IN RE STRYKER REJUVENATE HIP STEM AND ABG II MODULAR HIP STEM LITIGATION	**SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY** **MASTER DOCKET NO. BER-L-936-13** **CASE NO. 296**

MASTER LONG FORM COMPLAINT AND JURY DEMAND FOR REJUVENATE MODULAR HIP STEM CASES

Plaintiffs, by and through their counsel, bring this Master Long Form Complaint as an administrative device to set forth potential claims that individual Plaintiffs may assert against Defendant in this litigation. In accordance with Implementing Order dated April 10, 2013, all allegations pled herein are deemed pled in any previously filed Complaint and in any Short Form Complaint hereafter filed. Further pursuant to Implementing Order dated April 10, 2013, each individual Plaintiff shall amend his or her complaint no later than thirty (30) days after the date of selection for bellwether consideration, identifying the actual claims he or she intends to pursue at trial and setting forth specific allegations to conform with applicable state law specific to the individual Plaintiff's claims. This Master Long Form Complaint shall be subject to further Order of the Court regarding any future amendments and related motion practice.

Plaintiffs allege as follows:

1. This is an action for damages relating to Defendant's development, testing, assembling, manufacturing, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "The Rejuvenate® System" which includes the Rejuvenate Modular Neck and Rejuvenate Modular Stem components (hereinafter "Rejuvenate" or "Hip Stem(s)").

PARTIES, JURISDICTION AND VENUE

2. Plaintiffs include women and men who were implanted with the Rejuvenate. Plaintiffs also include the spouses of said women and men, as well as others with standing to file claims arising from the Rejuvenate.
3. Venue in this action properly lies in Bergen County as the Defendant conducts substantial business in this county.
4. Defendant, Howmedica Osteonics Corp (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, NJ 07430 and conducts business throughout the United States including in the States of New Jersey and New Jersey.
5. Jill Doe Manufacturers (1-10), Jack Doe Wholesalers (1-10), Jake Doe Sellers (1-10), Jane Doe Distributors and Marketers (1-10), Jim Doe Health Care Providers (1-10), and Jean Doe (1-10), are corporations, partnerships, companies, persons or other entities involved in the marketing, design, development, manufacture, testing, selling, labeling, packaging, advertising, promoting, supplying, distribution or implantation of the Products, whose identities are not presently known by Plaintiffs. The Doe defendants are sued individually in their official capacity.

THE PRODUCT

6. At all times material hereto, Defendant Howmedica Osteonics Corp, d/b/a Stryker Orthopaedics (hereinafter referred to as "Defendant") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Hip Stem under the name "The Rejuvenate ® System," either directly or indirectly, to

members of the general public within the State of New Jersey and outside the State of New Jersey, including Plaintiff herein.

7. Defendant's Hip Stem was placed into the stream of interstate commerce and was implanted in Plaintiffs.

8. As a direct and proximate result of Defendant placing the Hip Stem into the stream of commerce, Plaintiffs have suffered and continue to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; past, present and future medical, hospital, rehabilitative and pharmaceutical expenses; lost wages; and other related damages.

9. On June 3, 2008, Defendant received FDA clearance to sell its Rejuvenate System in the United States. Sometime during the first week of July of 2012, Defendant issued a voluntary worldwide recall of both the Rejuvenate and ABG II hip replacement systems.

10. The Rejuvenate System is a dual modular hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to painful joint disease of the hip resulting from non-inflammatory degenerative arthritis.

11. Unlike most prosthetic hip implants, the Rejuvenate System is an artificial hip replacement device consisting of two basic components: a chrome cobalt neck that is inserted into a titanium stem. The Rejuvenate System can be used interchangeably with any number of Stryker bearing surface components (which comprise the ball and an acetabular cup or socket). The bearing surface system or components are unrelated to the Rejuvenate System's method of failure.

12. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zirconium, and iron, which is commonly referred to as "TMZF."

This alloy was designed and patented by Defendant and is unlike any other titanium alloy employed in the manufacture of other prosthetic hip implants. Defendant claims in its promotional materials for the Rejuvenate System that its proprietary alloy is both stronger and less rigid than other titanium alloys. Defendant also claims that this particular TMZF titanium alloy has been tested and proven by Defendant to resist the effects of corrosion and fretting.

