UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "N" (5)

THIS DOCUMENT RELATES TO
Case #2:16-cv-17731
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MOTION TO CERTIFY CLASS

Now into court through undersigned counsel come plaintiffs, Sheila Matthews, Debra Chetta and Emily Barre who hereby move this honorable court to certify a class as set forth in the memo in support attached hereto and made a part hereof as if copies herein in extenso.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the above and foregoing pleading has been sent to counsel of record for all parties by delivery of same by the ECF system this 25th day of April, 2017.

/s/Val Patrick Exnicios
VAL PATRICK EXNICIOS

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

SHEILA MATTHEWS, DEBRA CHETTA, and EMILY BARRE, Individually and on behalf of all others similarly situated	*	**CLASS ACTION COMPLAINT**
Plaintiffs	*	**MDL NO. 2740**
versus	*	
SANOFI S.A., AVENTIS PHARMA S.A., SANOFI US SERVICES INC., f/k/a/ SANOFI-AVENTIS U.S. INC. SANOFI-AVENTIS U.S. LLC	*	**JUDGE KURT D. ENGELHARDT**
	*	**MAG. MICHAEL NORTH**
Defendants	*	

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MEMORANDUM IN SUPPPORT OF MOTION TO CERTIFY CLASS

NOW INTO COURT, through the undersigned counsel, come Putative Class Plaintiffs, **Sheila Matthews, Debra Chetta and Emily Barre** ("Plaintiffs" or "Putative Class Representatives"), individually and on behalf of all others similarly situated, who file this Memorandum in Support of the Motion to Certify Class in compliance with LR 23.1, to wit:

MAY IT PLEASE THE COURT:

Class certification is proper and should be granted in this case. At an early practicable time after a person sues or is sued as a class representative, the court must determine by order whether to certify the action as a class action. F.R.C.P. 23(c)(1)(A).

The requirements set forth in Rule 23 of the Federal Rules of Civil Procedure are met. This case involves common issues of fact and law. The claims of the named class members and

the claims of the persons to be named as class representatives are typical of the claims of members of the putative class. The claims of the members of the putative class are so numerous as to make mass joinder an ineffective tool.

Moreover, common issues predominate over any individual issues that may exist and certification is the superior procedural device to handle these cases. Class certification would result in a definable class boundaries and in a single liability trial on the predominant issues.

FACTS

Putative Class Plaintiffs filed their Class Action Complaint on December 8, 2016 to challenge the practices of the Defendants. This class action seeks to recover damages for injuries sustained by Plaintiffs as the direct and proximate result of the wrongful conduct of Defendants, Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC, (collectively, the "Defendants") in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of TAXOTERE®, a prescription medication used in the treatment of breast cancer that has been scientifically linked to causing permanent alopecia and other injuries to the general public, including Putative Class Plaintiffs.

TAXOTERE® is a drug used in the treatment of various forms of cancer, including, but not limited to, breast cancer. Docetaxel (TAXOTERE®) is a part of a family of drugs commonly referred to as Taxanes. Taxanes are diterpenes produced by the plants of the genus Taxus (yews) featuring a taxadiene core. Taxanes are widely used as chemotherapy agents. Taxane agents include paclitaxel (TAXOL®) and docetaxel (TAXOTERE®). Paclitaxel (TAXOL®), which was developed, manufactured, and distributed by Bristol-Myers Squibb and is the main competitor drug to TAXOTERE®, was first approved by the U.S. Food and Drug Administration (FDA) in December 1992.

The drug and chemical compound that would become known as TAXOTERE® was invented and developed by Michel Colin, Daniel Guenard, Francoise Gueritte–Voegelein, and Pierre Potier of Rhone-Poulence Santé. TAXOTERE® was designed as an increased potency Taxane. The initial patent disclosing the formulation and computation of docetaxel (TAXOTERE®) was issued to Rhone-Poulence Santé and subsequently assigned to Defendant Aventis Pharma S.A. in March 1989. Since March 1989, Sanofi S.A., through its wholly-owned subsidiary, Aventis Pharma S.A., has controlled the development and been the owner, holder, or assignee of the patents related to TAXOTERE®.

Sanofi began enrolling patients in Phase I clinical testing trials on June 21, 1990. The study reporting on these trials was called the "TAX 001" study, which continued until May 13, 1992. The results from the TAX 001 study were reported on May 24, 1994. Accordingly, Sanofi was not only involved in the patenting and assignment of the compound TAXOTERE®, but Sanofi was also directly involved in the clinical trials and testing of the compound TAXOTERE®. Accordingly, Sanofi S.A. and Aventis Pharma S.A. have direct and personal knowledge of the results of those tests and Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC's decisions to withhold information and data from those tests from physicians, healthcare providers, patients, and Plaintiff in the United States.

