UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA

JOAN CONBOY MILLER,	)	
	)	
	)	
Plaintiff,	)	JURY TRIAL DEMANDED
	)	
v.	)	
	)	Civil Action No.
DePUY ORTHOPAEDICS, INC., DePUY PRODUCTS, INC., JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC.,	)	
	)	
Defendants.	)	

COMPLAINT AND JURY DEMAND

Plaintiff, **Joan Conboy Miller,** brings this Complaint against DePuy Orthopaedics, Inc. ("DePuy Orthopaedics"), DePuy Products, Inc. ("DePuy Products"), Johnson & Johnson, and Johnson & Johnson Services, Inc. (hereinafter collectively referred to as "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages suffered by Joan Conboy Miller as a direct and proximate result of Defendants' defective development, design, testing, manufacturing, distribution and sale of the DePuy Prodigy stem.

2. Joan Conboy Miller has suffered and continues to suffer very serious bodily injuries, including pain and suffering as a direct and proximate result of the defective DePuy Prodigy stem implanted on or about October 8, 2006.

THE PARTIES

3. Plaintiff, Joan Conboy Miller, is a resident and citizen of Raleigh, North Carolina.

4. Defendant, DePuy Orthopaedics, Inc. 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 at 700 Orthopedic Drive, Warsaw, Indiana 46581.

5. At all times relevant, DePuy Products, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the DePuy Prodigy stem, as well as monitoring and reporting adverse events. DePuy Products, Inc. had a role in the decision process and response of the Defendants, if any, related to these adverse events.

6. Upon information and belief, Defendant DePuy Orthopaedics, Inc. is a wholly owned subsidiary of DePuy Products, Inc. which in turn is a subsidiary of Johnson & Johnson.

7. Defendant DePuy Products, Inc. is, and at all times relevant was, a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at 700 Orthopedic Drive, Warsaw, Indiana 46581.

8. Defendant Johnson & Johnson Services, Inc., is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

9. Defendant Johnson & Johnson is a publicly traded corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

10. As DePuy's most senior parent company, Johnson & Johnson was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the DePuy Prodigy stem, as well as monitoring and reporting adverse events. Johnson & Johnson had a role in the decision process and response of the Defendants, if any, related to these adverse events.

11. At all times relevant, each of the Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and was acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

JURISDICTION AND VENUE

12. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The amount in controversy exceeds $75,000 exclusive of interest and costs, and this is an action by an individual Plaintiff against Defendants who are citizens of different states.

13. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

14. A natural hip joint is created by the femoral head, the bone at the top of the thigh bone, or femur, which rotates within the hip socket or acetabulum.

15. To place a Prodigy stem, the surgeon removes the patient's natural femoral head and places the Prodigy stem into the patient's natural femur.

16. DePuy gained market approval of the Prodigy stem through the FDA 510(k) process on or about July 7, 2000.

17. The 510(k) approval process by the FDA is regarded as a simplified application process, which does not require extensive review and approval by the FDA. A 510(k) is a pre-market submission made to the FDA by the manufacturer to demonstrate that the device to be marketed is "substantially equivalent" to a previously marketed device (known as the "predicate device") and is at least as safe and effective as the predicate device.

18. During this process the manufacturer states that the device to be marketed does not raise any new significant safety concerns.

19. This 510(k) pre-market approval process is reliant on the testing and integrity of the manufacturer of the device.

20. Upon information and belief, DePuy received numerous reports of failures of Prodigy stems prior to the date of Plaintiff's implant and revision similar to the failure alleged by Plaintiff.

21. At the same time, there were and are safer alternative artificial hip products readily available in the marketplace from other manufacturers which do not have elevated failure rates.

22. Based on information and belief, the true failure rates of these devices is substantially higher than what has been reported to date by the Defendants and/or the FDA.

FEDERAL REQUIREMENTS

23. 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.

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

25. 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 a death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to a death or serious injury. Federal law also requires the FDA to establish regulations requiring a manufacturer of a medical device to promptly report to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation federal law which may present a risk to health. *See* 21 U.S.C. § 360i.

26. 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, packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe, effective and otherwise in compliance with federal law. *See* 21 U.S.C. §360j(f).

27. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 *et seq*. The Federal Register explains that the Current Good Manufacturing Practice (CGMP) regulations do not prescribe the details of how a manufacturer must produce a device because the regulations must apply to a variety of medical devices. 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 process 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.

28. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provisions in section 820 renders a device adulterated under section 501(h) of the Act. *See* 21 U.S.C. § 351.

29. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. *See* 21 CFR § 820.3(v).

30. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

31. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

32. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

33. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

34. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, batches, or their equivalents. Design validations shall ensure that the devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

35. Pursuant to 21 CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

36. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation.

37. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

38. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification method, process, or procedure.

39. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to

have an adverse effect on product quality, including periodic inspection of environmental control systems to verify that the system, including necessary equipment, is adequate and functioning properly.

40. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or products by substances that could reasonably be expected to have an adverse impact on quality.

41. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

42. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality in order to ensure that it is removed or limited to an amount that does not adversely effect the device's quality.

43. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer is required to validate computer software for its intended use according to an established protocol.

44. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer must establish and maintain procedures to ensure that equipment is calibrated, inspected, checked, and maintained.

45. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspections and testing, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing, by objective evidence, that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

46. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring internal processes and establish control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualifies persons.

47. Pursuant to 21 CFR § 820.90, each manufacturer also must establish and maintain procedures to control products that do not conform to specified requirements.

48. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventative actions.

49. Based on information and belief, Defendants' Depuy DePuy Prodigy stem is adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage or installation and are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

50. Based on information and belief, Defendants' Prodigy stem is misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

51. Based on information and belief, Defendants' Prodigy stem is adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for its Prodigy stem in accordance with 21 CFR § 820 *et seq.*, as set forth above.

52. Based on information and belief, Defendants failed to establish and maintain CGMP with respect to quality audits, quality testing and process validation for its Prodigy stem.

53. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' DePuy Prodigy stem was defective and failed, resulting in injuries to Plaintiff.

54. If Defendants had complied with the federal requirements regarding CGMP, Defendants' DePuy Prodigy stem would have been manufactured properly and would not have resulted in injuries to Plaintiff.

CASE SPECIFIC FACTUAL ALLEGATIONS

55. Plaintiff, Joan Conboy Miller, underwent a left-sided total hip replacement surgery at Rex Healthcare, 4420 Lake Boone Trail, Raleigh, North Carolina 27607 on or about October 8, 2006, by Dr. John B. Chiavetta employing a DePuy Prodigy stem, DePuy Pinnacle Acetabular Cup woith a DePuy Pinnacle Marathon Liner and a DePuy Articul/Eze Femoral Head. Each device was manufactured and distributed throughout the United States by the Defendants.

56. Radiology imaging of the left-sided DePuy Prodigy hip stem on or about July 10, 2012 showed the stem was in the proper position.

57. By January 31, 2013 radiology imaging showed the DePuy Prodigy stem in situ.

58. Plaintiff, Joan Conboy Miller, underwent a left-sided total hip revision surgery to remove the defective DePuy Prodigy stem on or about February 13, 2013 at Rex Healthcare, 4420

Lake Boone Trail, Raleigh, North Carolina 27607 on or about October 8, 2006, by Dr. John B. Chiavetta.

FIRST CAUSE OF ACTION
STRICT LIABILITY

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

60. At all times material hereto, the DePuy Prodigy stem was defective as to design, testing, manufacture, and warnings, causing the DePuy Prodigy stem to be in a dangerous and defective condition that made it unsafe for its intended use. This condition existed at the time the DePuy Prodigy stem was placed into the stream of commerce by Defendants.

61. Defendants knew or reasonably should have known that the DePuy Prodigy stem, as designed, tested, assembled, fabricated, produced, constructed, marketed, or otherwise prepared, distributed and sold, was defective and posed an unreasonable risk of harm to individuals, including Plaintiff, who used the DePuy Prodigy stem as intended by Defendants.

62. Defendants failed to design, test, assemble, fabricate, produce, construct or otherwise prepare, distribute and sell a safe product, and failed to warn of the potential risks or hazards associated with the DePuy Prodigy stem.

63. As a direct and proximate result of the defective condition and the Defendants' failure to warn of the potential risks and hazards, Plaintiffs suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

SECOND CAUSE OF ACTION
NEGLIGENCE/WANTONNESS

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

65. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the DePuy Prodigy stems into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events as well as a duty to comply with federal requirements.

