

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

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OSA GREEN,		:
		:
	Plaintiff,	:
		:
	v.	:
		:
DEPUY ORTHOPAEDICS, INC.; DEPUY		:
SYNTHESES, INC.; DEPUY SYNTHESES		:
PRODUCTS, INC.; DEPUY SYNTHESES SALES,		:
INC. d/b/a DEPUY SYNTHESES JOINT		:
RECONSTRUCTION; DEPUY		:
INTERNATIONAL, LTD.; and		:
JOHNSON & JOHNSON,		:
		:
	Defendants.	:
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Civil Action No.: _____

**COMPLAINT AND JURY TRIAL
DEMAND**

COMPLAINT

Plaintiff Osa Green (hereinafter referred to as “Plaintiff”), by and through her undersigned attorneys, hereby files this Complaint and alleges against Defendants as follows:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Osa Rayfield Green is an adult resident of Alexandria, Louisiana.
2. Defendant DePuy Orthopaedics, Inc. (“DePuy”) is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582. DePuy is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.
3. Defendant DePuy Synthes, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581.

4. Defendant DePuy Synthes Products, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767.

5. Defendant DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction (“DSS”) is and, at all times relevant, was a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767.

6. Defendant DePuy International, Ltd. is a public entity or corporation organized and existing under the laws of the United Kingdom, with its principal place of business at St. Anthony’s Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United Kingdom.

7. Defendant Johnson & Johnson is and was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. At all relevant times, each Defendant was the representative, agent, employee or alter ego of the other Defendant, and in doing the things alleged herein was acting within the scope of its authority as such.

9. Jurisdiction is based upon diversity of citizenship and jurisdictional amount pursuant to 28 U.S.C. §§ 1332 and 1333.

10. A substantial part of the events and omissions giving rise to Plaintiff’s causes of action occurred in the Western District of Louisiana.

11. Pursuant to 28 U.S.C. § 1391, venue is proper in the United States District Court for the Western District of Louisiana.

BACKGROUND

12. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis.

13. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Knee replacement technology can provide a solution to the pain and restore basic function to those implanted. The knee replacement implants designed and approved in the 1990s met the goals of reducing pain and restoring function with low failure rates.

14. Total knee arthroplasty (“TKA”), also called total knee replacement (“TKR”), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

15. In a total knee replacement surgery, sometimes referred to as “arthroplasty,” physicians replace the joint surfaces and damaged bone and cartilage with artificial materials. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and thus reduces pain while improving the joint’s function. Replacement requires a mechanical connection between the bones and the implant components.

16. Bone cement, or epoxy, is used to attach components of the new artificial knee joint to the femur (thigh bone) and tibia (shin bone). Bone Cement includes a powder and a liquid that must be combined. The powder component consists mainly of polymer poly (methyl methacrylate) (“PMMA”) and includes a radiopacifier to make the cement visible on x-rays. The liquid component is a methyl methacrylate (“MMA”) monomer which is added to the powder to create a heat-generating (exothermic) reaction.

17. Cement “viscosity” determines the handling and working properties of the cement. Bone cement may be divided into three kinds: low, medium, and high viscosity (“HV”).

18. SmartSet GHV Gentamicin Bone Cement (“SmartSet GHV”), the product at issue, is a high viscosity cement.

19. According to Defendants, “SmartSet HV Bone Cement was first launched in 2003 together with a variant of the cement containing the active substance Gentamicin.”

20. In February 2004, Defendants received FDA clearance of the SmartSet GHV Bone Cement under the “510k” notification process. The basis for FDA clearance of SmartSet GHV Bone Cement was substantial similarity to prior bone cements, including, but not limited to, DePuy 1 Gentamicin and Simplex P with Tobramycin.

21. According to the 510(k) Summary of SmartSet GHV Bone Cement, under the Section titled “Substantial Equivalence,” it states that “[t]he determination of substantial equivalence for this device was based on a detailed device description, product testing and conformance with voluntary performance standards.”

22. However, SmartSet GHV Bone Cement was and is less effective, and more prone to failure, than the previously-approved bone cements, including DePuy 1 Gentamicin and Simplex P with Tobramycin. Defendants received FDA 510(k) approval of the SmartSet GHV

Bone Cement in February 2004 with only very limited, if any, testing of the new HV bone cement.