Rhône-Poulenc Rorer S.A., before it was acquired by or merged into Aventis Pharma S.A., initially sought FDA approval for TAXOTERE® in December 1994. The FDA's Oncologic Drugs Advisory Committee panel unanimously recommended the rejection of Rhône-Poulenc Rorer S.A.'s request for the approval of TAXOTERE®, because TAXOTERE® was more toxic than its competing drug TAXOL®, which had already received FDA approval, and because more studies of docetaxel's side effects were needed.

TAXOTERE® was ultimately approved by the FDA on May 14, 1996. According to its product labeling, TAXOTERE® was "indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy." After the initial FDA approval, Defendants sought and were granted FDA approval for additional indications for TAXOTERE®. Based on self-sponsored clinical trials, Defendants claimed superiority over other chemotherapy products approved to treat breast cancer. Defendants' marketing claims included claims of superior efficacy over the lower potency Taxane product paclitaxel (TAXOL®), which was the primary competitor product to TAXOTERE®.

Contrary to Defendants' claims of superior efficacy, post market surveillance has shown that the more potent and more toxic TAXOTERE® does not in fact offer increased efficacy or benefits over other Taxanes, as Defendants have claimed and advertised. Defendants concealed the existence of studies from the FDA, physicians, and patients that refuted Defendants' claims.

A study of available clinical studies concerning the relative efficacy of Taxanes in the treatment of breast cancer, published in the August 2007 journal Cancer Treatment Review, concluded that no significant differences were found in the efficacy and outcomes obtained with TAXOTERE® (docetaxel) or TAXOL® (paclitaxel).

A study published in 2008 in the New England Journal of Medicine, titled Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer, concluded that TAXOL® (paclitaxel) was more effective than TAXOTERE® for patients undergoing standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.

Despite the publication of these studies, Defendants continued to make false and misleading statements promoting the "superior efficacy" of TAXOTERE® over the competing product paclitaxel (TAXOL®). In June 2008, Sanofi-Aventis utilized marketing and promotional

materials for TAXOTERE® at the annual meeting for the American Society of Clinical Oncology, comparing the efficacy of TAXOTERE® versus paclitaxel (TAXOL®). Specifically, Sanofi-Aventis utilized a "reprint carrier," citing a clinical study published in the August 2005 edition of the Journal of Clinical Oncology ("JCO"). The 2005 JCO study concluded that "docetaxel (TAXOTERE®) demonstrated superior efficacy compared with paclitaxel (TAXOL®), providing significant clinical benefit in terms of survival and time to disease progression, with a numerically higher response rate and manageable toxicities."

Whatever the merits of the 2005 JCO study may have been, Defendants' statements in the "reprint carrier" marketing the conclusions of the 2005 JCO study were false and/or misleading in light of the 2007 and 2008 studies finding that docetaxel (TAXOTERE®) was not more effective than paclitaxel (TAXOL®) in the treatment of breast cancer.

As a result of these false and misleading statements, in 2009, the FDA issued a warning letter to Sanofi-Aventis (the same company as Defendant Sanofi S.A. before Sanofi-Aventis changed its name in 2011) citing these unsubstantiated claims of superiority over paclitaxel stating:

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a professional reprint carrier [US.DOC.07.04.078] for Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion (Taxotere) submitted under cover of Form FDA 2253 by sanofi-aventis (SA) and obtained at the American Society of Clinical Oncology annual meeting in June 2008. The reprint carrier includes a reprint[1] from the Journal of Clinical Oncology, which describes the TAX 311 study. This reprint carrier is false or misleading because it presents unsubstantiated superiority claims and overstates the efficacy of Taxotere. Therefore, this material misbrands the drug in violation

[1] Jones SE, Erban J, Overmoyer B, et al. Randomized phase III study of docetaxel compared with paclitaxel in metastatic breast cancer. *J Clin Oncol.* 2005;23(24):5542-51.

of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(a) and 321(n). *Cf.* 21 CFR 202.1(e)(6)(i), (ii) & (e)(7)(ii).[2]

A Qui Tam lawsuit was also filed against Sanofi-Aventis and its affiliates in the United States District Court for the Eastern District of Pennsylvania by a former employee accusing Sanofi-Aventis and its affiliates of engaging in a fraudulent marketing scheme, paying kickbacks, and providing other unlawful incentives to entice physicians to use docetaxel (TAXOTERE®). *See U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, Civil Action No. 02-2964 (E.D. Pa. 2015).