66. Defendants had an obligation 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 DePuy Prodigy stems, and otherwise distributing the Prodigy stems.

67. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

68. Plaintiff, as a purchaser of a DePuy Prodigy stem, is within the class of persons that the statutes and regulations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

69. Defendants failed to exercise ordinary care and/or were negligent and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the DePuy Prodigy stems into interstate commerce because Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

70. Despite the fact that Defendants knew or should have known that the DePuy Prodigy stems posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the DePuy Prodigy stems for use by consumers and/or continued to fail to comply with federal requirements.

71. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

72. As a direct and proximate result of Defendants' negligence and/or wantonness, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

73. Plaintiff contends that the conduct of the Defendants as described above, including, but not limited to, their failure to adequately design and manufacture, as well as their continued marketing and distribution of the DePuy Prodigy stems when they knew or should have known of the serious health risks these devices created and/or the failure to comply with federal requirements, is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, and constitutes a conscious, reckless and flagrant disregard for human life, which warrants the imposition of exemplary damages.

THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

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

75. Defendants expressly warranted that the DePuy Prodigy stems were safe and effective orthopedic devices for those patients requiring a hip replacement.

76. The DePuy Prodigy stems manufactured and sold by Defendants did not conform to these express representations because they caused serious injury to Plaintiff when used as recommended and directed.

77. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A SPECIFIC PURPOSE

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

79. At the time the Defendants designed, manufactured, marketed, sold, and distributed the DePuy Prodigy stems for use by Plaintiff, Defendants knew of the use for which the DePuy Prodigy stems were intended and impliedly warranted these products to be of merchantable quality and safe for their particular use in that their design, manufacture, labeling, and marketing complied with all applicable federal requirements.

80. Plaintiff and/or her physician reasonably relied upon the skill and judgment of Defendants as to whether the DePuy Prodigy stems were of merchantable quality and safe for their intended particular use and on Defendants' implied warranty as to such matters, including that they were in compliance with all federal requirements.

81. Contrary to such implied warranties, DePuy's Prodigy stems were not of merchantable quality or safe for their particular intended use because the products were defective as described above, and/or failed to comply with federal requirements.

82. As a direct and proximate result of Defendants' breach of warranties, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

FIFTH CAUSE OF ACTION
FAILURE TO WARN

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

84. In their regular course of business, Defendants designed, manufactured and sold the DePuy Prodigy stem for hip repair surgeries.

85. At the time of the design, manufacture and sale of the DePuy Prodigy stem, and specifically at the time Plaintiff received the DePuy Prodigy stem, it was defective and unreasonably dangerous when put to its intended and reasonably anticipated use. Furthermore, the DePuy Prodigy stem was not accompanied by proper warnings regarding significant adverse consequences associated with the device.

86. Defendants failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of these products involved significant dangers not readily obvious to the ordinary and intended user. Defendants failed to warn of the known or reasonably knowable injuries associated with malfunction of the DePuy Prodigy stem.

87. The dangerous and defective conditions of the DePuy Prodigy stem existed at the time it was delivered by the manufacturer to the distributor. At the time Plaintiff had her surgery, the DePuy Prodigy stem was in the same condition as when it was manufactured, distributed and sold.

88. Plaintiff did not know any defects existed in the Prodigy stem device at the time of use or at any time prior thereto.

89. Plaintiff suffered the aforementioned injuries and damages as a direct and proximate result of Defendants' failure to warn.

90. The conduct of Defendants in continuing to market, promote, sell and distribute the Prodigy stem after obtaining knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to and/or conscious disregard for the safety of others, which justifies an award in such sum that will serve to deter Defendants and others from similar conduct in the future.

SIXTH CAUSE OF ACTION
PUNITIVE DAMAGES: WILLFUL AND WANTON CONDUCT

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

92. Plaintiff is entitled to punitive damages because Defendants' wrongful acts and/or omissions were willful and wanton conduct and in conscious and intentional disregard of, and indifference to, the rights and safety of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and

effectiveness of the Prodigy stem and by failing to provide adequate instructions and training concerning its use.

93. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use if the Prodigy stem despite available information demonstrating that the Prodigy stem could cause particles of cobalt and chromium to be deposited into Plaintiff's body and cause the device to loosen and become displaced or separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious risks associated with the DePuy Prodigy stem or provided proper training and instruction to physicians regarding use of the DePuy Prodigy stem.

94. Defendants' misrepresentations include knowingly withholding material information from the medical community and the public including Plaintiff, concerning the safety of the DePuy Prodigy stem.

95. Defendants were or should have been in possession of evidence demonstrating that the DePuy Prodigy stem caused serious side effects. Nevertheless, Defendants continue to market the DePuy Prodigy stem by providing false and misleading information with regard to its safety and effectiveness.

96. Defendants failed to provide warnings that would have dissuaded health care professionals from using the DePuy Prodigy stem, thus preventing health care professionals, including Plaintiff's surgeon, and consumers, including Plaintiff, from weighing the true risks against the benefits of using the DePuy Prodigy stem.

97. Defendants failed to provide adequate training and instructions to surgeons, including Plaintiff's surgeon, which could have prevented failure of the DePuy Prodigy stem causing serious harm and suffering to patients, including Plaintiff.

98. As a result of Defendants' conduct, Defendants are liable to Plaintiff in an amount to be determined by a jury at trial.

PRAYER FOR RELIEF

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

a. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00);

b. For an award of punitive or exemplary damages against Defendants;

c. For reasonable attorney fees and costs;

d. For pre-judgment interest; and

e. For such further and other relief this Court deems just and equitable.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable with the maximum number of jurors permitted by law.

Respectfully submitted this 12th day of February 2016,

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Attorneys for Plaintiff

JS 44 (Rev. 12/12)

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

Joan Conboy Miller

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Douglas A. Dellccio-Cory Watson, P.C.-2131 Magnolia Blvd., Birmingham, AL 35205 (205) 328-2200

DEFENDANTS

Depuy Orthopaedics, Inc., DePuy Products, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc.

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

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

Attorneys *(If Known)*
Bob Tucker, Tucker Ellis & West, 1150 Huntington Building, 925 Euclid Avenue, Cleveland, OH 44115 (216) 696-4093

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

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- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC Section 1332

Brief description of cause:
Plaintiff injured as a direct result of Defendants' defective hip implant device.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ in excess of $75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
02/12/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Douglas A. Dellaccio

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Joan Conboy Miller *Plaintiff(s)* v. DePuy Orthopaedics, Inc., DePuy Products, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Depuy Orthopaedics, Inc.
700 Orhopaedic Drive
Warsaw, IN 46581

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: Douglas A. Dellaccio
Cory Watson Attorneys, P.C.
2131 Magnolia Avenue S, Ste 200
Birmingham, AL 35205

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)* _____ 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:

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UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Joan Conboy Miller *Plaintiff(s)* v. DePuy Orthopaedics, Inc., DePuy Products, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Depuy Products, Inc.
700 Orhopaedic Drive
Warsaw, IN 46581

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: Douglas A. Dellaccio
Cory Watson Attorneys, P.C.
2131 Magnolia Avenue S, Ste 200
Birmingham, AL 35205

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)* _____ 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:

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UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Joan Conboy Miller *Plaintiff(s)* v. DePuy Orthopaedics, Inc., DePuy Products, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Depuy International Limited
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: Douglas A. Dellaccio
Cory Watson Attorneys, P.C.
2131 Magnolia Ave S, Ste 200
Birmingham, AL 35205

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)* _____ 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:

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UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Joan Conboy Miller *Plaintiff(s)* v. DePuy Orthopaedics, Inc., DePuy Products, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Johnson & Johnson Services, Inc.
One JOhnson and Johnson Plaza
New Brunswick, NJ 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: Douglas A. Dellaccio
Cory Watson Attorneys, P.C.
2131 Magnolia Ave S, Ste 200
Birmingham, AL 35205

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)* _____ 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:

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UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Joan Conboy Miller *Plaintiff(s)* v. DePuy Orthopaedics, Inc., DePuy Products, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Johnson & Johnson
One Johnson and Johnson Plaza
New Brunswick, NJ 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: Douglas A. Dellaccio
Cory Watson Attorneys, P.C.
2131 Magnolia Ave S, Ste 200
Birmingham, AL 35205

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)* _____ 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:

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