CAUSE NO. DC-18-08923

TRACY FLEMING and NORMA EGEA	§	**IN THE DISTRICT COURT OF**
	§	
Plaintiffs,	§	
	§	
vs.	§	**DALLAS COUNTY, TEXAS**
	§	
BRIAN CHILDRESS; NEYLU, INC.; and RICHARD D. SCHUBERT, M.D.	§	
	§	
Defendants.	§	**192nd JUDICIAL DISTRICT**

PLAINTIFFS' FIRST AMENDED ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Plaintiffs, TRACY FLEMING and NORMA EGEA, husband and wife, and file this their First Amended Original Petition, complaining of Defendants BRIAN CHILDRESS, NEYLU, INC., and RICHARD D. SCHUBERT, M.D., sometimes referred to collectively as "DEFENDANTS," and for such would respectfully show the Court as follows:

I. DISCOVERY LEVEL

1. Plaintiffs TRACY FLEMING and NORMA EGEA intend to conduct discovery under Level 3 as set forth in Texas Rule of Civil Procedure 190.3, and they request that designation.

II. PARTIES

2. Plaintiffs Tracy Fleming and Norma Egea are husband and wife, and at the time of filing this lawsuit, resided in Dallas County, Texas. They now reside in Collin County, Texas. Tracy Fleming was surgically implanted with a hip implant manufactured by a company known as Smith & Nephew, and he has suffered damages as a result.

3. Brian Childress ("Childress") is a natural person and citizen of Texas. He was a sales representative for Smith & Nephew, Inc., the manufacturer of the implant that Tracy Fleming was implanted with. Brian Childress worked for Smith & Nephew, Inc. for twenty-four years, the

majority as an independent sales representative.

4. Neylu, Inc. is a Texas company. Neylu, Inc. is a sham corporation that Brian Childress and his wife established several years ago for the sole purpose of meeting Smith & Nephew's contracting requirements. Neylu, Inc. was contracted to Smith & Nephew, Inc. as its "independent" sales representative.

5. Neylu, Inc. and Childress may sometimes be referred to collectively as "the Sales Rep Defendants."

6. Richard D. Schubert, M.D. is a natural person and citizen of Texas. Plaintiffs have fully complied with the provisions of Texas Civil Practice & Remedies Code Sections 74.051 and 74.052.

7. No service of process is necessary on any of the Defendants, because they were served with the original suit and have appeared through their counsel of record.

III. JURISDICTION & VENUE

8. Jurisdiction is proper in this Court because the relief sought is within the jurisdictional limits of this Court and because the causes of action asserted herein accrued in the State of Texas.

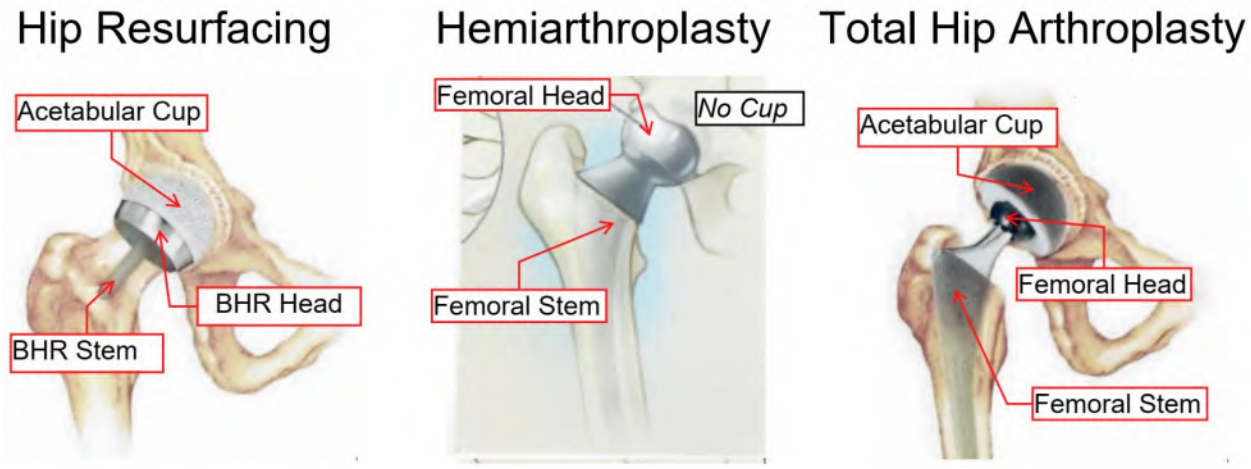
9. Venue is proper in Dallas County, Texas under Section 15.001, *et seq*. of the Texas Civil Practice & Remedies Code because most of the legally significant events and circumstances occurred in Dallas County, and there is no venue challenge pending.