23. According to the *Journal of Arthroplasty*, recent medical literature has shown that HV bone cements, including SmartSet HV Bone Cements, are causing tibial component debonding, even when utilized with historically well-performing knee implants.

24. Another case report published in *Knee Surgery, Sports Traumatology, Arthroscopy* found the tibial component loosened and debonded at the implant-cement interface in patients who received HV bone cement, including SmartSet HV Bone Cements. The case report explained that surgeons discontinued use of the HV bone cement and returned to using non-HV cement, including Simplex P, in which no cases of cement-implant debonding have been observed.

25. According to the Orthopaedic Research Society, researchers found HV cement less effective than low-viscosity or medium-viscosity bone cements (“non-HV”).

26. Also, medical literature has shown that antibiotics, such as the use of gentamicin in SmartSet GHV Bone Cement, has no statistical effect on the strength and ductility of bone cement materials. For this reason, SmartSet HV and SmartSet GHV are equivalent and share similar characteristics in mechanical properties and structural strength.

27. The primary reason the SmartSet GHV Bone Cement fails is mechanical loosening. The mechanical loosening is caused by a failure of the bond between the tibial baseplate at the implant-cement interface. Mechanical loosening means that the attachment between the artificial knee and the existing bone has become loose. Such loosening will eventually result in failure of the device. Mechanical loosening, as shown by recent studies, has

occurred at a significantly increased rate in patients implanted with HV bone cement, including the SmartSet GHV Bone Cement.

28. A loose artificial knee generally causes pain and wearing away of the bone. It can severely restrict a patient's daily activities as it can involve a severe physical and emotional burden for the patient.

29. Once the pain becomes unbearable or the individual loses function of the knee, another operation, often called a "revision surgery," may be required to remove the knee implant and replace it with a new one.

30. Unfortunately, a failed total knee prosthesis often causes severe bone loss. Therefore, revision surgeries on a failed total knee due to loosening often require reconstruction of the severe bone loss.

31. The success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including limitations in range of motion, the ability to walk, and even death.

32. Defendants knew or should have known about the early failure rates and safety issues with its HV Bone Cements, including SmartSet GHV Bone Cement.

33. Despite Defendants' knowledge of early failures, Defendants continue to represent that its HV bone cements, including SmartSet HV Bone Cement, are safe and effective. For instance, Defendants have made the following representations to consumers and physicians regarding their HV bone cements:

(a) "Available in medium and high viscosity formulations, with and without Gentamicin, SMARTSET Bone Cements were developed to meet the needs of today's orthopaedic surgeons."

(b) “SMARTSET GHV Gentamicin Bone Cement has greater fatigue strength than Palacos R+G Gentamicin bone cement (Zimmer) and Cobalt HV Gentamicin bone cement (Biomet).”

(c) “Fatigue life is influenced by a variety of factors, one of which is the method of sterilization. SMARTSET MV Bone Cement and GMV Gentamicin Bone Cement and SMARTSET HV Bone Cement and GHV Gentamicin Bone Cements are sterilized with ETO which preserves the molecular weight of the polymer chains. This leads to improved fatigue strength over cements that are Gamma sterilized.”

(d) “Gentamicin has long been the preferred choice for inclusion in antibiotic bone cements. The gentamicin used in *DePuy Synthes’* Bone Cements has been selected to optimize drug release and maintain mechanical properties like fatigue strength.”;

(e) “For high-viscosity needs, choose SmartSet HV Bone Cement.”

(f) DePuy’s high-viscosity bone cements, including the SmartSet GHV Bone Cement, “impart excellent fatigue strength, antibiotic elution, and handling properties.”

34. Although Defendants knew about the high number of SmartSet GHV Bone Cement early failures resulting in revision surgeries, Defendants failed to warn surgeons, consumers and patients, and allowed, marketed, and promoted the defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients, including Ms. Green and her physicians.

FEDERAL REQUIREMENTS

35. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or

controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

36. Pursuant to federal law, a device is deemed to be misbranded if, among other things, other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

37. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360i.

38. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practice (“CGMP”), as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. *See* 21 U.S.C. § 360j(f).