13. At all times material hereto, the Rejuvenate implanted in Plaintiff was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendant.

14. After the implantation of the Hip Stem, Plaintiff began experiencing significant pain and discomfort in the area of the Hip Stem.

15. Diagnostic workup revealed one or more of the following findings: the presence of pseudotumor formation, the existence of a fluid collection about the hip prosthesis, and/or blood testing indicating the presence of heavy metal ions.

16. Based upon these findings and in light of worsening symptoms, Plaintiff has or will undergo revision surgery for removal of the Hip Stem, or needs to have revision surgery but medically cannot endure such surgery at the present time. During that surgery, it has or will be discovered that, in fact, there was significant evidence of heavy metal toxicity including one or more of the following findings: the presence of milky, turbid fluid; large pseudotumor formation; soft tissue necrosis; muscle loss and/or bony necrosis at the proximal femur.

THE STRYKER REJUVENATE HISTORY

17. In February of 2009, Stryker officially released its Rejuvenate Modular Primary Hip System, the latest evolution in the Defendant's OmniFit and Secure-Fit Hip systems,

which was approved for market by the FDA on June 3, 2008. The Rejuvenate Modular hip is an extension of the Stryker Modular Hip, which was approved for market by the FDA on Sept 13, 2007.

18. According to Defendant's materials, the Rejuvenate Modular Primary Hip System was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity, and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version, and offset, the Rejuvenate Modular Primary Hip System was marketed to enable surgeons to better personalize the implant to each patient's unique anatomy.
19. The Rejuvenate System is comprised of separate femoral stem and neck components and offers a variety of sizing options intraoperatively. The benefit, according to Stryker, was that by allowing the surgeon to independently manage leg length, neck version, and femoral offset, the system provides surgeons the ability to better personalize the biomechanics of each patient's hip replacement implant.
20. The Rejuvenate System combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with a plasma sprayed coating of commercially-pure Ti and PureFix HA for the stem and CoCr for the neck. Defendant claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.
21. Despite Defendant's claims, this combination of materials has been reported to cause fretting, galvanization, and corrosion. Since the 1980s, medical and scientific literature has reported corrosion to be a problem when Ti and CoCr have been used at modular junctions in medical implants. However, in its marketing and sale of the device, Defendant

represented and warranted that its proprietary materials alleviate this corrosion and fretting problem.

22. Defendant holds two patents for modular implant devices. Currently, Defendant has a pending application to patent a modular hip prosthesis similar to the Rejuvenate System.

URGENT SAFETY NOTICES AND RECALLS

23. In April of 2012, Defendant issued an Urgent Field Safety Notice to surgeons and hospitals in the United States regarding the Rejuvenate System.

24. In this notice, Defendant acknowledged that it had received reports of device failure due to heavy metal contamination. The Urgent Field Safety Notice specifically referred to failures at the taper neck junction between the neck and stem due to corrosion and fretting.

25. This corrosion and fretting was exactly the same failure mechanism that Defendant had warranted would not occur because of the Rejuvenate System's design and composition. It was also exactly the same failure mechanism that the medical and scientific community had been studying and documenting in modular implant device designs since the 1980s.

26. The Urgent Field Safety Notice went on to describe symptoms and findings consistent with those experienced by Plaintiff herein.

27. Among those symptoms and findings specifically mentioned in the Urgent Field Safety Notice issued in April of 2012 by Defendant were tissue necrosis, metallosis, adverse soft tissue reaction, and pseudotumor formation.

28. Almost immediately following the Urgent Field Safety Notice, Defendant issued a voluntary recall of the Stryker Rejuvenate and ABGII in Canada. In the Canadian recall notice, Defendant stated that it was amending the Instructions for Use for the Rejuvenate System to include warnings that Defendant was on notice of the issues described in the Urgent Field Safety Notice above.

29. Finally, in the first week of July of 2012, Defendant issued a voluntary recall of all Stryker Rejuvenate and ABG II stems in the United States. As part of the July of 2012 recall notice, Defendant once again cited reports of device failure due to heavy metal fretting and corrosion.