IV. BACKGROUND MEDICAL FACTS

10. A basic description of the different types of hip replacement procedures that a surgeon may perform, and the products potentially used, is helpful for understanding how defendants failed to comply with accepted medical standards, as well as state and federal laws, and

permitted the implantation of an untested, unsafe device into plaintiff. The "primary" operation is the original surgery or arthroplasty where parts of the human joint system are removed and replaced with artificial hip parts. These artificial hip parts may consist of various combinations of synthetic materials, such as metal, polyethylene, or ceramic. The implant is frequently characterized by the composition of the two types of materials that "articulate," or rub, against one another, such as metal-on-polyethylene, metal-on-metal, metal-on-ceramic, or ceramic-on-polyethylene. Plaintiff's implant was "metal-on-metal."

11. There are three types of hip replacement procedures. Plaintiff's surgery in this case involves all three types in one way or another. The differences between these surgeries and these implants are described below:



12. In a "conventional" total hip arthroplasty, the patient's femur is replaced with a full femoral stem, the head is replaced with a ball, and the acetabulum is replaced with a cup. Plaintiff Tracy Fleming underwent a total hip replacement surgery. Hip resurfacing is also involved in this case because the acetabular cup implanted in Plaintiff was only approved for resurfacing procedures. A "hemiarthroplasty" procedure, where only the femoral side of a hip is revised, is also involved in this case because the modular femoral head and sleeve were only cleared by the FDA for hemiarthroplasties.

13. This case involves a Smith & Nephew metal-on-metal hip implant device that Dr. Richard D. Schubert surgically implanted into Plaintiff Tracy Fleming's left hip on September 28, 2009 during a total hip arthroplasty surgery performed at North Central Surgical Center in Dallas, Texas. The implant used in the surgery was made of four separate Smith & Nephew metal components:

(1) A 56mm BHR Acetabular Shell (Ref. No. 7412-0156);
(2) A 50mm Modular Femoral (Hemi) Head (Ref. No. 7412-2550);[1]
(3) A 12/14 taper, +4mm offset Modular Head Sleeve (Ref. No. 7422-2300);
(4) A Size 15 Synergy Porous Plus HA-Coated Femoral Stem (Ref. No. 7130-9015).

These four components were never cleared or approved for use together like they were used here. These four unapproved components will sometimes be referred to as the "Device Components."

14. Shortly after the Plaintiff's primary hip surgery, grinding of the Device Components created metal-on-metal friction allowing metal debris to enter the space around the hip implant and migrate into the bloodstream. The metal debris caused a physiological reaction in the Plaintiff. This metal wear continued causing damage to Plaintiff's surrounding tissue and bone resulting in toxic metallosis, necessitating revision surgery.[2] Plaintiff's left hip arthroplasty was surgically revised at Baylor University Medical Center in Dallas on April 12, 2018 at great expense, pain, and inconvenience to the Plaintiffs.

V. BACKGROUND DEVICE FACTS

[1] Recalled from the market in March 2015 for safety reasons.

[2] All of the following claims for relief, when referring to the Device Components, allege liability based on the failure of the Device Components both individually and as a single device. The corrosion and failure of the Device Components happened at multiple locations on the device, including at the sleeve-stem surface, the sleeve-head surface, and the cup-head surface. Each of these contact points were metal-metal surfaces, sometimes of different metal types, and each separately corroded and released dangerous Cobalt and Chrome metal ions into plaintiff's body and bloodstream, causing the injuries complained of herein and necessitating revision of the implant.

15. Metal-on-metal total hip arthroplasties have been remarkably unsuccessful in the United States over the years. The metal-on-metal hip device used in Plaintiff is no exception. Smith & Nephew failed at least three times from 2004 to 2009 to secure FDA clearance for the combination of metal parts the Plaintiff received. They used the name, "Birmingham Hip Modular Head System" or "Birmingham Hip Modular Hip System" when applying for clearance for the Device Components. Smith & Nephew eventually withdrew every FDA application for clearance to sell the Device Components in this country. To this day, the FDA has not approved or cleared the Device Components. Rather, the modular femoral head component was cleared through the 510(k) process for use only in hemiarthroplasty (or "hemi-hip") procedures in September 2006.[3] Through this 510(k) shortcut, Smith & Nephew got the limited FDA clearance they wanted for the modular femoral head without spending time and money trying to satisfy the FDA's safety concerns about using the modular femoral head in total hip arthroplasties. Tracy Fleming's hip surgery did not involve a hemiarthroplasty even though the modular femoral head used in it was only approved for that procedure.

16. Smith & Nephew, armed with the regulatory loophole clearances described above, turned to its sales representatives throughout the country to promote the modular femoral head for use in total hip arthroplasties. Brian Childress was eager to help. The tactics that Childress employed were consistently deceptive, manipulative, illegal, and aimed at maximizing sales. The Sales Rep Defendants emphasized "converting" surgeons to use Smith & Nephew's unapproved hip implants. Childress tried for years to "convert" Dr. Schubert to the unapproved Device Components, but he was not successful until Dr. Schubert started having significant complications with the Johnson & Johnson metal hip implants he was using at the time. Brian Childress stepped

[3] K062408. Smith & Nephew also received 510(k) clearance to market the original version of this modular head, which it stopped manufacturing in 2008. K061243.

in and convinced Dr. Schubert to give the unapproved Smith & Nephew implants a try.

