). In that case, however, the district court was faced with hundreds pending asbestos cases that were creating a crisis in the district court's docket. In response to this, the trial court certified a limited, single state class on a few specified issues that were common to all of the pending cases, thereby saving both the court and the litigants an enormous amount of time.

As every court since has held, *Jenkins* was a unique response to an unprecedented problem. *Castano*, 84 F.3d at 747 ("Not every mass tort is asbestos, and not every mass tort will result in the same judicial crisis"); *In the Matter of Rhone-Poulenc Rorer*, 51 F.3d at 1303 ("The number of asbestos cases was so great a to exert a well-nigh irresistible pressure to bend the normal rules"). Plaintiffs also ignore a later opinion in *Jenkins* in which the trial court attempted

to develop a plan under which there would be class-wide trial for both causation and damage. The Fifth Circuit reversed that trial plan because causation and damage are individual issues. *In re Fibreboard Corp.*, 893 F.2d 706, 711 (5th Cir. 1990).

The specific problem addressed in Jenkins is clearly not present here, as plaintiffs seek a class only ***after*** they have finished litigating approximately 150 individual claims. Indeed, the reliance on *Jenkins* is rather ironic, because in contrast to that case, plaintiffs here seek class certification here to extend litigation that would otherwise be approaching its conclusion, not to bring efficiency to a situation where multiple cases await a resolution.

While there is, therefore, no *per se* rule against class certification in mass tort cases, the situations where classes are appropriate are few and far between. Defendants will show that plaintiffs have not made the kind of showing necessary to certify such a class.

A. PLAINTIFFS CARRY THE BURDEN ON ALL CLASS CERTIFICATION ISSUES.

Plaintiffs, as the parties seeking certification, bear the burden of establishing that the requisite elements of Rule 23(a) and (b) have been satisfied. *See Castano v. American Tobacco Co.*, 84 F.3d 734, 740 (5th Cir. 1996). While Plaintiffs do not have to prove the merits of the class claim or even establish likelihood that they will ultimately prevail, it is necessary that Plaintiffs make a sufficient exploration of their causes of action so that the Court can determine if the prerequisites of class certification have been satisfied. *See Gyarmathy & Assocs., Inc. v. TIG Insurance Co.*, 2003 WL21339279 at *1 (ND Tex.)(citation omitted). The Fifth Circuit has directed district courts to look beyond the pleadings to determine whether Rule 23 requirements have been met. This is necessary because a Court must understand the claims, defenses, relevant facts, and applicable substantive of law in order to make a meaningful determination of the certification issues. *Id.* (citing *Castano,* 83 F.3d at 744). Furthermore, surrounding the confines

of the Court's discretion to certify a class, is the necessity for the Court to vigorously analyze whether the requisite elements of Rule 23 have been satisfied. *Id.*

Plaintiffs seek a class pursuant to Rule 23(b)(3). This requires plaintiffs to prove the four elements of Rule 23(a) -- numerosity, commonality, typicality and adequacy of representation, as well as the requirements of Rule 23(b)(3) – predominance and superiority. The primary problem with the class sought by plaintiffs lies in the (b)(3) requirements of predominance of common issues and superiority. Defendants will, however, briefly point out that plaintiffs have also failed to meet some of the requirements of Rule 23(a).

B. A THRESHOLD PROBLEM WITH THE CLASS DEFINITION

Plaintiffs seek certification of a class that includes, in addition to the infants who were administered E-Ferol, "parents, spouses, children, guardians, and legal representatives of such persons with direct or derivative claims." There is no basis for including these "secondary" individuals in the class. To begin with, the Amended Complaint does not indicate what claims these individuals might have. The Complaint alleges injury caused by the administration of E-Ferol; there is no indication of what these secondary individuals might claim. Absent such allegations, there is therefore no basis for evaluating whether a class can properly be certified. Added to this is the fact that plaintiffs do not mention these secondary individuals in their Motion for Class Certification. Plaintiffs have, therefore, defaulted on meet their burden to show that a class that includes these secondary claimants meets the requirements of Rule 23.

C. PLAINTIFFS HAVE NOT MET CERTAIN OF THE REQUIREMENTS OF RULE 23(a).

Rule 23(a) requires the plaintiff to demonstrate numerosity, typicality, commonality and adequacy of representation. Plaintiffs cannot meet two of these, typicality and adequacy of representation.