Beginning in 1996, Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC and their predecessors and affiliates designed, directed, and/or engaged in a marketing scheme that promoted TAXOTERE® for off-label uses not approved by the FDA. The scheme took two forms: first, Defendants trained and directed their employees to misrepresent the safety and effectiveness of the off-label use of TAXOTERE® to expand the market for TAXOTERE® in unapproved settings; and second, Defendants paid healthcare providers illegal kickbacks in the form of sham grants, speaking fees, travel, entertainment, sports and concert tickets, preceptorship fees, and free reimbursement assistance to incentivize healthcare providers to prescribe TAXOTERE® for off-label uses. As a direct result of Defendants' fraudulent marketing scheme, Defendants dramatically increased revenue on sales of TAXOTERE® from $424 million in 2000 to $1.4 billion in 2004. *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 508 (E.D. Pa. 2015).

[2] Correspondence signed by Keith Olin, Pharm.D., Regulatory Review Officer in the FDA's Division of Drug Marketing, Advertising and Communications to MaryRose Salvacion, Director of US Regulatory Affairs Marketed Products at sanofi-aventis.

As a direct result of their wrongful conduct and illegal kickback schemes, Defendants 1) directly caused thousands of individuals including the Putative Class Plaintiffs to be exposed to TAXOTERE®'s increased toxicity as compared to other available less toxic products, and 2) caused thousands of individuals to be exposed to increased frequency and more severe side effects, including, but not limited to, disfiguring permanent alopecia (hair loss).

CAUSES OF ACTION

Putative Class Plaintiffs, on behalf of themselves and all other similarly effected Louisiana women, have brought causes of action against the Defendants under the Louisiana Products Liability Act. Under the Louisiana Products Liability Act, Putative Class Plaintiffs show that the serious risk of developing disfiguring permanent alopecia and other injuries are the direct and proximate result of breaches of obligations owed by Defendants to Putative Class Plaintiffs, including defects in design, marketing, manufacture, distribution, instructions and warnings by Defendants, which breaches and defects are listed more particularly, but not exclusively, as follows:

FIRST CLAIM FOR RELIEF

(Design Defect under LSA-RS 9:2800.56)

At all times relevant, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed TAXOTERE® as hereinabove described that was used by Putative Class Plaintiffs.

TAXOTERE® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants. At those times,

TAXOTERE® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Putative Class Plaintiffs.

The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of TAXOTERE®.

The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of Defendants, manufacturers, and/or suppliers, it was unreasonably dangerous, and it was more dangerous and posed risk greater than an ordinary consumer would expect. At all times relevant, TAXOTERE® was in a defective condition and unsafe, and Defendants knew or had reason to know that TAXOTERE® was defective and unsafe, especially when used in the form and manner as provided by Defendants. Defendants knew, or should have known, that at all times relevant, TAXOTERE® was in a defective condition and was and is inherently dangerous and unsafe.

At the time of Putative Class Plaintiffs' use of TAXOTERE®, the TAXOTERE® was being used for the purposes and in a manner normally intended, namely for the treatment of breast cancer. Defendants with this knowledge voluntarily designed TAXOTERE® in a dangerous condition for use by the public, and in particular, Putative Class Plaintiffs. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use. In creating TAXOTERE®, Defendants created a product that was and is unreasonably dangerous for its normal, intended use, and a safer alternative design existed.

The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was manufactured defectively and was unreasonably dangerous to its intended users. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants reached the intended users in the same defective and unreasonably dangerous condition in which Defendants' TAXOTERE® was manufactured.

Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk to the health of consumers and to Putative Class Plaintiffs in particular; and Defendants are therefore liable for the injuries sustained by Putative Class Plaintiffs in accordance with Louisiana Products Liability Act.

At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of TAXOTERE®. This was demonstrated by the existence of other breast cancer medications which had a more established safety profile and a considerably lower risk profile, namely paclitaxel (TAXOL®).

Putative Class Plaintiffs and Putative Class Plaintiffs' physicians could not, by the exercise of reasonable care, have discovered TAXOTERE®'s defects mentioned herein and perceived its danger.

The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that the product created a risk of serious

and dangerous side effects, including disfigurement as well as other severe and personal injuries that are permanent and lasting in nature, and Defendants failed to adequately warn of these risks.

The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including disfigurement and/or permanent disfiguring alopecia, as well as other severe and permanent health consequences from TAXOTERE®, they failed to provide adequate warnings to users or consumers of the product, and they continued to improperly advertise, market, and/or promote TAXOTERE®.