THE FEDERAL REQUIREMENTS

30. Federal regulation states: "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR §7.3(g).
31. Federal regulation states: "Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR §7.3 (m).
32. Federal regulation states: "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR §7.3 (m).
33. The classification of the product withdrawals and corrections of the Defendant's Defective Device (as described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these Hip Stems.
34. Pursuant to federal law, a 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.

35. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, 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.

36. 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 of its medical devices may have caused or contributed to death or serious injury, or if the devices have 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. §360(i).

37. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury, or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or

other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

38. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR §803.52.

39. Pursuant to federal regulations, manufacturers must report any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events. See 21 CFR §803.53.

40. Pursuant to federal regulations, device manufacturers must report promptly to FDA any device corrections and removals and must also maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

41. Pursuant to federal regulations, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production of the devices. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Further, Manufacturers are required to use statistical techniques, where necessary, to evaluate product performance. See 21 CFR §820.

42. Pursuant to federal regulations, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of its devices. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." See 21 CFR §814.

43. Specifically, it is believed that with respect to the Rejuvenate System, Defendant failed to timely report adverse events; failed to timely conduct failure investigations and analyses; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or

device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

CAUSES OF ACTION

COUNT I – NEGLIGENCE

44. Plaintiffs reallege and incorporate by reference the allegations set forth above.

45. Defendant designed, manufactured, marketed, detailed, advertised both to physicians and consumers the Rejuvenate System.

46. As a result, Defendant had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the devices would be implanted, including Plaintiffs herein.

47. Defendant failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted, including Plaintiffs herein, and is therefore negligent in the following respects:

    a. Defendant failed to adequately design and manufacture the device to insure that it would not corrode, erode, deteriorate, and induce severe metal toxicity in the patient. The flaws include but are not limited to: incompatibility of the TMZF titanium alloy with other device components; poor design of the taper neck junction between stem and neck, such that micro-motion was predictable; poor manufacturing practices such that the taper neck junction between the neck and stem do not "fit" the way they were intended; and a combination of the above factors leads to rapid, severe heavy metal cast-off causing soft tissue and bony necrosis, pain, and premature failure of the device.

    b. Defendant failed to adequately test the device to insure that it would not corrode, erode, deteriorate and/or induce severe metal toxicity in the patients;

    c. Defendant failed to conduct anything other than bench testing so that when manufactured and marketed, patients became, in essence, Defendant's first clinical trial;

    d. Defendant made affirmative representations that the device would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer, including Plaintiffs herein;

e. Defendant trained its sales force to detail the device utilizing representations that Defendant knew or should have known were false, creating in the minds of both surgeons and consumers, including Plaintiffs herein, that the device would not cause metal toxicity;

f. Defendant specifically marketed the device as a safe alternative to metal-on-metal bearing surface devices that had been widely publicized as capable of causing premature failure due to heavy metal toxicity;

g. Defendant marketed the Rejuvenate as a "perfect fit" for younger patients due to its modular design, creating in the minds of physicians and consumers, including Plaintiffs herein, that the Rejuvenate was superior to other available hip implants when in fact the Rejuvenate was so poorly designed, constructed, and tested that it had to be recalled from the market only three years after it was introduced;

h. Defendant failed to manufacture the product to FDA-cleared and/or Defendant's own internal specifications, such that the taper neck junction between the neck and stem prematurely failed causing metal debris cast-off and severe metal toxicity in patients;

i. Defendant failed to adequately test the TMZF alloy's compatibility with chrome cobalt components in an effort to prevent corrosion and fretting at the neck/stem taper neck junction of this modular device;

j. Defendant failed to promptly act upon reports of early failure, such that the Rejuvenate continued to be implanted in unknowing patients by surgeons well after it should have been recalled or sales suspended;

k. Defendant chose as its predicate device a hip implant system that had known failures in the past; had to be redesigned due to design flaws; and has been the subject of protracted litigation filed by patients who have been harmed by defects in the predicate modular device; and

l. Defendant was on actual knowledge prior to marketing the Rejuvenate System and ABG II that its TMZF titanium alloy performed poorly when mated with chrome cobalt components. Defendant also knew when it introduced the Rejuvenate System to the market that the Stryker Accolade (as well as other Stryker devices that were also made of TMZF alloy) was experiencing corrosion, fretting, and failure issues at the taper neck junction between the neck and chrome cobalt head or ball. Nevertheless, Defendant either suppressed or ignored these reports and marketed the Rejuvenate anyway, knowing that these two dissimilar metals when utilized in various hip implant devices were performing poorly in the market and causing harm to patients.