17. Smith & Nephew did everything they could to shield themselves from personal liability while ensuring they controlled everything its "independent" sales representatives did. The Sales Representative Agreement entered into between Smith & Nephew and the Sales Rep Defendants on May 24, 2002, disclaims any relationship of principal and agent, joint venturers, partners, employer and employee, franchisor and franchisee, manufacturer and distributor, "or any other similar relationship." This sales representative agreement was structured and designed to give Smith & Nephew a convenient scapegoat if anyone ever wanted to sue them—they could simply blame the independent sales representative. However, Smith & Nephew gave the independent sales representatives proprietary, confidential sales information, training manuals, surgical techniques, and "special knowledge" about Smith & Nephew products. Using this secret, proprietary "special knowledge" and information, the independent Sales Rep Defendants systematically marketed and sold the unapproved and non-cleared Device Components to American surgeons, violating state and federal law. The Sales Rep Defendants eventually convinced Dr. Schubert to start using the unapproved Device Components, and Tracy Fleming was implanted with them shortly thereafter.

VI. THE SALES REPS' MARKETING SCHEME

18. This section of this Petition will provide an overview of the Sales Rep Defendants' marketing scheme that finally resulted in "converting" Dr. Schubert from using approved Johnson & Johnson products to using Smith & Nephew's unapproved Device Components.

19. The Sales Rep Defendants are Smith & Nephew's local distributors and physician contact points. Their role as Smith & Nephew, Inc.'s contact with physicians gave them substantial control over the warnings, instructions, and product information accompanying the Device Components, and they made express representations about the implants and their use and adverse

event history that were false, incomplete, and misleading. Specifically, sometime in 2008, Brian Childress told Dr. Schubert that Smith & Nephew had an approved metal hip system that was at least as good, if not better than, the Johnson & Johnson implants that Schubert had used and studied for years. Childress knew he was actively misleading Dr. Schubert when telling him this, and he worded the sales pitch carefully because he knew he was breaking the law and was "misbranding" the Device Components with his untrue statements.

20. The Sales Rep Defendants and their employees frequently observed, commented on, and assisted with device implantation surgery. A sales representative was almost always present at surgeries that Dr. Schubert performed with Smith & Nephew metal implant products. The Sales Rep Defendants were responsible for independently verifying that their unapproved Device Components got to the operating room as needed. The Sales Rep Defendants knew about Mr. Fleming's surgery before it occurred and thus played a key role in the hiding of information and the provision of the Device Components to Dr. Schubert

21. Brian Childress knew that Dr. Schubert believed the Device Components were approved for use together. This was Schubert's belief because that's what Brian Childress told him. Brian Childress did not simply pass on the written warnings that accompanied the Device Components. Instead, he made material misrepresentations, understatements, and omissions that directly conflicted with the written materials provided with the Device Components. The Sales Rep Defendants knew that telling the truth about the Device Components or even showing Dr. Schubert the written warnings that accompanied the products would have caused him to refuse to use them. The Sales Rep Defendants also knew that the written instructions accompanying the products were hopelessly confusing and outdated, and that showing those writings to Dr. Schubert would make him aware that the products were not approved for use together. Childress decided to

conceal this information from Dr. Schubert

VII. NEGLIGENCE: DR. SCHUBERT

22. Dr. Schubert breached his duty to act with reasonable care when selecting the experimental Device Components and when failing to adequately inform the Plaintiffs about the risks and uncertainties of those parts. Dr. Schubert owed the Plaintiffs a duty to use reasonable care when receiving money and other benefits for participating in the commercial distribution of medical devices intended for permanent human implantation. Dr. Schubert was negligent, and his conduct fell below the standard of care because he implanted an unapproved, untested combination of parts into the Plaintiff without obtaining adequate informed consent and without having a reasonable medical basis to believe the Device Components were safe and effective for long-term use in humans.

23. Dr. Schubert knew that Smith & Nephew was under indictment for bribing doctors and paying them kickbacks when he decided to use that company's products in total hip replacements. He knew that Smith & Nephew paid large kickbacks to orthopaedic surgeons through sham "consulting agreements," and routinely showered U.S. surgeons with money and benefits in exchange for using the manufacturer's medical devices. The company got caught doing this and paid a multimillion dollar fine and entered into a "Deferred Prosecution Agreement" with the U.S. Department of Justice. The term of this Deferred Prosecution Agreement lasted until March of 2009, and Brian Childress violated that Agreement when he "converted" Dr. Schubert to the Smith & Nephew products sometime in 2008.