39. The federal regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 et seq. As explained in the Federal Register, because the CGMP regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

40. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act (“the Act”) (21 U.S.C. § 351).

41. The regulations under 21 CFR Part 820 include, but are not limited to, and require Defendants to:

(a) establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. 21 CFR § 820.5;

(b) establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. 21 CFR § 820.30(a);

(c) establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. 21 CFR § 820.30(d);

(d) establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements. 21 CFR § 820.30(f);

(e) establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation. 21 CFR § 820.30(i); and

(f) develop, conduct, control, and monitor production process to ensure that a device conforms to its specifications. 21 CFR § 820.70(a).

42. Upon information and belief, Defendants' SmartSet GHV Bone Cement is adulterated pursuant to 21 U.S.C. § 351 because, among other things, Defendants failed to comply with the numerous regulations under 21 CFR § 820 regarding product design and manufacturing.

43. Upon information and belief, Defendants' SmartSet GHV Bone Cement is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

44. As a result of Defendants' failure to establish and maintain CGMP, Defendants' SmartSet GHV Bone Cement was defective and failed, resulting in a failure to properly adhere to the bone and/or prosthetic device, causing loosening of the device, and injury to Plaintiff.

45. Upon information and belief, Defendants' SmartSet GHV Bone Cement Gentamicin is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

CASE SPECIFIC FACTUAL ALLEGATIONS

46. On August 25, 2016, Osa Green underwent right-sided total knee replacement surgery performed by Dr. Terry C. Texada at Central Louisiana Surgical Hospital in Alexandria, Louisiana. Ms. Green was implanted with DePuy PFC Sigma components.

47. On August 25, 2016, in order to bond these components, Dr. Texada utilized the defective SmartSet GHV Bone Cement (Ref # 54503500), which was designed, manufactured, marketed, distributed, labeled, marketed and sold throughout the United States by the Defendants. The SmartSet GHV Bone Cement was purchased by Ms. Green and this action relates to the SmartSet GHV Bone Cement.

48. After the SmartSet GHV Bone Cement was implanted, Ms. Green began experiencing severe and persistent pain, discomfort, instability and difficulty ambulating caused by aseptic loosening caused by the defective SmartSet GHV Bone Cement.

49. On August 16, 2017, Dr. Timothy Randell evaluated Ms. Green's knee and performed a bone scan. The bone scan was positive for evidence of loosening of the tibial component. Dr. Randell discussed this with Ms. Green and ultimately planned to proceed with right-sided revision surgery.

50. On September 28, 2017, Ms. Green underwent revision surgery due to loosening of her knee components caused by the defective SmartSet GHV Bone Cement implanted in her right knee. This surgery was performed by Dr. Randell at Christus St. Frances Cabrini Hospital in Alexandria, Louisiana. In this procedure, Dr. Randell assessed the implant components and found "[t]he tibial component was loose." Further, Dr. Randell chose to utilize Simplex P bone cement, a non-HV bone cement, to bond the new Stryker Triathlon components.

51. Neither Ms. Green nor her physicians were aware, by warning or otherwise, of the defects of the SmartSet GHV Bone Cement, and would not have used the SmartSet GHV Bone Cement in the original total knee replacement surgery had they been aware of the defective nature of the product.

52. As a direct and proximate result of Defendants placing the defective SmartSet GHV Bone Cement in the stream of commerce, Ms. Green has suffered and continues to suffer both injuries and damages, including, but not limited to past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative, monitoring, and pharmaceutical expenses, economic damages, severe and possibly permanent injuries, and other related damages.

53. All of the injuries and complications suffered by Ms. Green were caused by the defective design, warnings, construction, and unreasonably dangerous character of the SmartSet GHV Bone Cement. Had Defendants not concealed the known defects, the early failure rate, the known complications, and the unreasonable risks associated with the use of the SmartSet GHV Bone Cement, Ms. Green would not have consented to the SmartSet GHV Bone Cement being used in her total knee arthroplasty.