There is a fundamental problem inherent in plaintiffs' class. It includes those who will claim actual past injuries due to E-Ferol along with those who seek only damages sufficient to pay for future medical monitoring. In addition, the class potentially includes people claiming a wide variety of injuries due to E-Ferol, running the gamut from wrongful death to learning disability claims. The named plaintiffs, although alleging that they were "injured" by their E-Ferol, have not identified any actual injuries that they suffered due to E-Ferol. [cite their depositions?] Some class members, therefore, would be fully compensated solely by securing funds for future medical monitoring, while others would be pursuing serious claims based on the past injuries. Among those past injury claimants, some would be attempting to prove that E-Ferol caused liver damage, while others would try to prove it caused retinal problems. Each constituency would be looking at a very different kind of case.

Typicality "focuses on the similarity between the named plaintiffs' legal and remedial theories and the theories of those whom they purport to represent.... Class representatives must have 'the same interest and suffer the same injury' as all other members of the class...." *Kase v. Salomon Smith Barney, Inc.*, 2003 WL 22300013 (S.D.Tex. 2003). Adequacy requires that the class representative "fairly and adequately protect the interest of the class." *Fed.R.Civ.P. 23(a)(4)*. These two requirements are frequently addressed in combination because they raise similar issues.

The claims of the two plaintiffs, since they claim no specific past injury due to E-Ferol, may be typical of those who seek only medical monitoring, but they are not typical of, and will potentially conflict with, the claims of those who seek recovery for past injuries. For example, how can a plaintiff seeking only medical monitoring represent a class member who wants to prove wrongful death? As the court held in *Wall v. Sunoco, Inc.*, 211 F.R.D. 272, 280 (M.D.Pa.

2002):

> Several cases have addressed the conflict between representatives who are already injured and those who have only been exposed to a hazardous substance and seek medical monitoring although they currently suffer no injury. The cases find that a conflict of interest exists between the presently injured and the exposure-only plaintiffs.

Accord, Valentino v. Carter-Wallace, Inc., 97 F.3d 1227, 1234 (9th Cir. 1996) (named plaintiff not typical or adequate because she didn't suffer some of the injuries other allege); *In re Paxil Litigation*, 212 F.R.D. 539, 550 (C.D.Cal. 2003) (different injuries precludes typicality or injury).

In addition, the fact that plaintiffs seek a multi-state class defeats typicality and adequacy of representation. This factor will be discussed more fully in the commonality section, but we briefly note that plaintiffs' claims are not typical of a claim or claims of other putative class members under other states' laws. *See Stirman v. Exxon Corp.*, 280 F.3d 554, 562 (5th Cir. 2002) (finding differences among state laws made class representative's claims atypical); *In re Ford Motor Co. Bronco II Liab. Litig.*, 177 F.R.D. 369, 367 (E.D.La. 1997) (holding 120 named plaintiffs not typical of the class in part because the laws of fifty-one jurisdictions were implicated in the case but plaintiffs came from only nine of them).

D. PLAINTIFFS HAVE FAILED TO MEET THE REQUIREMENTS OF RULE 23(b)(3).

Under Rule 23(b)(3), plaintiffs must demonstrate both that common issues predominate over individual issues, and that a class action is the superior to other means for the fair and efficient adjudication of this litigation. Plaintiffs have failed to meet their burden under either of these requirements.

1. COMMON ISSUES DO NOT PREDOMINATE

Plaintiffs assert a class action is needed to provide damages for past injuries, funds to pay for future medical monitoring, and to give notice to class members that they were given E-Ferol.

Defendants will examine each of these claims and show that they do not, either singly or as a group, support the certification of a class.

a. The Claim For Past Damages

There are multiple and overwhelming reasons why this claim cannot be litigated as a class action. It is precisely this type of damage claim that has led courts to almost universally reject certification of mass tort class actions.

i. Plaintiffs Seek A Multi-State Class, A Concept That Has Been Rejected By Virtually Every Court.

One of the issue most troubling to courts that have been asked to certify classes in mass tort cases has been the need to apply the law of many states in one case. Nearly very court to address the question has held that the need to apply the law of multiple states, by itself, defeats predominance unless the plaintiff can somehow show a way to try the case despite this fact.

The Fifth Circuit has left no room for equivocation on this issue. In *Castano*, 84 F.3d 734, 741 (5th Cir. 1996), the court held that "In a multi-state class action, variations in state law may swamp any common issues and defeat predominance." Therefore, "a district court ***must*** consider how variations in state law affect predominance and superiority." *Id.* Finally, and most critically, the plaintiff bears the burden and "a court cannot rely on assurances of counsel that any problems with predominance or superiority can be overcome.

The only way a plaintiff can hope to overcome this problem is to carefully determine which states laws will apply and show how the case can be tried:

> The able opinion in *School Asbestos* demonstrates what is required from a district court when variations in state law exist. There, the court affirmed class certification, despite variations in state law, because: "To meet the problem of diversity in applicable state law, class plaintiffs have undertaken an extensive analysis of the variances in products liability among the jurisdictions."