48. The above conduct exhibits Defendant's failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, permanent, debilitating injury to patients, including Plaintiffs herein.

49. As a direct and proximate result of Defendant's negligence, Plaintiffs suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; incurred medical and nursing expenses; incurred surgical expenses; and lost wages and loss of earning capacity. These damages have occurred in the past and will continue into the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT II – NEGLIGENCE PER SE

50. Plaintiffs reallege and incorporate by reference the allegations set above as if set forth herein.

51. Defendant had an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying marketing, selling, advertising, preparing for use, and warning of the risks and dangers of the Rejuvenate.

52. Defendant failed to comply with federal requirements. Specifically, it is believed that with respect to the Rejuvenate System, Defendant failed to timely report adverse events; failed to timely conduct failure investigations and analyses; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT III – STRICT PRODUCTS LIABILITY- DEFECTIVE DESIGN

53. Plaintiffs reallege and incorporate by reference the allegations set above as if set forth herein.
54. This is an action for strict liability based upon design defect against Defendant.
55. Defendant's Rejuvenate System is designed in such a way that, when used as intended, the Hip Stem causes serious, permanent, and devastating damage to patients in whom the devices are implanted. The damage and mechanism of injury have been previously described herein. Defendant acted unreasonably in its design of the Hip Stem in that Defendant failed to adopt a safer design for the Hip Stem that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.
56. Defendant's Rejuvenate System does not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant.
57. The risks of using Defendant's Rejuvenate System outweigh the benefits of using the devices.
58. There were numerous safer alternative designs to the Rejuvenate stem which in reasonable probability would have prevented or significantly reduced the risk of the personal injuries suffered by Plaintiffs herein without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the Rejuvenate Hip Stem left the control of Defendant by the application of existing or reasonably- achievable scientific knowledge.

59. The design defects in Defendant's Rejuvenate System caused serious damage to Plaintiffs herein, including all or some of the following: bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT IV – STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT

60. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.
61. This is an action for strict liability based on a manufacturing defect.
62. The Rejuvenate System is designed for implantation into the human body and to last for fifteen or more years. The Rejuvenate System was also designed to be compatible with human tissue and bone.
63. The Rejuvenate System implanted in Plaintiffs herein failed and were removed (or will be required to be removed) within a short period of time after the original dates of implantation.
64. The Rejuvenate System installed in the hips of Plaintiffs herein were not compatible with human tissue and bone. Through a process of fretting and corrosion, the Rejuvenate System released heavy metals into the bodies of Plaintiffs' herein causing severe and permanent destruction of bone and tissue. Defendant failed to manufacture the Rejuvenate System in a manner that prevented fretting and corrosion, and, in fact, manufactured the product such that it caused fretting and corrosion.

65. The Rejuvenate System implanted in the hips of Plaintiffs herein contained manufacturing defects.

66. The manufacturing defects in the Rejuvenate System implanted in the hips of Plaintiffs herein caused serious damage to Plaintiffs including all or some of the following: bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT V – STRICT PRODUCTS LIABILITY- FAILURE TO WARN

67. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

68. The Rejuvenate System implanted into Plaintiffs herein contained no warnings or, in the alternative, inadequate warnings as to the risks that the product could cause fretting, corrosion, and significant heavy metal toxicity. Similar, although still inadequate, warnings were added in 2012 just prior to the recall of the product by Defendant. Defendant acted unreasonably in failing to provide such warning or instruction prior to 2012.