LIABILITY UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

54. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

55. Under the Louisiana Products Liability Act, Plaintiff shows that the serious risk of failure of the SmartSet GHV Bone Cement and other related injuries are the direct and proximate result of breaches of obligations owed by Defendants to Plaintiff, including defects in design,

marketing, manufacturing, distribution, instructions and warnings by Defendants, which breaches and defects are listed more particularly, but not exclusively, as follows:

(a) Failure to instruct and/or warn of the serious risk of loosening of the tibial baseplate and failure of the SmartSet GHV Bone Cement resulting in injuries;

(b) Failure to adequately instruct and/or warn healthcare providers, including those healthcare providers who utilized the SmartSet GHV Bone Cement in Plaintiff, of the serious risk of loosening of the tibial baseplate and failure of the SmartSet GHV Bone Cement resulting in injuries;

(c) Manufacturing, producing, promoting, creating, and/or designing the SmartSet GHV Bone Cement without adequately testing it;

(d) Failing to provide adequate warning of the dangers associated with the SmartSet GHV Bone Cement;

(e) The defects in designing, researching, developing, manufacturing, marketing, promoting and selling a medical device when it knew or reasonably should have known of the high risk of loosening and failure;

(f) Defendants' liability under the Louisiana Products Liability Act as a result of its design, development, manufacture, marketing, labeling and sale of a medical device which is defective and unreasonably dangerous;

(g) The continued production and sale of the SmartSet GHV Bone Cement given the propensity of the medical device to loosen and fail at high rates resulting in subsequent surgery and injuries;

(h) Providing inaccurate labeling and inadequate warnings and instructions with the SmartSet GHV Bone Cement;

(i) Other breaches and defects which may be shown through discovery or at trial; and

(j) Generally, the failure of Defendants to act with the required degree of care.

56. At all times relevant, Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the SmartSet GHV Bone Cement into the stream of commerce, including a duty to assure that the SmartSet GHV Bone Cement did not pose a significantly increased risk of bodily harm to its users as well as a duty to comply with federal requirements. Defendants breached this duty.

57. Defendants owed a duty to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the SmartSet GHV Bone Cement, and otherwise distributing the SmartSet GHV Bone Cements. Defendants breached this duty.

58. Defendants owed a duty of care to provide adequate warnings and instructions to the physicians, providers, suppliers, patients, distributors, or other end users of the SmartSet GHV Bone Cement. Defendants breached this duty.

59. Defendants performed inadequate evaluation and testing on the SmartSet GHV Bone Cement where such evaluation and testing would have revealed the propensity of the tibial baseplate to detach, disconnect and ultimately fail causing pain, swelling, instability and other complications and injuries that Plaintiff has experienced.

60. Prior to and after the date of Plaintiff's initial knee replacement surgery in which the SmartSet GHV Bone Cement was utilized and implanted, the Defendants were on notice that

the SmartSet GHV Bone Cement caused serious complications, including debonding and detachment at the tibial baseplate – cement interface.

61. Defendants had a duty to perform post-marketing testing of the SmartSet GHV Bone Cement; investigate the root cause of these complications; suspend sales and distribution; and warn physicians and patients of the propensity of SmartSet GHV Bone Cement to debond, detach and fail. Defendants breached this duty.

62. Plaintiff, as a purchaser of an SmartSet GHV Bone Cement, is within the class of persons that the statutes, regulations and obligations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes, regulations, and obligations are designed to prevent.

63. Defendants knew or should have known that the Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

64. As a direct and proximate result of Defendants' breach of the Louisiana Products Liability Act, Plaintiff suffered serious physical and mental injury, harm, damages, including but not limited to past, present, and future medical expenses and economic loss and will continue to suffer harm, damages, and economic loss in the future.

COUNT I
(Design Defect under LSA-RS 9:2800.56)

65. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

66. At all times herein mentioned, the SmartSet GHV Bone Cement researched, designed, manufactured, tested, advertised, promoted, marketed, packaged, labeled, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiff.

67. The SmartSet GHV Bone Cement was expected to and did reach the usual consumers, handlers, and persons, including Plaintiff, coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by Defendants.

68. At all times herein, the SmartSet GHV Bone Cement researched, designed, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition when it left Defendants' possession and entered the stream of commerce. As designer, manufacturer, and/or seller of such medical devices, Defendants had a duty to design, manufacture, and sell devices that would not cause harm to users, including Plaintiff.