Id.

Here, plaintiffs have not even addressed this issue, much less shown how they can overcome the problems involved in a multi-state class. Numerous courts have rejected tort class actions solely or primarily for this reason. (See App ___ for Cases....) Although plaintiffs' failure to meet their burden is alone dispositive of this issue, it is clear that this is a burden defendants can never meet. Records show that E-Ferol was used in at least 96 hospitals in at least 26 states plus the District of Columbia. (see p. __ above) Every court to address this issue has held that in mass tort cases, choice of law rules inevitably require that each class members' claim will be governed by the law of state where they were injured. *E.g.*, *In re Propulsid Products Liability Litigation*, 208 F.R.D. 133, 142 (E.D.La. 2002) (state where drug ingested); *Ford Motor Co. Ignition Switch Products Liability*, 174 F.R.D. 332, 348 (D.N.J. 1997) ("Defendants maintain that a choice of law analysis leads to the conclusion that the laws of each plaintiff's home state must be applied because those states have interests that outweigh the interests of Michigan. The court agrees").[2] ***Plaintiffs' class, therefore, would require the court to apply the law of at least 27 jurisdictions.***

The problems involved in applying the laws of multiple states would be particularly severe in this case because of the substantial number of legal issues involved. Plaintiffs assert claims for Negligence, Breach of Express Warranties, Breach of Implied Warranty, Misrepresentation, Product Liability, punitive damages and medical monitoring. Defendants assert many defenses, including the state of limitations. Each of these claims would have to be litigated under the law of the 27 different jurisdictions, and courts have held that the law of even a simple negligence claim varies too much from state to state permit a multi-state class. *E.g.*, *Castano*, 84 F.3d at 743 ("Products liability law also differs among states"); *In the Matter of*

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[2] [If you want, Brad: Appendix __ provides a choice of law analysis showing that under the

Rhone-Poulenc Rorer, 51 F.3d 1293, 1300 (law of negligence varies).

The irony of this is that, up until now, choice of law has not been a problem because plaintiffs have filed their individual E-Ferol claims in the appropriate states. Now, however, plaintiffs seek to harness the class action device, which is designed to foster efficiency, in a way that will disrupt what has been an efficient judicial process.

ii. Plaintiffs Have Not Shown How Causation Can Be Proven On A Class-Wide Basis.

Plaintiffs claim predominance based on the following:

> The claims ... are all based upon the same actions by the Defendants in failing to obtain proper approval and testing of the drug before marketing and misrepresenting the fact it had or did not need the FDA approval and that it was safe and effective when no testing whatsoever had been undertaken to make that determination. (Plts. Br. at 9)

Plaintiffs do not and cannot claim that causation is a common issue. Furthermore, defendants' expert Dr. Kramer definitively shows that causation is an issue that requires a careful, case-by-case analysis. (see pages ___ above) Plaintiffs are therefore arguing that the common issue of whether defendants improperly marketed the drug will predominate over individual issues of causation, an argument that defies common sense. Even if one assumes the "improper marketing" issue is common to the class, that will not prevent the case from devolving into 1,000 individual trials on whether E-Ferol caused injury.

What plaintiffs appear to be proposing is that the court certify the class to try the question of whether defendants improperly marketed E-Ferol, leaving the issue of whether E-Ferol injured any particular class member to some undefined individual proceeding. This would rid the court of a mouse while leaving the elephant. The questions of whether E-Ferol caused a particular injury, and if so, what is the fair compensation for that injury, require most of the time and

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facts of this case the law of state where E-Ferol was administered will control.]

resources of an E-Ferol claim. As shown in the Statement of Facts, each such claim required extensive experts reports and expert discovery, in addition to other discovery, all directed towards this issue.

To satisfy the predominance requirement, plaintiffs must show how these individual causation claims could be tried in the context of a class action. *Castano*, 84 F.3d at 743 ("The district court's second error was that it failed to consider how the plaintiffs' addition claim would be tried, individually or on a class basis"). In *O'Sullivan v. Countrywide Home Loans, Inc.*, 319 F.3d 732, 744 (5th Cir. 2003), the Fifth Circuit held that even a complex damage calculation precluded finding predominance. Furthermore, nearly all the courts to address this question have found that causation in a tort claim is an individual issue that precludes predominance. *E.g. Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601, 611 (W.D.Wash. 2001) ("plaintiff is pursuing a negligence claim, which requires an individualized examination of causation); *In re Phenylpropanolamine (PPA) Products Liability Litig.*, 208 F.R.D. 625) ("whether an individual suffered in injury ...necessarily dissolves into a myriad of individualized causation inquiries"); *In re Paxil Litig.*, 212 F.R.D. 539, 545-46 (C.D.Cal. 2003) ("relevant question, therefore, is not ... generic causation issue, but whether it *did* cause harm and to whom").