By reason of the foregoing, Defendants are liable to Putative Class Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of TAXOTERE®, a defective product. Defendants' defective design, manufacturing defect, and inadequate warnings of TAXOTERE® were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

The defects in Defendants' drug TAXOTERE® were a substantial and contributing factors in causing Putative Class Plaintiffs' injuries. As a result of the foregoing acts and omissions, Defendants caused Putative Class Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; future psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

SECOND CLAIM FOR RELIEF

(Inadequate Warning Under LSA-RS 9:2800.57)

Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced TAXOTERE® into the stream of commerce, and in the course of same, directly advertised or marketed TAXOTERE® to consumers or persons responsible for consumers, and therefore, had a duty to both Putative Class Plaintiffs directly and their physicians to warn of risks associated with the use of the product, including, but not limited to, permanent disfiguring alopecia.

Defendants had/have a duty to warn of adverse drug reactions, including, but not limited to, permanent disfiguring alopecia, which they knew or should have known can be caused by the use of TAXOTERE® and/or are associated with the use of TAXOTERE®.

The TAXOTERE® designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects, including, but not limited to, permanent disfiguring alopecia, associated with the use of TAXOTERE®. The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in particular, the risks of disfiguring permanent alopecia.

Defendants failed to provide adequate warnings to physicians and users, including Putative Class Plaintiffs' physicians and Putative Class Plaintiffs, of the increased risk of disfiguring permanent alopecia associated with TAXOTERE®, although Defendants aggressively and fraudulently promoted the product to physicians.

Due to the inadequate warning regarding the serious risk for disfiguring permanent alopecia, TAXOTERE® was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

Defendants' failure to adequately warn Putative Class Plaintiffs and their prescribing physicians of the serious risk of disfiguring permanent alopecia prevented Putative Class Plaintiffs' prescribing physicians and Putative Class Plaintiffs themselves from correctly and fully evaluating the risks and benefits of TAXOTERE®. Had Putative Class Plaintiffs been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Putative Class Plaintiffs would not have taken TAXOTERE®. Upon information and belief, had Putative Class Plaintiffs' prescribing physicians been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Putative Class Plaintiffs' physicians would have discussed the risks of disfiguring permanent alopecia with Putative Class Plaintiffs and/or would not have prescribed it.

As a result of the foregoing acts and omissions, Defendants caused Putative Class Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

THIRD CLAIM FOR RELIEF

(Breach of Express Warranty Under LSA-RS 9:2800.58)

Defendants expressly warranted that TAXOTERE® was safe and well accepted by users.

TAXOTERE® does not conform to these express representations, because TAXOTERE® is not safe and has numerous serious side effects, including, but not limited to, permanent and disfiguring alopecia, many of which were not accurately warned about by Defendants.

As a direct and proximate result of the breach of these warranties, Putative Class Plaintiffs suffered and will continue to suffer severe and permanent personal injuries, disfigurement, losses, and damages.

Putative Class Plaintiffs and Putative Class Plaintiffs' physicians relied on Defendants' express warranties. Furthermore, the express warranties represented by Defendants were a part of the basis for Putative Class Plaintiffs and Putative Class Plaintiffs' physicians use of TAXOTERE® and she relied upon these warranties in deciding to use TAXOTERE®.

Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendants for use of TAXOTERE® in recommending, prescribing, and/or dispensing TAXOTERE®. Defendants breached the aforesaid express warranties, as their drug TAXOTERE® was and is defective and causes harm and injury as discussed herein.

At the time of the making of express warranties, Defendants had knowledge of the purpose for which TAXOTERE® was to be used, and warranted same to be in all respects safe, effective, and proper for such use.

Defendants expressly represented to Putative Class Plaintiffs, Putative Class Plaintiffs' physicians, and/or healthcare providers that TAXOTERE® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side

effects in excess of those risks associated with other forms of treatment for cancer, that the side effects it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

Defendants knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue in that TAXOTERE® was not safe and fit for the use intended, and, in fact, TAXOTERE® produced serious injuries to the users that were not accurately identified and represented by Defendants.

As a result of the foregoing acts and omissions, Defendants caused Putative Class Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

FOURTH CLAIM FOR RELIEF

(Breach of Warranty in Redhibition)

TAXOTERE® contains a vice or defect which renders it useless or its use so inconvenient that consumers would not have purchased it had they known about the vice or defect.