69. The SmartSet GHV Bone Cement's unsafe, defective, and inherently dangerous condition was a cause of the injuries to the Plaintiff.

70. At all times herein mentioned, the SmartSet GHV Bone Cement failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

71. The SmartSet GHV Bone Cement is defective in design of both the liquid formulation and the powder component because of the HV Bone Cement's propensity to cause loosening, failure, and repeat surgical procedures, including revision surgery, resulting in additional bone loss and other complications.

72. The SmartSet GHV Bone Cement is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other non-HV Bone Cements.

73. Plaintiff is and was a foreseeable user of the SmartSet GHV Bone Cement.

74. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of the SmartSet GHV Bone Cement. Further, in no way could Plaintiff have known that Defendants had designed, developed and manufactured the SmartSet GHV Bone Cement in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

75. The SmartSet GHV Bone Cement is and was being used in the Defendants' intended manner at the time it was surgically implanted into Plaintiff and during the time it remained in Plaintiff.

76. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

77. Defendants knew or should have known that the SmartSet GHV Bone Cement would be implanted in patients and that physicians and patients were relying on them to furnish a suitable product.

78. Defendants knew and foresaw, or should have known or foreseen, that patients in whom the SmartSet GHV Bone Cement would be implanted, such as Plaintiff, could be and should have been affected by the defective design and composition of the SmartSet GHV Bone Cement.

79. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

80. As a direct and proximate result of Defendants' placement of the defective SmartSet GHV Bone Cement into the stream of commerce and Plaintiff's use of the defective

SmartSet GHV Bone Cement as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical and mental injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future including all damages available under the Louisiana Products Liability Act.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

COUNT II
(Inadequate Warning Under LSA-RS 9:2800.57)

81. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

82. At all times material hereto, the Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or introduced the SmartSet GHV Bone Cement into the stream of commerce knowing the devices would then be utilized and implanted in patients in need of a knee prosthesis. In the course of the same, Defendants directly advertised and/or marketed the product to health care professionals and consumers, including the Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of the SmartSet GHV Bone Cement. Defendants breached this duty.

83. The SmartSet GHV Bone Cement was expected to, and did, reach the Plaintiff without substantial change or adjustment in its condition as designed, manufactured, and sold by the Defendants.

84. The SmartSet GHV was in an unreasonably dangerous and defective condition when it left the hands of the Defendants and posed a threat to any user of the device when put to its intended and reasonably anticipated use.

85. The SmartSet GHV Bone Cement is defective due to inadequate warning because Defendants knew or should have known that the SmartSet GHV Bone Cement could fail in patients therefore giving rise to physical injury, pain and suffering, and the potential need for a revision surgery to replace the defective device with the attendant risks of complications from such further surgery, but failed to give consumers adequate warning of such risks.

86. Defendants failed to timely and reasonably warn Plaintiff and Plaintiff's physicians of material facts regarding the safety and efficacy of the SmartSet GHV Bone Cement. Had Defendants done so, proper warnings would have been heeded and healthcare professionals, including Plaintiff's physicians, would not have used the SmartSet GHV Bone Cement, and consumers, including Plaintiff, would not have purchased and/or used the SmartSet GHV Bone Cement.

87. The SmartSet GHV Bone Cement was defective due to inadequate warnings and/or instructions because, after Defendants knew or should have known that there was reasonable evidence of an association between the SmartSet GHV Bone Cement and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to healthcare professionals and the consumer public, including Plaintiff and Plaintiff's physician, and continued to actively promote the SmartSet GHV Bone Cement.

88. Defendants' acts and omissions constitute an adulteration, misbranding, or both, and constitute a breach of duty.

89. Defendants failed to provide adequate and timely warnings regarding the SmartSet GHV Bone Cement and its known defects, including but not limiting to the propensity for mechanical loosening caused by a failure of the bond of the tibial baseplate.

90. In addition, Defendants acquired knowledge of a characteristic of the SmartSet GHV Bone Cement, including loosening of the tibial baseplate, that may cause damage and the danger of such characteristic, or the Defendants would have acquired such knowledge had the Defendants acted as reasonably prudent manufacturers. Accordingly, Defendants are liable for the damages caused by their subsequent failure to use reasonable care to provide an adequate warning regarding such characteristics and their dangers to users and handlers of the SmartSet GHV Bone Cement.