Plaintiffs have consequently failed to meet their burden on this issue.

b. <u>The Medical Monitoring Claim</u>

Plaintiffs contend that every individual who ingested E-Ferol runs a risk of developing several serious latent injuries, and that each putative class member should therefore receive funds sufficient to pay for various medical tests to monitor for these latent injuries.[3] There is no separate claim for lifetime of medical monitoring; rather, it is pled is another element of the

[3] The Amended Complaint speaks somewhat vaguely of the creation of a fund for these

damages sought under plaintiffs' tort claims.

Significantly, and unlike most medical monitoring claims, plaintiffs do not seek the certification of a separate medical monitoring class. Implicit in plaintiffs' Motion, however, is the suggestion that if the claim for past damages does not support a class, the medical monitoring claim should. Therefore, although it is really an inseparable part of plaintiffs' damage claims, defendants will show that, even standing by itself, the medical monitoring claim would not support a class.

i. Plaintiffs Seek A Multi-State Class

As pointed out above, the courts have almost unanimously rejected multi-state classes, and they cannot even consider such classes without plaintiffs first providing a careful analysis of the law of the applicable states, and a plan for how the case can be tried in light of that problem. The medical monitoring claim does not avoid this problem; in fact, it exacerbates it by adding yet another issue to already overloaded the multi-state bin.

Although the court should deny the class based solely on plaintiffs' failure to meet their burden on this score, we note that several courts have looked at this issue and found that the law of medical monitoring varies considerably from state to state, and thus class certification is not appropriate. *E.g.*, *Duncan*, 203 F.R.D. at 607 ("there is no uniformity regarding the elements of the claim"); *In re Telectronics Pacing Systems, Inc.*, 168 F.R.D. 203, 214 (S.D.Ohio 1996) (surveys the various states and show variance); *Dahmer*, 183 F.R.D. at 532 ("Medical monitoring is not a uniform concept among the states"). Thus, medical monitoring adds one more issue that makes plaintiffs' multi-state class impossible to certify.

Indeed, this issue would be particularly difficult in this case because both plaintiffs were

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purposes. Whatever this might mean, the claim is clearly one for money damages.

treated in Texas and thus Texas law would likely control their claims. There is, however, no appellate authority on the question of whether a claim for medical monitoring exists in Texas or what its elements might be.[4] Plaintiffs are therefore seeking a medical monitoring claim when they themselves may not have such a claim.

ii. <u>The Medical Monitoring Claim Presents Individual Issues.</u>

If one assumes that there is a need for medical monitoring as alleged by plaintiffs, the actual program would necessarily to vary from individual to individual

(See Snyder....) The opinion of plaintiffs' expert, Dr. Brown, is actually consistent with this. Dr. Brown's program suggests certain baseline tests for each class member, ***followed by other tests based on the results of those initial baseline tests suggest.*** Thus, for example, certain baseline tests of the female reproductive organs are suggested, followed by "as indicated and if necessary, hysterosalpingography." (Brown Aff. p. 3). Similarly, for the males, there should be an initial sperm count that "may require additional studies such as sperm penetration assays." (Brown Aff. p. 4) For the liver, first the baseline tests, and then "percutaneous liver biopsy, if suggested by the above studies." (Brown Aff. p. 5) Finally, baseline kidney tests followed by a referral "to a nephrologist, if any of the above parameters are abnormal, for additional studies." (Brown Aff. p. 6) Thus, in each case, Dr. Brown is actually recommending an individual program that begins with certain common tests, but soon varies greatly depending upon the individual's condition.

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[4] In *Crofton v. Amoco Chemical Co.*, 2003 WL 21297588 (Tex.App.Hous. 1st Dist. 2003), the appellate court affirmed a grant of summary judgment based on a lack of evidence against, among others claims, a medical monitoring. The opinion never addresses the question of whether such a claim exists under Texas law, and if so, what its elements are. The court affirmed the trial court's finding that there was no "evidence regarding any specific medical monitoring protocol that any special [appellant] should undergo or any evidence that any such medical monitoring protocol is medically necessary for any specific [appellant]."