24. Dr. Schubert had a duty to investigate whether the combination of Device Components used in plaintiff's surgery was cleared or approved by the FDA for use in conventional total hip arthroplasties and whether there was adequate clinical evidence to support

the safety and effectiveness of the Device Components. The implantation of the Device Components in Plaintiff was negligent because Dr. Schubert knew or should have known that:

- The Device Components were neither cleared nor approved by the FDA for use in conventional total hip arthroplasties;
- There was inadequate clinical evidence to support the safety of the Device Components for use in conventional total hip arthroplasties;
- There was inadequate laboratory testing (i.e. simulator wear testing) to support the safety of these devices for use in conventional total hip arthroplasties;
- There was inadequate clinical evidence to support the long-term safety or efficacy of metal-on-metal conventional total hip arthroplasties;
- Pairing a cobalt-chrome sleeve and titanium femoral stem exposed plaintiff to an unnecessarily high risk of galvanic corrosion at the sleeve-neck taper; and
- The product packaging and labeling stated that the Device Components were only cleared for limited purposes that did not include a conventional total hip arthroplasty.

25. Dr. Schubert was an "Original Core Surgeon" for Smith & Nephew, meaning he was one of only fifty surgeons nationwide who Smith & Nephew flew to the United Kingdom to learn about Smith & Nephew's hip implant products. Any reasonable surgeon in Dr. Schubert's position knew or should have known that the Device Components posed an unreasonable and unknowable risk to patients, but Dr. Schubert negligently implanted them without telling the Plaintiffs of these concerns. There was no justification for exposing the Plaintiff to the Device Components when there were safer alternatives readily available from Smith & Nephew and other manufacturers.

26. Dr. Schubert was also negligent for naively believing what Brian Childress told him about the safety, effectiveness, and regulatory history of the Device Components. Dr. Schubert should have known there was a significant problem with the Device Components because he was not given a package insert, assembly instructions, a surgical technique, or any written guidance to use when implanting them together. At no point did he inquire about the FDA status of the Device

Components or look at registry information overseas for them. Instead, Dr. Schubert decided to use Smith & Nephew's untested metal-on-metal device based primarily on the assurances of Brian Childress, a commission-based independent sales representative for the company.

27. Dr. Schubert knew or should have known that clinical studies and academic articles evaluating the safety of the Device Components were either nonexistent or were very limited in their patient population, duration and design. All of this misconduct and the limited experience with these relatively new devices should have made Dr. Schubert very concerned about the company and the safety history of its new products. Healthy skepticism should have been in order by September 28, 2009. A reasonable physician dealing with new devices and a relatively new company with this dubious criminal history should have used the new devices very cautiously, but Dr. Schubert instead created a metal-on-metal total hip implant without any knowledge about that device's safety and efficacy. A reasonable investigation would have revealed that the company he was blindly trusting and taking money from had recently paid illegal kickbacks to many hip implant surgeons before him, and that the alleged good safety experience with this exact product internationally was in part based on reports from surgeons who insisted on receiving cash payments in exchange for using Smith & Nephew's products.

28. Dr. Schubert was negligent for not disclosing various facts to Plaintiffs. He did not disclose that he was going to use implants in an off-label manner, that there was no safety or efficacy data available to support his continued use of the Device Components, or that he had never reviewed any product labeling for the Device Components. He also did not disclose that he was a highly-paid Smith & Nephew "consultant" and that he continued to do business with Smith & Nephew despite all the facts he knew or should have known about the company, its orthopedic products, and its ongoing criminal problems by September 2009. Had any of this been disclosed

to Plaintiffs, Tracy Fleming would not have consented to undergo the procedure that Dr. Schubert performed on him on September 28, 2009. The standard of care required Dr. Schubert to have a reasonable medical basis for combining these parts without informing the Plaintiff, and he failed to meet that standard, resulting in the implantation of the Device Components in Plaintiff.

VIII. NEGLIGENCE: THE SALES REP DEFENDANTS

29. Plaintiffs incorporate by reference the allegations above in Paragraphs 18 to 21 regarding the Sales Rep Defendants' misrepresentations to Dr. Schubert. The Sales Rep Defendants were negligent for:

- Failing to follow the basic requirements for off-label promotion of implantable medical devices, including the standards set forth in 21 C.F.R. Part 99, the Smith & Nephew Code of Conduct, their Sales Rep Agreement and extensive training with Smith & Nephew, and the AdvaMed Code of Conduct;
- Representing to Dr. Schubert that the Device Components were as effective as, or more effective than, competitors' devices;
- Representing to Dr. Schubert that the Device Components were as safe as, or safer than, competitors' devices;
- Removing the Device Components from boxes that noted the parts were cleared only for specific types of surgeries that plaintiff did not undergo, thereby concealing from Dr. Schubert the limited indications for use of these parts; and
- Concealing the true risks of the Device Components implanted in plaintiff by routinely failing to report complications and injuries associated with them.