Pursuant to Louisiana Civil code article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold. TAXOTERE®, which was sold and promoted by

Defendants, possesses a redhibitory defect because it is unreasonably dangerous, as described above, which renders TAXOTERE® useless or so inconvenient that it must be presumed that Putative Class Plaintiffs would not have bought TAXOTERE® had she known of the defects.

In accordance with Louisiana Civil Code article 2545, Defendants, as the manufacturers, distributors and sellers of TAXOTERE®, are deemed to be aware of its redhibitory defects. Had Putative Class Plaintiffs been made aware of the defects contained in TAXOTERE®, they would not have purchased TAXOTERE®. This characteristic rendered TAXOTERE® unfit for its intended purposes.

Defendants are liable to Putative Class Plaintiffs under the theory of redhibition as a consequence of the sale to Putative Class Plaintiffs a product unfit for its intended use. Putative Class Plaintiffs are entitled to the return of purchase price paid for TAXOTERE®, including, but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys' fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Putative Class Plaintiffs may be entitled.

CLASS DEFINITION

Putative Class Plaintiffs seek the certification of the following class:

> All Louisiana residents who were administered TAXOTERE® during chemotherapy and have suffered permanent alopecia and other legally cognizable injuries as a result.

Putative Class Plaintiffs pray that the requested class be certified, and class counsel and class representatives be appointed.

I. LAW

A singular and consistent unlawful pattern and practice engaged in by defendants that causes monetary damage and other damage to a large number of people should be handled through a class action. The applicable law favors class treatment in this type of case, to wit:

A. *THIS COURT HAS DISCRETION ON THE ISSUE OF CLASS CERTIFICATION.*

A District Court has substantial discretion in determining whether to certify a class pursuant to F.R.C.P. 23. *Berger v. Compaq Computer Corp.*, 257 F.3d 475, 479 (5th Cir. 2001); *In Re: Vulcan Litigation January 5 Incident*, No. 01-05-D-M3 (M.D. La. 2005). In exercising this discretion, the Court does not evaluate the merits of the case but considers only whether the requirements of Rule 23 are met. *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177-78 (1974). The Court may consider materials beyond the pleadings such as relevant facts, the claims of the parties and the applicable substantive law. *Castano v. American Tobacco Company*, 84 F.3d 734, 744 (5th Cir. 1996).

It is respectfully suggested that most, if not all Defendants oppose use of the class action procedural device (at least initially, i.e., pre settlement) based upon a mistaken belief that aggregating all similarly situated claimants into a "class" affords Plaintiffs some significant legal and/or strategic advantage. By the same token, when settlement terms have been reached, Defendants customarily insist on class certification so as to secure the greatest "closure" for their clients in the aggragated class settlement; the attendant irony should, with respect, not be lost on this Honorable Court. While it is anticipated that Defendants in the instant matter will argue vociferously the same tired old mantras that "commonality" is not present" and "typicality is not present" and "superiority is not present" and it is sanctionable for these Plaintiffs to even suggest to Your Honor that these "personal injury type" claims should be certified, it will be these very same Defendants who will argue for class certification if and when settlement terms are reached.

It is respectfully suggested that once the irrational and unfounded fears of the utilization of the class action procedural device are eliminated from consideration, the fact of the matter is that Rule 23 is a procedural device and nothing more. There is no substantive "strategic advantage" for Plaintiffs through its use. In fact, restricting Plaintiff to the proverbial "one bite at the liability apple" in a single class wide liability trial as opposed to multiple opportunities to refine and enhance the presentation of the evidence through multiple bellweather trials poses significant risk to Plaintiffs. If Defendants truly believe (as they assert in their pleadings) that they bear no liability as their product poses no increased risk of adverse effects to those patients having been administered their drug during chemotherapy, then they should vigorously support the opportunity to be able to present their evidence but a single time and a single cost to their clients and have a single jury declare them legally free from the harm alleged by all claimants.

Proceeding via the class action procedure affords no side of the proverbial :v: with any particular advantage but rather simply provides the most efficient manner of procedure and with ample FRCP and interpreting jurisprudence providing clear guidance to the Court and to the litigants and to their respective counsel as to the law applicable and the obligations attendant to its use. The MDL procedural device absent a certified class on the other hand poses significant challenges as it is virtually devoid of guiding statutory law, is forced to rely upon "Judge made doctrine based upon 'inherent authority'" and denies claimants the specific Judicial protection afforded by the class action procedural device.