Plaintiffs, therefore, have not shown that they can prove their medical monitoring claim on a class-wide basis. To the contrary, their own expert has shown that medical monitoring is an individual issue. If plaintiffs are seeking a lump sum, up front, payment for this, it would involve individual proceedings for each class member to determine what monitoring was appropriate, and how much defendants should pay. If, on the other hand, plaintiffs seek payment as these procedures are performed, this would embroil in the monitoring of 1,000 individuals for the rest of their lives in order to determine what procedures defendants should pay for. Several courts have denied certification of medical monitoring claims for precisely this reason. (See App ____)

iii. Even If The Medical Monitoring Claim Presented A Common Issue, The Class Members' Claims Would Present Overwhelmingly Individual Issues.

If one assumes (contrary to what has just been shown) that the medical monitoring relief presents a common issue, the individual issues presented by the damage claims for past injuries would still dominate this litigation. Since Plaintiffs do not seek a separate medical monitoring class, this court would still be called upon to litigate the damage claims of over 1,000 individuals, which would present overwhelming individual issues.

iv. There Is No Credible Basis For The Medical Monitoring Claim.

Plaintiffs' medical monitoring claim is based on the affidavit of one expert, Dr. Robert Brown. While class certification does not call for a determination on the merits:

> A district court must ensure that the basis of the expert opinion is not so flawed that it would be inadmissible as a matter of law.

In re Visa Check/Mastermoney Antitrust Litigation, 280 F.3d 124, 134 (2d Cir. 2001).

> Whether Dr Brown's affidavit could support a medical monitoring claim depends on what the legal standard for such a claim is. This, of course, highlights the problem in certifying a class for this claim because the legal standard varies from jurisdiction to jurisdiction. That said, any expert opinion must meet a

> minimum threshold of reliability, *Moore v. Ashland Chemicals, Inc.*, 151 F.3d 269, 277 (5th Cir. 1998), and Dr. Brown's opinion does not meet the most minimal requirement. Plaintiffs three experts, Drs. Snyder, Kramer and Kurt point out in detail the multiple flaws in Dr. Brown's opinion. However, the simplest and most dispositive flaw is that Brown's theory is quite simply, untested.

Dr. Brown's claim is his opinion and his opinion alone. Whatever the merits of this opinion might be, it cannot support a medical monitoring claim. As one federal judge held in refusing to certify a medical monitoring class in a case involving a drug:

> Neither the FDA, nor any medical organization or institution, nor anyone else for that matter, except the plaintiff's expert, has recommended or suggested that a program of medical monitoring or a group study of all former Propulsid users be undertaken. This raises the issue of the role of the courts in such an instance. Stated succinctly, the question is whether the courts should lead the scientific community in an area of medical science.
>
> [I]n the present case there is an absence of recommendations from the medical community regarding the need for a medical monitoring program or a clinical study of the effects of Propulsid on former users. In such a situation the courts should not attempt to fill the void. "The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science, it does not lead it."

In re Propulsid Products Liability Litigation, 208 F.R.D. 133, 147 (E.D.La. 2002).

c. <u>The "Need" For Notice</u>

Plaintiffs contend that many individuals may not know they received E-Ferol, and therefore one function of certifying a class would be to ensure they all learn of this fact. Putting aside the complete lack of factual support for the assertion (see pages __ above), plaintiffs have not cited, and defendants are unaware of, any cases in which a class has been certified so that individuals could receive notice. Notice is sent under Rule 23 to inform the class members that a class has been certified. Now, plaintiffs apparently assert that a class should be certified so that notice can be sent. There is neither legal authority nor logic supporting such a position.

The notice issue is no doubt an attempt to present a "sympathetic" situation in the hopes that the Court will certify a class where nothing else justifies that certification. As discussed in

heavily against their attempt to show that a class action at this late date would be "manageable" and "superior" to continued individual litigation.[6]

CONCLUSION

WHEREFORE, Defendants ask that the Court deny Plaintiffs' motion for class certification, and for such other relief to which they may be entitled.

Respectfully submitted,

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[6] Courts also hold that the need to apply the law of multiple states can affect a finding of manageability. *E.g.*, *Castano*, 84 F.3d at 743 ("The Court also failed to perform its duty to determine whether the class action would be manageable in light of state law variations"). Since that matter has been thoroughly discussed in the predominance section, however, we will not repeat it here.

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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 7-03CV-102-R
O'NEAL, INC., d/b/a O'NEAL, JONES & FELDMAN PHARMACEUTICALS, CVS REVCO D.S., INC.; and RETRAC, INC.,	§	
Defendants.	§	

DEFENDANTS' APPENDIX IN SUPPORT OF DEFENDANTS' OPPOSITION TO MOTION FOR CLASS CERTIFICATION

Respectfully submitted,

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