30. The Sales Rep Defendants had a duty under Texas law to disclose to Dr. Schubert the truth about the safety of the Device Components because they were in a superior position to know the true regulatory history, quality, safety, and efficacy of its products. They were trained to only make representations to surgeons that were true and accurate, but they disregarded those obligations for the sake of increased sales if they could "convert" Dr. Schubert. Their marketing and distribution of the Device Components violated the Texas Food, Drug, and Cosmetic Act and the federal Food, Drug and Cosmetic Act ("Act"), and also violated regulations promulgated under

them (including those obligations under 21 C.F.R. § 201.6(a)). They also had a duty to promptly correct material misstatements they knew Dr. Schubert was relying on in making healthcare decisions, but they purposely chose not to do so.

31. The Sales Rep Defendants failed to exercise reasonable care to ensure that the information they disseminated to Dr. Schubert about the Device Components was accurate, complete, and not misleading. They also omitted material information and deliberately created a false impression about the safety, efficacy, and approval status of the Device Components. They also consistently and negligently under-reported product problems and withheld information about product problems. They also negligently misrepresented the efficacy and safety of the Device Components. This false information was disseminated to Dr. Schubert with the intention to deceive him and his patients and to induce him to prescribe the Device Components.

32. These representations and omissions went beyond mere sales "puffery," and such statements were a material factor in Dr. Schubert choosing to use the Device Components. Dr. Schubert's decision to implant the Device Components was based on misrepresentations the Sales Rep Defendants made to Dr. Schubert, including:

- Telling Dr. Schubert it was permissible to use the Device Components together;
- Bringing the Device Components to total hip arthroplasty and revision procedures on other patients of Dr. Schubert's, leading him to believe that they were safe to use together; and/or
- Bringing the Device Components to Plaintiff's initial total hip arthroplasty surgery, without telling Dr. Schubert that the FDA had not cleared them for use together.

33. The conduct of the Sales Rep Defendants resulted in Dr. Schubert using an unreasonably dangerous device in Plaintiff that was not FDA approved. The Sales Rep Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of the Sales Rep Defendants' failure to exercise ordinary care as described above. This conduct and these products placed Plaintiff in peril of developing serious, life-threatening, and

life-long injuries and requiring additional surgery. Had the Sales Rep Defendants exercised ordinary care, and complied with the then-existing standards of care, Plaintiffs would not have been injured because Dr. Schubert simply would not have selected the Device Components and would have chosen a safer option.

A. Failure to Warn

34. The product modification that occurred here was the result of the Sales Rep Defendants' intentional and knowing acts and omissions as described above in Paragraphs 18 to 21.

35. The Sales Rep Defendants directly promoted the use of the Device Components as a conventional total hip arthroplasty to Dr. Schubert. They failed to inform him that the Device Components were not intended or approved to be used together, and they actively led him to believe they could be used together. This conduct resulted in Dr. Schubert using unapproved parts that he would not have used if he had been adequately informed.

B. Negligence Per Se

36. Texas Health & Safety Code Chapter 431 incorporates much of the language of the federal FDCA. Specifically, Texas Health & Safety Code Chapter 431 prohibits:

- "[T]he introduction or delivery for introduction into commerce of any . . . device . . . that is adulterated or misbranded,"[4]
- "[T]he receipt in commerce of any . . . device . . . that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise,"[5]
- The "dissemination of any false advertisement,"[6]
- "[T]he using, . . . in any advertising relating to [a] device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under Section 431.114 or Section 505, 515, or 520(g) of the federal Act, as the case may be, or that such drug or device complies with the provisions

[4] TEX. HEALTH & SAFETY CODE Section 431.021(a).
[5] *Id.* Section 431.021(c).
[6] *Id.* Section 431.021(f).

of such sections,"[7] and

- "[T]he failure to register in accordance with Section 510 of the federal Act [or] the failure to provide any information required by Section 510(j) or (k) of the federal Act."[8]

37. Through their actions as alleged above, the Sales Rep Defendants violated Texas law and its statutorily-imposed duties by introducing misbranded[9] Device Components into state commerce, disseminating false advertisements[10] about the Device Components, and by making false representations about the approval status of the Device Components.