91. As a direct and proximate result of Defendants' placement of the defective SmartSet GHV Bone Cement into the stream of commerce and Plaintiff's use of the defective SmartSet GHV, Plaintiff suffered serious physical and mental injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

COUNT III
(Construction/Composition Defect under LSA-RS 9:2800.55)

92. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

93. SmartSet GHV Bone Cement is, and was at all relevant times, unreasonably dangerous due to its propensity to result in failure of the device and was unreasonably dangerous in construction or composition.

94. The SmartSet GHV Bone Cement surgically implanted in Plaintiff was defective in its construction and/or composition when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that could fail in patients therefore giving rise to physical injury, pain and suffering, and the potential need for a revision surgery to replace the knee implant device with the attendant risks of complications from such further surgery.

95. Defendants knew or should have known that the SmartSet GHV Bone Cements could fail in patients therefore giving rise to injury.

96. As a direct and proximate result of the defective manufacture or construction of the Defendants' SmartSet GHV Bone Cement and Plaintiff's use of the defective SmartSet GHV Bone, Plaintiff suffered serious physical and mental injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

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

97. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

98. Defendants made and continue to make representations to consumers, including Plaintiff and/or her physicians, regarding the character or quality of the SmartSet GHV Bone

Cement, including, but not limited to, statements that the SmartSet GHV Bone Cements are a safe and effective bone cement, with safety and efficiency features similar to other bone cements.

99. The SmartSet GHV Bone Cement was defective in that it did not conform to Defendants' representations.

100. Plaintiff and/or Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of the SmartSet GHV Bone Cement.

101. As a direct and proximate result of Defendants' placement of the defective SmartSet GHV Bone Cement into the stream of commerce and Plaintiff's use of the defective SmartSet GHV, Plaintiff suffered serious physical and mental injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

COUNT V
(Breach of Warranty in Redhibition)

102. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.

103. The SmartSet GHV Bone Cement contains a vice or defect which renders it useless or its use so inconvenient that consumers, including Plaintiff, would not have purchased it had they known about the vice or defect.

104. Pursuant to Louisiana Civil Code Article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The SmartSet GHV Bone Cement, which was sold and promoted by Defendants, possess a redhibitory defect because it is unreasonably dangerous,

as described above, which renders the SmartSet GHV Bone Cement useless or so inconvenient that it must be presumed that Plaintiff would not have bought the SmartSet GHV Bone Cement had she known of the defects.

105. Defendants were aware of the substantial risk of failure of the SmartSet GHV Bone Cement but failed to fully disclose those risks to Plaintiff.

106. In accordance with Louisiana Civil Code article 2545, Defendants, as the manufacturers, distributors and sellers of the SmartSet GHV Bone Cement, are deemed to be aware of its redhibitory defects.

107. Had Plaintiff been made aware of the defects contained in the SmartSet GHV Bone Cement, she would not have purchased the device. The loosening of the tibial baseplate cause by the defective SmartSet GHV Bone Cement is a characteristic that renders it unfit for its intended purpose.

108. Defendants are liable to Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff a product unfit for its intended use.

109. Plaintiff is entitled to the return of purchase price paid for the SmartSet GHV Bone Cement, as well as any other legal and equitable relief to which Plaintiffs may be entitled.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages, and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, individually and collectively, jointly and severally, as follows:

1. Trial by jury;
2. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;
3. Compensation for economic and non-economic damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, and pain and suffering;
4. For reasonable attorneys' fees and costs;
5. For pre-judgment interest; and
6. For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: June 13, 2018

Respectfully Submitted,

/s/ M. Palmer Lambert
M. Palmer Lambert (La. Bar 33228)
**GAINSBURGH, BENJAMIN, DAVID,
MEUNIER & WARSHAUER, L.L.C.**
2800 Energy Centre
1100 Poydras Street
New Orleans, Louisiana 70163
Phone: (504) 522-2304
Fax: (504) 528-9973
Email: plambert@gainsben.com