As even a cursory review of the relevant literature will attest, an MDL "mass joinder" is, with respect, fraught with potential ethical issues, conflicts of interest, and opportunities for overreaching. Some law professors and commentators even argue that a court appointed MDL Plaintiffs Steering Committee has no fiduciary obligations to MDL claimants as a whole, or to

the individually retained counsel they hired. *See* e.g., Prof. Geoffrey Miller and for a contrary view, Prof. Charles Silver). (Profs. Lynn Baker of UT Texas, Jaime Dodge of Emory U. and Francis McGovern of Duke have likewise commented and Prof. McGovern has Co-Authored an MDL Report on the JPMl/MDL process.)

In short, FRCP 23 was enacted for a purpose, to wit, to provide an efficient manner of procedure for a USDC to manage the claims of multiple claimants asserting substantially similar claims and to protect the interests of those claimants and of all party litigants. It is resectfully suggested that it is long past time to discard the irrational, unfounded fears that have developed over time and recognize the inherent advantages of its use in situation exactly like the instant matter. Simply because "personal injury", in this case in the form of hair loss, is alleged is no reason to discard the benefits to the Court and protections afforded to all litigants through its use.

B. *THE REQUIREMENTS OF FRCP 23*

The requirements for class certification in federal courts are found in FRCP 23. In particular, FRCP 23(a) sets out four prerequisites to be met in class actions: numerosity, commonality, typicality, and adequacy. Once the Court finds that these four prerequisites are met, it then considers the three categories listed in FRCP 23(b). Class certification is appropriate if the Court finds that any one of the three categories of FRCP 23(b) is satisfied. Here, plaintiffs seek certification under FRCP 23(b)(3) which in turn contains two requirements: (1) that questions of law or fact common to members of the class predominate over questions affecting only individual members and (2) that a class action is superior to other methods of adjudication.

II. ARGUMENT

This Honorable Court should certify the class for the following reasons:

(1) The requirements of numerosity, commonality, typicality and adequacy are met.

(2) The issues common to the class predominate over any individual issues which might arise.

(3) A class action is superior to any other methods of adjudication available to the Court.

Plaintiffs will demonstrate why each of the above requirements is met by this litigation.

A. *NUMEROSITY*

FRCP 23(a)(1) simply requires that the class be so large that joinder of all members is impracticable. Plaintiffs must merely demonstrate some evidence or reasonable estimate of the number of purported class members. *James v. City of Dallas*, 254 F.3d 551, 570 (5th Cir. 2001). Generally, a potential class of over one hundred members is sufficient for purposes of numerosity and some courts have noted that any class consisting of more than forty members should raise a presumption that joinder is impracticable. *Street v. Diamond Offshore Drilling*, 2001 WL 568111 (E.D.La. May 25, 2001, Duval, J.).

In the instant case, upon information and belief, the precise number of individuals in the class is believed to include over several hundred Louisiana women. Even in excess of 100 class members certainly meets the numerosity prong of the test.

B. *COMMONALITY*

FRCP 23(a)(2) requires that a question or questions of law and/or fact common to the class exist.

A common question is one that, when answered as to one class member, "will affect all or a significant number of the putative class members." *Forbush v. J.C. Penny Co.*, 994 F.2d 1101, 1106 (5th Cir. 1993); *James v. City of Dallas*, 254 F.3d 551, 570 (5th Cir. 2001).

When the party opposing the class has engaged in some course of conduct that affects a group of persons and gives rise to a cause of action, one or more elements of that cause of action will be common to all of the persons affected. Hebert B. Newberg, Newberg on Class Actions § 310 at 3-49 (4th ed. 2002).

In the instant case, there are numerous common issues of fact and law that affect all of the putative class members. This action presents questions of law and fact common to the Class including:

a. Whether Defendants failed to instruct and/or warn of the serious risk of developing disfiguring permanent alopecia and other injuries to the Class after taking TAXOTERE®;

b. Whether the Defendants failed to adequately instruct and/or warn healthcare providers, including those healthcare providers who administered TAXOTERE® to the Class of the serious risk of developing disfiguring permanent alopecia and other injuries;

c. Whether Defendants manufactured, produced, promoted, formulated, created, and/or designed TAXOTERE® without adequately testing it;

d. Whether Defendants failed to provide adequate warning of the dangers associated with TAXOTERE®;

e. Whether Defendants knew or should have reasonably known of the propensity of TAXOTERE® to cause disfiguring permanent alopecia and other injuries;

f. Whether Defendants' conduct violates the Louisiana Products Liability Act;

g. Whether Defendants' were unjustly enriched as a result of their actions.

Once these common questions of law and fact have been answered, those common issues will have been decided for all class members. The claims of all class members will hinge on common questions regarding the defendants' negligence and liability.