38. In addition, federal device regulations strictly control when the off-label promotion of medical devices is permitted. 21 C.F.R. Part 99 applies to the "dissemination of information" about drugs and devices where the information "concerns the safety, effectiveness, or benefit of a use" not included in the approved labeling or in the statement of intended use (if the device is cleared), 21 C.F.R. § 99.1(a), and that information is disseminated to a health care practitioner[11] or a group health plan. *Id.* § 99.1(b). Written information concerning the safety or effectiveness of a medical device must comply with certain requirements before it can be distributed[12] to health

[7] *Id.* Section 431.021(n).
[8] *Id.* Section 431.021(s).
[9] "[I]n the case of any restricted device distributed or offered for sale in this state," is misbranded if "its advertising is false or misleading in any particular." *Id.* Section 431.112(o)(1). As discussed above, many of the communications and representations made to Plaintiffs and Schubert were false or misleading.
[10] "If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or any combination of these, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof, or under such conditions of use as are customary or usual." *Id.* Section 431.003.
[11] Dr. Schubert falls within the definition of a "health care practitioner." *See* 21 C.F.R. § 99.3(d).
[12] These regulations apply to "manufacturers," which is defined as "A person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device." 21 C.F.R. § 99.3(f). The Sales Rep Defendants were licensed by Smith & Nephew, the manufacturer of the Device Components, to market the Device Components.

care practitioners, including:

- The information must be about a device that has been approved, licensed, or cleared for marketing by the FDA. *Id.* § 99.101(a)(1).
- The information must be in the form of (A) an unabridged reprint or copy of an article, peer-reviewed by experts, published in a scientific/medical journal, about a clinical investigation about the device, which is considered clinically sound, *id.* § 99.101(a)(2)(i), or (B) an unabridged reference publication about scientifically sound clinical data. *Id.* § 99.101(a)(2)(ii).
- The information must not pose a "significant risk to public health." 21 C.F.R. § 99.101(a)(3).
- The information must not be "false or misleading." *Id.* § 99.103(a)(4).
- the information must be accompanied by the device's "official labeling," *id.* § 99.103(a)(2), and include "A Bibliography of other articles covering the new use and information being disseminated," *id.* § 99.103(a)(3), and "Additional information required by § 301(a)(2), including a sticker/notation advising of the additional information." *Id.* § 99.103(a)(4).

39. Various additional documents must also be submitted to the FDA at least sixty days before disseminating off label information to healthcare practitioners. *Id.* § 99.201(a). The foregoing statutes apply to sales reps who modify written information through oral statements, and the Sales Rep Defendants did not comply with any of these requirements before engaging in off-label promotion of the Device Components.

40. Because of these statutory violations, Plaintiffs suffered injury, and the Sales Rep Defendants are negligent per se.

C. Proximate Cause

41. All of the acts and omissions described above were negligent, and they all resulted in a product design change and commercial distribution of an unreasonably dangerous product, in violation of the above and other laws. Tracy Fleming suffered the injuries herein described as a direct and proximate result of the above-described negligence in the marketing, distribution, and sale of the Device Components. All of the negligent acts and omissions alleged herein were a

proximate cause of the device failure and the injuries to the Plaintiffs, for which they sue the Defendants, jointly and severally.

IX. STRICT PRODUCTS LIABILITY: MARKETING DEFECT

42. The Sales Rep Defendants placed the Device Components into the stream of commerce, and they were surgically implanted in Tracy Fleming in a manner that the Sales Rep Defendants reasonably anticipated. The Sales Rep Defendants failed to comply with U.S. medical device regulations in that they marketed hip prostheses in the U.S. with an intended use that was neither cleared nor approved by federal regulators. The Device Components, when used together as part of a metal-on-metal total hip arthroplasty, failed at impermissibly high rates when implanted in patients, including when Dr. Schubert performed the implantation. The increased metal wear led to symptoms in patients, including Tracy Fleming, such as metallosis and osteolysis, eventually leading to invasive revision surgery. The Device Components, when used together, were defective, and in this case, failed within a few years of implantation—far sooner than the expected lifetime of a hip implant.

43. Written information must always be provided to the implanting surgeons and sometimes it is even provided directly to the patient. A medical device sold without adequate, intelligible warnings is defective. A medical device that the FDA repeatedly ordered the company not to sell is a product that is lacking adequate warnings unless the prescribing surgeon is advised of those important facts. Adequate written instructions did not accompany the Device Components and the FDA rejected[13] any efforts to obtain clearance to sell them. They were defective and

[13] The FDA was in the process of a fourth rejection of the company's application to market the Device Components at the time of the Plaintiff's surgery. One rejection, of the original MMT head, was on April 29, 2005. Smith & Nephew also withdrew an application on March 1, 2006 after the FDA rejected it and withdrew another one on March 21, 2007 after the FDA rejected it. The company withdrew its fourth and final application on February 24, 2010 after the FDA rejected it.

unreasonably dangerous for all of these reasons.

44. The Sales Rep Defendants promoted the Device Components as a metal-on-metal device in a total hip configuration. Off-label promotion is strictly prohibited by state and federal law except in very specific circumstances which are not implicated here. In this case, the warnings and "Surgical Techniques" provided with the device were inconsistent, outdated, and contradictory, because the parts came from three different device systems with different indications, intended uses, and regulatory histories. Because they promoted the use of the Device Components in an off-label manner to Dr. Schubert, the Sales Rep Defendants had a duty to provide a whole and complete disclosure about the Device Components, including regulatory status, risks, safety, and effectiveness. They failed to do this.