69. The warnings that accompanied the Rejuvenate System failed to provide that level of information that an ordinary consumer, including Plaintiffs herein, would expect when using the implants in a manner reasonably foreseeable to the Defendant. Moreover, the Rejuvenate System left the Defendant's control without an adequate warning or instruction, and created an unreasonably dangerous condition in that Defendant, as the

seller and manufacturer, knew or in the exercise of ordinary care should have known that the Hip Stem posed a substantial risk of harm. Alternatively, after the Rejuvenate System left the Defendant's control, Defendant became aware of, or in the exercise of ordinary care should have known, that the Hip Stem posed a substantial risk of harm to patients, including Plaintiffs herein, yet Defendant failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

70. Had Plaintiffs received proper or adequate warnings as to the risks associated with using the Hip Stem, Plaintiffs would not have used the product.

71. Had Plaintiffs' surgeons received a proper or adequate warning as to the risks associated with using the Rejuvenate System, Plaintiffs' surgeons would not have recommended the device; would have used an alternate device; or, at a minimum, would have provided Plaintiffs with adequate warnings and obtained informed consent.

72. Defendant's failure to warn of the Rejuvenate System's risks caused serious damage to Plaintiffs herein, including one or more of the following: bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT VI – BREACH OF EXPRESS WARRANTY

73. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

74. Through Defendant's public statements, descriptions of the Rejuvenate System, and promises relating to the Rejuvenate System, Defendant expressly warranted, among other things, that the Rejuvenate System was efficacious and safe for its intended use; was designed and constructed of materials that would prevent fretting and corrosion; would last longer than competing hip implant devices; and was more suitable for implantation in younger adults than other devices given its purported longevity and/or modular design.

75. These warranties came in the form of (i) publicly-made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Rejuvenate System (but which contained material misrepresentations and utterly failed to warn of the risks of the Rejuvenate System); (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the safety of the Rejuvenate System that also downplayed the risks associated with implantation of the Hip Stems; and (iv) false and misleading written information supplied by Defendant.

76. The most prominent representation made by Defendant was on its website where Defendant expressly warranted that the design, testing, and materials utilized in the Rejuvenate System would prevent fretting and corrosion.

77. Plaintiffs herein further allege that all of the aforementioned written materials are known to Defendant and in its possession, and it is Plaintiffs' reasonable belief that these

materials shall be produced by Defendant and be made of record once Plaintiffs are afforded the opportunity to conduct discovery.

78. When Defendant made these express warranties, Defendant knew the purposes for which Rejuvenate System was to be used and warranted the Hip Stems to be in all respects safe and proper for such purposes.

79. Defendant drafted the documents and/or made the statements upon which these warranty claims are based and, in so doing, defined the terms of those warranties.

80. Defendant's representations and promises regarding the Hip Stems had the natural tendency to induce those in need of prosthetic hip implants, including Plaintiffs herein, to purchase the Hip Stems in reliance thereon.

81. The Rejuvenate System does not conform to Defendant's representations in that the devices are not safe and produce serious side effects.

82. As such, the Rejuvenate System did not conform to Defendant's promises, descriptions, or affirmations of fact and was not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.

83. Defendant therefore breached its express warranties to Plaintiffs herein in violation of applicable state statutes and common law, by manufacturing, marketing, and selling the Rejuvenate System to Plaintiffs herein and causing damages as will be established at trial.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT VII - BREACH OF WARRANTY AS TO MERCHANTABILITY

84. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

85. At all times material, Defendant was a merchant with respect to the Hip Stems.

86. The Rejuvenate was defectively designed and manufactured, and was distributed and sold without the provision of reasonable instructions or warnings regarding the foreseeable risk of harm posed by the Rejuvenate to patients, including Plaintiffs herein.

87. The Rejuvenate was not fit for its ordinary purposes.

88. Plaintiffs herein were foreseeable users of the Hip Stem.

89. The Hip Stem was being used in the intended manner at the time of the injuries sustained by Plaintiffs herein.

90. Plaintiffs suffered harm as a direct and proximate result of the above said defects in the Rejuvenate.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT VIII - BREACH OF IMPLIED WARRANTIES

91. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

92. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Hip Stems.