C. *TYPICALITY*

FRCP 23(a)(3) requires that the claims of the class representative(s) be typical of the claims of the class members as a whole. It does not require a complete identity of claims but simply requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." FRCP23(a)(3). Like commonality, the test for typicality is not demanding. *Mullen v. Treasure Chest Casino*, 186 F.2d 620, 625 (5th Cir. 1999). It exists when the claims of the named and unnamed plaintiffs have a common source and rest upon the same legal and remedial theories. *Mullen v. Treasure Chest Casino*, 186 F.2d 620, 625 (5th Cir. 1999). Generally, when it is alleged that the same unlawful tortious conduct was directed at or affected both the class representatives and the class sought to be represented, the typicality requirement is met irrespective of varying fact patterns which may underlie individual claims. Hebert B. Newberg, Newberg on Class Actions § 313 at 3-77 (3rd ed.).

Here, the claims brought by the proposed Class Representative Plaintiffs are typical of the Class because the claims of the proposed Class Representative Plaintiffs and the Class Members arise from the same set of facts and they all seek the same relief. The claims of all arise from the ingestion of TAXOTERE® and the resulting permanent alopecia and other injuries. All proposed Class Representative Plaintiffs were prescribed this drug, were administered this drug, and were damages by their exposure to this drug. Moreover, the claims of the proposed Class Representative Plaintiffs and the Class Members arise out of the same concerted course of conduct by Defendants. The Proposed Class Representative Plaintiffs and the Class Members

were all administered the drug TAXOTERE® which was manufactured, produced, promoted, formulated, created, and/or designed by the Defendants. Plaintiffs and Class Members sustained the same injuries and damages arising out of Defendants' conduct in violation of the law. The injuries and damages of each Class Member were caused directly by Defendants' wrongful conduct in violation of law as alleged.

Thus, the requirement of typicality is met.

D. *ADEQUACY*

FRCP 23(a)(4) requires that the class representatives be adequate to represent the interests of the class. To satisfy this requirement, the class representatives' interests must be aligned with, and not antagonistic to, unnamed class members. *Mullen v. Treasure Chest Casino*, 186 F.2d 620, 625-626 (5th Cir. 1999).

A sufficient alignment of interest exists when "all class members are united in asserting a common right, such as achieving the maximum possible recovery for the class." *In re: Corrugated Container Antitrust Litigation*, 643 F.2d 195, 208 (5th Cir. 1981). The question is whether the representatives will "fairly and adequately" represent the interests of the class. FRCP 23(a)(4). Proving individual damages is not required at the class certification stage. *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156 (1974). Class certification is procedural, not merits dispositive.

The U.S. Supreme Court has recognized that the adequacy and representation requirements "tends to merge" with the commonality and typicality requirements, all of which "serve as guideposts for determining whether the maintenance of the class is economical and whether the named plaintiffs and the class claims are so interrelated that the interest of the class

members will be fairly and adequately protected in their absence." *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 626 n.20 (1997); *General Telephone Company of Southwest v. Falcon*, 457 U.S. 147, 151, n.13 (1982).

The proposed Class Representative Plaintiffs will fairly and adequately represent the interests of the Class because it is in their best interests to prosecute the claims alleged herein to obtain full compensation due to them for the unfair and illegal conduct of which they complain. In this case, the claims of the proposed class representatives are interrelated with the claims of the absent class members to such a degree that it is certain that the interests of the absent class members will be adequately and fairly protected. The proposed Class Representative Plaintiffs also have no interests that are in conflict with or antagonistic to the interests of Class Members. Here, the proposed class representatives have met with counsel, provided relevant documents, will provide relevant testimony, and are willing to testify at deposition and at trial.

Also, the Proposed Class Representative Plaintiffs have hired counsel who are able and experienced in class action litigation and will vigorously litigate this action. The Proposed Class Representative Plaintiffs and their counsel have the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiffs and their counsel are aware of their fiduciary responsibilities to the Class Members and are determined to diligently discharge those duties by seeking the maximum possible recovery for Class Members. Plaintiffs, with respect, seek to reserve their right to provide this Honorable Court with ample evidence of their experience in class action matters and their ability to fund the litigation until after the Class Certification Hearing date.

E. *PREDOMINANCE*

FRCP 23(b)(3) states that a class can be maintained if the Rule 23(a) factors are met and "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. FRCP 23(b)(3). In order to "predominate," common issues must constitute a significant part of the individual cases. *Jenkins v. Raymark Industries, Inc.*, 782 F.2d 468, 472 (5th Cir. 1986). The purpose of the predominance requirement is to ensure that a proposed class is "sufficiently cohesive to warrant adjudication by representation." *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 623 (1997). Individual questions of causation or damages which do not predominate over common issues will not prevent certification. 7A Charles Allen Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1780 at 576-577 (2nd ed. 1986).