45. The Sales Rep Defendants provided none of the required information, instead permitting Dr. Schubert to believe that the FDA had deemed the Device Components to be safe and effective when they had not. The Device Components distributed to Tracy Fleming were defectively marketed because the warnings and instructions either were not provided to Dr. Schubert at all, or were hopelessly inconsistent and confusing.

46. The testimony of Dr. Schubert in previous litigation indicates that he was not informed that the Device Components were "off-label" for total hip arthroplasty applications. He was not informed that the FDA had specifically rejected this device for the procedure he used on Tracy Fleming. Such marketing defects in the warnings and instructions rendered the device unreasonably dangerous as marketed and were a producing cause of the damages and injuries sued for herein. Tracy Fleming's hip device required a revision surgery in April 2018 as a direct result of the defective Device Components.

X. DECEPTIVE TRADE PRACTICES

47. As described above, the behavior of the Sales Rep Defendants also constituted violations of the Texas Deceptive Trade Practices Consumer Protection Act ("DTPA"). All notice and pre-suit requirements for Brian Childress, and Neylu, Inc. have been complied with. The Sales Rep Defendants, through their illegal, negligent, and false marketing of the Device Components, violated the following sections of the DTPA:

- 17.46(b)(2): They caused confusion or misunderstanding as to the Device Components' approval and certification for use in a conventional THA;
- 17.46(b)(5): They represented that the Device Components had approval, characteristics, uses, or benefits which they did not have with regard to safety, effectiveness, FDA-status, approved uses, and indicated uses;
- 17.46(b)(7): They represented that the Device Components were of a particular standard, quality, or grade when they were not as represented;
- 17.46(b)(9): They advertised the Device Components as FDA-approved and indicated for use in traditional THAs with intent not to sell them as advertised;
- 17.46(b)(24): They intentionally failed to disclose material and relevant information concerning the Device Components which was known at the time they were implanted. They failed to disclose such information because they knew that no doctor or patient would accept the Device Components if such information had been disclosed.
- 17.50(a)(3): They engaged in an unconscionable action or course of action by intentionally and falsely marketing the Device Components to induce Plaintiff into consenting to their implantation in his body.

48. In addition, Plaintiffs allege that Brian Childress and Neylu, Inc. acted knowingly and intentionally, as those terms are used in Section 17.50(b)(1) of the DTPA. As a consequence of these knowing and intentional acts and omissions with regard to the marketing, sale, and implantation of the Device Components, Plaintiffs are entitled to recover actual damages from Brian Childress and Neylu, Inc. for their economic damages, mental anguish, attorneys' fees, and treble damages, as well as additional damages permitted by law.

XI. GROSS NEGLIGENCE

49. As described above, the Sales Rep Defendants engaged in a scheme to convince Dr. Schubert and Plaintiffs to choose the Device Components for implantation as a metal-on-metal

total hip arthroplasty. This was despite the known risks of metal-on-metal implants, the fact that the Device Components had no data supporting their safety or efficacy as used, and solely for the goal of making money. Promoting the Device Components for off-label use involved an extreme degree of risk because metal-on-metal components are likely to fail and are more likely to fail when there's no supporting evidence or FDA finding of safety and effectiveness. The Sales Rep Defendants knew this, but decided to promote this untested, uncleared, unapproved combination without giving any warnings or accurate information. This willful, reckless, careless, and cruel conduct amounts to gross negligence and caused the occurrence in question; it warrants the imposition of punitive or exemplary damages against Childress and Neylu to punish such conduct and to deter them and other "independent sales reps" from engaging in such conduct in the future.

XII. FRAUD

50. The Sales Rep Defendants approached Dr. Schubert sometime in 2008 and made material misrepresentations about the safety and effectiveness of the Device Components that were false, including the misrepresentations that are detailed above. The Sales Rep Defendants were in a superior position to know the true quality, safety, and efficacy of its products, and so either knew that these representations were false or that these statements were made recklessly without any knowledge of their truth and as a positive assertion. By actively promoting the off-label use of these devices together, the Sales Rep Defendants were obligated to fully and accurately disclose all information necessary to ensure that Dr. Schubert did not mistakenly believe that the Device Components were FDA-cleared or approved, or that such use was safe, effective, or supported by any data.

51. Brain Childress' misrepresentations about the regulatory status of the Device Components was intended to make Dr. Schubert believe that the parts had FDA approval or

clearance for use together as a conventional total hip arthroplasty. Any representation about the safety or effectiveness of the Device Components, especially when compared to other conventional total hip arthroplasties already commercially available in the U.S. at the time, were known to be false or at least made without knowledge of their truth. At the time of their conversation with Dr. Schubert as described above, the Sales Rep Defendants did not know of any clinical, medical, academic, or any other data that supported the use of the Device Components together. There is still no such evidence of safety even today.