93. At all relevant times, Defendant intended that the Hip Stems be used in the manner that Plaintiffs herein in fact used the Hip Stems, and Defendant impliedly warranted each of the Hip Stems to be of merchantable quality; safe and fit for such use; and warranted that each of the Hip Stems was adequately tested.

94. Defendant was aware that consumers, including Plaintiffs herein, would use the Rejuvenate as a hip implant; which is to say that Plaintiffs herein were foreseeable users.

95. Plaintiffs were at all relevant times in privity with Defendants.

96. The Rejuvenate was expected to reach and did in fact reach consumers, including Plaintiffs herein, without substantial changes in the condition in which the Hip Stems were manufactured and sold by Defendant.

97. Defendant breached various implied warranties with respect to the Hip Stems in the following manner:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Rejuvenate were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Rejuvenate;

b. Defendant represented that the Hip Stems were safe, and/or safer than other alternative hip implants and fraudulently concealed information which demonstrated that the Hip Stems were not safer than alternatives available on the market; and

c. Defendant represented that the Hip Stems were more efficacious than other alternative devices and fraudulently concealed information, regarding the true efficacy of the Rejuvenate System.

98. In reliance upon Defendant's implied warranties, Plaintiffs herein used the Rejuvenate as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

99. Defendant breached their implied warranty to Plaintiffs in that the Rejuvenate were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of the following statutes: Ala. Code §§ 7-2-314, *et seq.;* Alaska. Stat. §§ 45.02.314, *et seq.;* Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.;* Ark. Code Ann. §§ 4-2-314, *et seq.;* Cal. Comm. Code §§ 2314, *et seq.;* Colo. Rev. Stat. §§ 4-2-314, *et seq.;* Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.;* Del. Code Ann. tit. 6, §§ 2-314, *et seq.;* D.C. Code Ann. §§ 28:2-314, *et seq.;* Fla. Stat. Ann. §§ 672.314, *et seq.;* O.C.G.A. §§ 11-2-314, *et seq.;* Haw. Rev.

Stat. §§ 490:2-314, *et seq.;* Id. Code §§ 28-2-314, *et seq.;* Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.;* Indiana Code Ann. §§ 26-1-2-314, *et seq.;* Iowa Code Ann. §§ 554.2314, *et seq.;* Kan. Stat. Ann. §§ 84-2-314, *et seq.;* Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.;* La. Civ. Code Ann. art. 2520, *et seq. (*and is liable for redhibition under this statute); Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.;* Md. Code Ann., Com. Law §§ 2-314, *et seq.;* Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.;* Mich. Comp. Laws Ann. §§ 440.2314, *et seq.;* Minn. Stat. Ann. §§ 336.2-314, *et seq.;* Miss. Code Ann. §§ 75-2-314, *et seq.;* Mo. Rev. Stat. Ann. §§ 400.2-314, *et seq.;* Mont. Code Ann. §§ 30-2-314, *et seq.;* Neb. Rev. Stat. §§ 2-314, *et seq.;* Nev. Rev. Stat. §§ 104.2314, *et seq.;* N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.;* N.J. Stat. Ann. §§ 12A:2-314, *et seq.;* N.M. Stat. Ann. § 55-2-314, *et seq.;* N.Y. U.C.C. Law §§ 2-314, *et seq.;* N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.;* N.D. Cent. Code §§ 41-02-31, *et seq.;* Ohio Rev. Code Ann. §§ 1302.27, *et seq.;* Okl. Stat. Tit. 12A, §§ 2-314 *et seq.;* Or. Rev. Stat. §§ 72.3140, *et seq.;* 13 Pa. Stat. Ann. §§ 2314 *et seq.;* R.I. Gen. Laws §§ 6A-2-314, *et seq.;* S.C. Code Ann. §§ 36-2-314, *et seq.;* S.D. Codified Laws §§ 57A-2-314, *et seq.;* Tenn. Code Ann. §§ 47-2-314, *et seq.;* Tex. Bus. & Com. Code Aim. §§ 2.314, *et seq.;* Utah Code Ann. §§ 70A-2-314, *et seq.;* Va. Code Ann. §§ 8.2-314, *et seq.;* Vt. Stat. Ann. §§ 9A-2-314, *et seq.;* Wash. Rev. Code §§ 62A.2-314, *et seq.;* W. Va. Code §§ 46-2-314, *et seq.;* Wis. Stat. Ann. §§ 402.314, *et seq.;* and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq.*

100. As a result of Defendants' foregoing acts and omissions, Plaintiffs herein were and/or still are caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects.

101. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs herein have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT IX - CONSUMER FRAUD AND/OR UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

102. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

103. Certain Plaintiffs herein will bring a cause of action for consumer fraud and/or unfair and deceptive trade practice under applicable state law.

104. Defendant is on notice that such claims may be asserted by individual Plaintiffs herein.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief and as permitted by the applicable state laws.

COUNT X - GROSS NEGLIGENCE/MALICE

105. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein.

106. The wrongs done by Defendant were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs herein for which the law would allow the imposition of exemplary damages (and which Plaintiffs herein will seek at the appropriate time under governing law). Such

exemplary damages are appropriate given Defendant's conduct, as further alleged herein, which includes the failure to comply with applicable Federal standards and or basic metallurgy and implant design practices, which recklessly caused substantial injuries to Plaintiffs herein (or, when viewed objectively from Defendant's standpoint at the time of the conduct, involved an extreme degree of risk considering the probability and magnitude of the potential harm to others), of which Defendant was actually, subjectively aware of the risks involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, or included a material representation that was false, with Defendant knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs herein.

107. Plaintiffs herein relied on the representations and suffered injuries as a proximate result of this reliance.

108. Plaintiffs herein will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

109. Plaintiffs herein also allege that the acts and omissions of the Defendant, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs herein. In that regard, Plaintiffs herein will seek exemplary damages in amounts that would punish Defendant for its conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT XI - LOSS OF CONSORTIUM

110. Plaintiffs reallege and incorporate by reference the allegations set above as if set forth herein.

111. At all times material, Plaintiff was married to Plaintiff's spouse. As a result of the injuries and damages sustained by Plaintiff, Plaintiff's spouse has suffered the loss of care, comfort, society and affections from Plaintiff.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT XII – PUNITIVE DAMAGES UNDER COMMON LAW, PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, et seq.), and PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1 et seq.)

112. Plaintiffs reallege and incorporate by reference the paragraphs above, as though fully set forth herein.

113. At all times material hereto, Defendant knew or should have known that the Hip Stems were inherently more dangerous than alternative hip replacement systems on the market, including having a greater risk of fretting and corrosion, shorter life span, and an increased need for additional surgeries due to premature failure of the Rejuvenate System.

114. At all times material hereto, Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the Rejuvenate System.

115. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs herein, concerning the safety and efficacy of the Rejuvenate System.

116. At all times material hereto, Defendant knew and recklessly disregarded the fact that the Rejuvenate System was subject to causing fretting and corrosion in patients

implanted with the device, including Plaintiffs herein, with far greater frequency than safer alternative hip replacement systems.

117. Notwithstanding the foregoing, Defendant continued to aggressively market the without disclosing the aforesaid side effects and risks to Plaintiffs herein when there were safer alternative methods and products available.

118. Defendant knew of the Rejuvenate System's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute, and sell the Rejuvenate System so as to maximize Defendant's sales and profits at the expense of the health and safety of the public, including Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm.

119. Defendant's intentional and/or reckless, fraudulent, and malicious failure to disclose information deprived Plaintiffs herein and Plaintiffs' surgeons of necessary information to enable Plaintiffs herein to weigh the true risks of using the Rejuvenate System against its benefits.

120. As a direct and proximate result of the Defendant's conscious and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, Plaintiffs suffered severe and permanent physical injuries as set forth above.

121. The aforesaid conduct of Defendant was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

122. Defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that demonstrated entire want of care raises the presumption of conscious indifference to the consequences.

123. Plaintiffs herein allege the cause of action for punitive damages, despite the holding of *McDarby v. Merck*, in that these Hip Stems were never approved as safe and effective, and the holding in that case is otherwise inapplicable herein.