-and-

W. Roger Smith, III
Ryan J. Duplechin
**BEASLEY, ALLEN, CROW,
METHVIN, PORTIS & MILES, P.C.**
(Pending Admission Pro Hac Vice)
Post Office Box 4160
Montgomery, Alabama 36103-4160
Phone: (334) 269-2343
Fax: (334) 954-7555
Email: Roger.Smith@BeasleyAllen.com

Counsel for Plaintiff

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

OSA GREEN

(b) County of Residence of First Listed Plaintiff Rapides, LA (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) M. Palmer Lambert of GAINSBURGH, BENJAMIN, DAVID, MEUNIER & WARSHAUER, L.L.C., 2800 Energy Centre, 1100 Poydras Street, New Orleans, Louisiana 70163; Phone: (504) 522-2304

DEFENDANTS

DEPUY ORTHOPAEDICS, INC., et al.

County of Residence of First Listed Defendant Kosciusko County, IN (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location (Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation).

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District (specify), 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. § 1332 (Diversity)
Brief description of cause: Products Liability, Personal Injury

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: X Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 06/13/2018 SIGNATURE OF ATTORNEY OF RECORD /s/ M. Palmer Lambert

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Louisiana

OSA GREEN,

Plaintiff(s)

v.

DEPUY ORTHOPAEDICS, INC., et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) DePuy Orthopaedics, Inc.
Through its agent for service of process:
CT Corporation System
150 West Market St., Suite 800
Indianapolis, IN 46204

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

M. Palmer Lambert
GAINSBURGH, BENJAMIN, DAVID,
MEUNIER & WARSHAUER, L.L.C.
2800 Energy Centre
1100 Poydras Street
New Orleans, Louisiana 70163

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Louisiana

OSA GREEN,

Plaintiff(s)

v.

DEPUY ORTHOPAEDICS, INC., et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) DePuy Synthes, Inc.
Through its agent for service of process:
CT Corporation System
150 West Market Street, Suite 800
Indianapolis, IN 46204

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

M. Palmer Lambert
GAINSBURGH, BENJAMIN, DAVID,
MEUNIER & WARSHAUER, L.L.C.
2800 Energy Centre
1100 Poydras Street
New Orleans, Louisiana 70163

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

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I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____; or

I returned the summons unexecuted because _____; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Louisiana

OSA GREEN,

Plaintiff(s)

v.

DEPUY ORTHOPAEDICS, INC., et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) DePuy Synthes Products, Inc. Through its agent for service of process: CT Corporation System 155 Federal St., Suite 700 Boston, MA 02110

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

M. Palmer Lambert GAINSBURGH, BENJAMIN, DAVID, MEUNIER & WARSHAUER, L.L.C. 2800 Energy Centre 1100 Poydras Street New Orleans, Louisiana 70163

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
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I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 _____ .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Louisiana

OSA GREEN,

Plaintiff(s)

v.

DEPUY ORTHOPAEDICS, INC., et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction Through its agent for service of process: CT Corporation System 155 Federal St., Suite 700 Boston, MA 02110

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

M. Palmer Lambert GAINSBURGH, BENJAMIN, DAVID, MEUNIER & WARSHAUER, L.L.C. 2800 Energy Centre 1100 Poydras Street New Orleans, Louisiana 70163

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

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I returned the summons unexecuted because _____ ; or

Other *(specify)*:

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Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Louisiana

OSA GREEN,

Plaintiff(s)

v.

DEPUY ORTHOPAEDICS, INC., et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

M. Palmer Lambert
GAINSBURGH, BENJAMIN, DAVID,
MEUNIER & WARSHAUER, L.L.C.
2800 Energy Centre
1100 Poydras Street
New Orleans, Louisiana 70163

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CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

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Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Louisiana

OSA GREEN,

Plaintiff(s)

v.

DEPUY ORTHOPAEDICS, INC., et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) DePuy International, Ltd.
St. Anthony's Road
Beeston
Leeds
West Yorkshire, LS11 8DT, United Kingdom

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

M. Palmer Lambert
GAINSBURGH, BENJAMIN, DAVID,
MEUNIER & WARSHAUER, L.L.C.
2800 Energy Centre
1100 Poydras Street
New Orleans, Louisiana 70163

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CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

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