52. The fraudulent, inaccurate, incomplete, and misleading statements identified in Paragraphs 18 to 21 above were disseminated to Dr. Schubert with the intention to deceive him and his patients to use the Device Components. They were designed to create a false impression about the safety, efficacy, and approval status of the Device Components. Such statements were a material factor in Dr. Schubert choosing to perform Tracy Fleming's hip replacement surgery using the Device Components.

53. The conduct of the Sales Rep Defendants foreseeably resulted in Dr. Schubert using an unreasonably dangerous and unapproved device in Plaintiff. Absent this conduct, Plaintiffs would not have been injured because Dr. Schubert simply would not have selected the Device Components and would have chosen a safer option, including but not limited to FDA-approved or cleared metal devices and/or devices using ceramic or polyethylene materials.

XIII. STATUTE OF LIMITATIONS EQUITABLY TOLLED

54. The Statute of Limitations applicable to the claims against Dr. Schubert was tolled by his negligent failure to obtain informed consent before the surgery in question. The statute of limitations for the claims against Dr. Schubert in this case does not begin to run until informed consent is obtained or full disclosure after surgery is provided.

55. In addition, a post-sale duty to disclose material risks existed in this case by virtue of the modular femoral head market withdrawal in March of 2015. The applicable statute of limitations against Dr. Schubert is equitably tolled under the facts of this case. Dr. Schubert knew as a matter of law—by March 2015 at the very latest—that the recalled parts implanted in Mr. Fleming had never been approved for this type of hip procedure. The failure of Dr. Schubert to notify the Plaintiff of the modular femoral head market withdrawal in 2015 amounts to fraudulent concealment just as surely as it would be fraudulent concealment not to reveal that a sponge or surgical instrument was left inside the patient.

56. All of these facts operate to toll, abate, or extend the statute of limitations that applies to the claims asserted herein against Dr. Schubert. This conduct serves to toll, abate, and suspend the continued running of the statute of limitations against Dr. Schubert until full disclosure is made.

XIV. DAMAGES

57. Tracy Fleming sues the Defendants, and each of them, for all damages he is entitled to sue them for under Texas law, including past and future medical expenses, past and future physical pain and suffering, past and future mental anguish, lost earnings, diminished earning capacity, and prejudgment and post-judgment interest. Tracy Fleming has suffered severe harmful effects including but not limited to partial loss of mobility and diminished range of motion. He also suffers and will continue to suffer personal injuries which are permanent and lasting in nature, including physical pain and mental anguish, diminished enjoyment of life and reasonable fear of future harm from the substantial amounts of metal particles and metal wear debris that were in his body for years. Tracy Fleming's left hip implant was surgically revised at great expense to him. Plaintiffs' damages are within the jurisdictional limits of this Court.

58. Plaintiff Norma Egea is Tracy Fleming's wife. She sues the Defendants, and each of them, for all damages she is entitled to sue them for under Texas law, including past and future loss of consortium and past and future loss of services. Plaintiffs' damages are within the jurisdictional limits of this Court.

XV. DEMAND FOR JURY TRIAL

59. Plaintiffs demand a jury trial of all issues of fact. A jury fee has been paid.

XVI. PRAYER

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that upon final trial of this matter, Plaintiffs have and recover of and from the Defendants the following:

a. Judgment for all of their recoverable damages as pleaded and as shown by the evidence;

b. Pre- and post-judgment interest as allowed by law;

c. Award of treble economic damages and mental anguish damages;

d. Award of exemplary damages against Brian Childress, and Neylu, Inc., in a sum determined by the trier of fact;

e. Reasonable and necessary attorneys' fees in prosecuting the DTPA allegations against the Sales Rep Defendants;

f. All costs of court; and

g. Such other and further relief, at law or in equity, to which Plaintiffs are justly entitled.

Respectfully submitted,

LAW OFFICE OF KIP PETROFF

By: _____/s/__Kip Petroff_____
Kip A. Petroff
State Bar No. 15851800
Caio Formenti

State Bar No. 24104676
10440 North Central Expressway, Suite 1540
Dallas, Texas 75231
Telephone: (972) 294-7530
Fax: (972) 294-7530
Email: kpetroff@petroffassociates.com
Email: caio@kippetroff.com
ATTORNEYS FOR PLAINTIFFS

Certificate of Service

I hereby certify that on April 12, 2019, a true and correct copy of the foregoing document has been served by email only on the attorneys of record for the Defendants as follows: Defendant**s Brian Childress** and **Neylu, Inc.,** to: Mr. Brian P. Johnson, Ms. Kealy C. Sehic, Mr. David W. O'Quinn, and Ms. Leila D'Aquin; Defendant **Richard D. Schubert, M.D,** to: Mr. David Criss and Ms. Alexandra Sallade.

_____/s/ _____
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