WHEREFORE, Plaintiffs herein demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XIII - MEDICAL MONITORING

124. Plaintiffs reallege and incorporate by reference the allegations set above as if set forth herein.

125. At all times relevant to this cause of action, Defendant was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Rejuvenate System.

126. Defendant, in designing, developing, manufacturing, marketing, labeling, selling, monitoring and overseeing the Hip Stems, had a duty to act with reasonable care and to warn Plaintiffs herein and Plaintiffs' physicians of the risks; dangers; adverse events involving fretting and corrosion; and other potential failures and defects of the Rejuvenate System.

127. At the time of the manufacture and sale of the Rejuvenate System (from 2008 through July of 2012), Defendant knew or should have known the following with regard to the Hip Stems:

a. That the Hip Stems were designed and manufactured in such a manner so as to present an unreasonable risk of failure;

b. That the Hip Stems were substandard and dangerous in that they combined a cobalt and chromium neck with a titanium stem;

c. That the Hip Stems were designed and manufactured so as to present an unreasonable risk of fretting and/or corrosion;

d. That the Hip Stems were designed and manufactured so as to present an unreasonable risk of metallosis; and/or

e. That the Hip Stems were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

128. Defendant committed one or more breaches of the duty of reasonable care and were negligent in the following manner:

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Hip Stems, including, but not limited to, the incidence of fretting and/or corrosion and/or the likelihood that these Hip Stems could not be safely removed.

b. Unreasonably and carelessly manufacturing the Rejuvenate System in such a manner that the Hip Stems had insufficient strength or structural integrity and/or the appropriate materials utilized in the product to withstand the foreseeable use of normal placement within the human body; and/or

c. Unreasonably and carelessly designing the Rejuvenate System in such a manner that that the Hip Stems presented increased risks of harm to Plaintiffs herein in that the devices were prone to fretting, corrosion or other modes of failure.

129. Plaintiffs herein have been and continue to be exposed to greater than normal background levels of metal debris because all have had the Hip Stems implanted in their bodies and those Hip Stems are likely to fret, corrode, and/or otherwise fail and cause future injuries due to their defective design and manufacture.

130. The Hip Stems that have been implanted in Plaintiffs herein have been proven to be hazardous.

131. Defendant's negligent design, manufacture and/or failure to warn caused the Hip Stems to be implanted in the bodies of Plaintiffs' herein.

132. As a direct and proximate result of Defendant's negligence and/or defects in the design and manufacture of the Rejuvenate System, Plaintiffs herein face a significantly increased risk of adverse local tissue reactions, metallosis, and/or other serious latent diseases due to the fretting, corrosion, and/or other failure modes of the Hip Stems.

133. As a further direct and proximate result of the foregoing negligence and/or defects in the design and manufacture of the Rejuvenate System, Plaintiffs herein require regular and frequent medical monitoring for the duration of time that Defendant's Hip Stems remain in the bodies of Plaintiffs herein, and Plaintiffs will also be required to expend money and incur obligations to undergo tests to determine their risks and the onset of the diseases and injuries caused by the Hip Stems and associated metallosis, corrosion, and adverse local tissue reactions.

134. Medical monitoring tests and procedures exist which make the early detection of adverse local tissue reaction, metallosis, and other conditions that maybe caused by the failure of the Hip Stems possible. The necessary medical monitoring includes, but is not limited to, blood tests and imaging studies such as magnetic resonance imaging.

135. The proposed medical monitoring for Plaintiffs herein are unnecessary for individuals who have not been implanted with the Hip Stems, since such individuals do not have hip implants that are prone to fretting, corrosion or other failure implanted in their bodies.

136. The proposed medical monitoring program set forth herein is reasonably necessary according to contemporary principles of medicine.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendant, as contained in the Prayer For Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendant as follows:

1. Awarding compensatory damages;
2. Awarding punitive damages ;
3. Awarding pre-judgment and post-judgment interest to Plaintiff;
4. Awarding the costs and the expenses of this litigation to Plaintiff;
5. Awarding medical monitoring;
6. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and
7. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

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Attorney for Plaintiffs