In the instant case, the common questions of liability clearly predominate over any pertinent questions to individual members. Specifically, questions of law and fact regarding liability of Defendants are common to Class Members and predominate over any individual issues that may exist, such, that by prevailing on their own claims, Plaintiffs necessarily will establish Defendants' liability to all Class Members. There are no individual questions which predominate over the overarching common liability questions.

F. *SUPERIORITY*

FRCP 23(b)(3) requires that the class action be superior to other available methods for fairly and efficiently adjudicating the controversy. FRCP 23(b)(3). In mass actions such as this one, the legal and factual issues involving a defendant's liability do not differ dramatically from one plaintiff to the next. The common liability issues can be tried in a single class action trial with any individual issues of damages reserved for individual treatment. *Hernandez v. Motor*

Vessel Skyward, 61 F.R.D. 558 (S.D. Fla. 1973), affirmed without opinion, 507 F.2d 1279 (5th Cir. 1975); *Sterling v. Velisicol Chemical Corp.*, 855 F.2d 1188, 1197 (2nd Cir. 1987).

A class action is superior to other available methods of adjudicating the claims in this action because individual damages to any one class member are relatively small, making the expense of prosecuting or controlling individual litigations prohibitive or impractical for Class Members. Moreover, a class action can be managed with efficiency and without undue difficulty because Defendants have used standardized contracts, standardized sales tactics, and standardized fraudulent and extra-contractual charges, and the Plaintiffs and Class Members were similarly affected by Defendants' deceptive and fraudulent schemes.

Finally, it would save an enormous amount of judicial resources to have the common liability and causation issues tried one time instead of having these same issues tried over and over again, risking inconsistent verdicts and resulting in lengthy delays as plaintiffs have to wait in line to try the same issues of liability and causation over and over again. Considering judicial economy and the desire for consistent judicial rulings, the class mechanism is superior to multiple trials where the same liability questions would have to be answered by the trier of fact.

III. PROPOSED CLASS COUNSEL

Proposed Class Counsel are Val Patrick Exnicios of Liska, Exnicios & Nungesser and Michael Stag of Smith Stag. Proposed Class Counsel represent that they satisfy the criteria set forth in Rule 23(g), having extensive experience not only in class action litigation, but also, specifically, class actions arising from consumer contracts. Further, proposed Class Counsel represent that they will invest significant time and resources in this case, including reviewing documents, meeting with clients, drafting pleadings, hiring experts and participating in court

hearings. Proposed Class Counsel are also qualified based upon extensive experience litigating major class actions and multi-district litigation cases.

IV. PROPOSED CLASS REPRESENATIVES

The proposed Class Representatives are Sheila Matthews, Debra Chetta and Emily Barre. The proposed Class Representatives were administered TAXOTERE® during chemotherapy and have suffered from permanent alopecia and other injuries as a result. The proposed Class Representatives have been actively involved in fact development in this putative class action, have kept apprised of the litigation, are knowledgeable of the facts of this case, and are willing to provide relevant testimony at deposition, the class certification hearing, and at trial.

WHEREFORE, for the reasons set forth herein, the Putative Class Representatives respectfully request that the Court:

A. Certify for litigation purposes only the following class of persons:

> All Louisiana women who were administered TAXOTERE® during chemotherapy and have suffered from permanent alopecia and other injuries as a result.

B. Appoint Val Patrick Exnicios from Liska, Exnicios & Nungesser and Michael Stag of Smith Stag as Class Counsel pursuant to FRCP 23(g) for purposes of representing the Class and Class Members in this litigation; and

C. Appoint Sheila Matthews, Debra Chetta and Emily Barre as Class Representatives.

Respectfully Submitted,

LISKA, EXNICIOS & NUNGESSER

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the above and foregoing pleading has been sent to counsel of record for all parties by delivery of same by the ECF system this 25th day of April, 2017.

/s/Val Patrick Exnicios
VAL PATRICK EXNICIOS

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "N" (5)

THIS DOCUMENT RELATES TO
Case #2:16-cv-17731
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NOTICE OF SUBMISSION

Please take notice that Plaintiffs' *Motion for Class Certification* is hereby set for submission before the Honorable Judge Kurt D. Engelhardt, on May 10, 2017, at 9:30 a.m.

Respectfully Submitted,

/s/Val Patrick Exnicios
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/s/Val Patrick Exnicios
VAL PATRICK EXNICIOS