EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: STRYKER REJUVENATE HIP STEM AND ABG II MODULAR HIP STEM LITIGATION	**MDL NO. 13-2441 (DWF-FLN)**
This Document Relates to All Actions.	
PLAINTIFFS, **v.** **HOWMEDICA OSTEONICS d/b/a STRYKER ORTHOPAEDICS, STRYKER CORP., STRYKER SALES CORPORATION and STRYKER IRELAND LIMITED,** **DEFENDANTS.**	**MASTER LONG FORM COMPLAINT AND JURY DEMAND**

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

COMES NOW, MDL Plaintiffs by and through the undersigned and their individual counsel, bring this Master Long Form Complaint as an administrative device to set forth potential claims that individual Plaintiffs may assert in this litigation against Defendants Howmedica Osteonics d/b/a Stryker Orthopaedics, Stryker Corporation, Stryker Sales Corporation and Stryker Ireland Limited (hereinafter collectively "Defendants" and "Stryker"). In accordance with Pretrial Order #10, all allegations pled herein are deemed pled in any previously filed Complaint and in any Short Form

Complaint hereafter filed. Further pursuant to Pretrial Order #10, 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:

INTRODUCTION

1. This is an action for damages relating to Defendants' design, research, development, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, advertising, promoting, supplying, and/or selling the defective product sold under the name "The Rejuvenate® System," and the "ABG™ II" which includes the Rejuvenate® Modular Primary Hip System and ABG™II[1] Modular Femoral Hip Implant System (hereinafter "Rejuvenate®", "ABG™ II", "Defective Device", "Device" or "Hip Stems").

2. Defendants developed, manufactured, promoted and sold the Rejuvenate® and the ABG™ II to be sold and placed into women and men's hips as a replacement implanted device. Defendants' Hip Stems were placed into the stream of interstate commerce and were implanted in Plaintiffs.

[1] ABG™II stands for "Anatomic Benoist Girard" II, which is the latest iteration of earlier models of monolithic femoral stems referred to as ABG™ I or ABG™ II.

3. As a direct and proximate result of Defendants placing these Defective Devices 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; loss of normal life; permanent disability; and other related damages.

4. On June 3, 2008, Defendants Howmedica Osteonics d/b/a Stryker Orthopaedics and Stryker Corporation received FDA clearance to sell its Rejuvenate System in the United States as marketed by Defendant Howmedica Osteonics d/b/a Stryker Orthopaedics and sold throughout the United States through and by Stryker Sales Corporation.

5. Sometime during the first week of July of 2012, Defendants issued a voluntary worldwide recall of both the Rejuvenate® and ABG™ II hip replacement systems.

6. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is often characterized as a ball and socket joint. The acetabulum is the cup shaped socket portion of the hip, and the femoral head (ball) at the top of the femur bone rotates within the curved surface of the acetabulum.

7. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal, plastic, or ceramic. A total hip replacement typically consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) an acetabular liner, and (4) an acetabular shell. After the surgeon hollows out a patient's

femur bone, the metal femoral stem is implanted. The femoral head is usually a metal or ceramic ball that is fixed on top of the femoral stem. The femoral head forms the hip joint that can rotate when it is placed inside a plastic or ceramic acetabular liner that is attached to the interior portion of the metal acetabular shell comprised of metal on its outer surface. When complete, the femoral stem anchors the femoral head that rotates within the acetabular liner sitting inside the acetabular shell. Historically, most femoral stems were one piece, or "monolithic." The ABG™ II and Rejuvenate® femoral stems, however, were two-piece, or "modular."

8. The Hip Stems are modular femoral hip replacement devices to be used in total hip replacement surgery. The Hip Stems are both indicated for patients requiring primary total hip arthroplasty due to painful joint disease of the hip resulting from non-inflammatory degenerative arthritis including osteoarthritis and avascular necrosis.

9. As noted, the Hip Stems are critically different from most traditional "monolithic" femoral stems used in total hip replacements because they consist of two basic components: a cobalt-chromium neck component that is inserted into a titanium stem component.

10. The larger portion of the femoral stem, which is placed down into the patient's femur, is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. This alloy is commonly referred to as "TMZF® ," and was designed and patented by Defendants. It is unlike any other titanium alloy employed in the manufacture of other prosthetic hip implants. The Hip Stems combined the material characteristics of TMZF® with a plasma sprayed coating of commercially

pure Ti (Titanium) and PureFix HA (Hydroxyapatite) for the stem and CoCr (cobalt and chromium) for the neck. Defendants claimed in promotional materials for the Rejuvenate® and ABG™II Systems that the proprietary alloy was both stronger and less rigid than other titanium alloys. Defendants also claimed that this particular TMZF® titanium alloy was tested and proven by Defendants to resist the effects of corrosion and fretting.

11. Attempting to seize onto this potentially lucrative opportunity to develop a new hip implant that was not a "metal-on-metal" system, Defendants aggressively launched the Rejuvenate® System. Unlike most prosthetic hip implants, the Rejuvenate® and ABG™II devices are not part of a single system that requires a particular acetabular component, but rather can be used in conjunction with any number of Defendants' currently available compatible articular-bearing surface components which comprise the femoral head and an acetabular shell. The bearing-surface system or components are unrelated to the mode of failure now seen in the Hip Stems.

12. 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.

13. 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.

14. On November 4, 2009, Defendant received FDA clearance to sell its ABG™ II Modular Hip Stem in the United States. This was predicated on the prior approval of the Stryker Modular Hip System. Sometime during the first week of July of 2012, Defendant issued a voluntary worldwide recall of the ABG™ II Modular Hip Stem and Rejuvenate® Modular Hip Stem.

15. The ABG™ II Modular Hip Stem is also a dual modular hip replacement prosthesis. It is indicated for patients requiring primary or revision total hip arthroplasty or replacement to alleviate pain and restore function resulting from a variety of medical conditions including non- inflammatory degenerative joint disease, rheumatoid arthritis, and functional deformities.

16. Similarly to the Rejuvenate® Hip System, the ABG™ II Modular Hip Stem is an artificial hip replacement device consisting of two basic components: a gas-atomized dispersion strengthened chrome cobalt (GADS CoCr) neck that is inserted into a titanium stem. The neck rests inside of the stem, which is implanted in the patient's femur. The stem has a PureFix hydroxyapatite coating. Scales are incorporated into the stem's anterior, posterior and medial surfaces to encourage the transmission of vertical loading from the implant to the bone and reduce the dependence on friction at the hydroxyapatite surface. The ABG™ II Modular Hip Stem can also 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 ABG™ II Modular Hip Stem's method of failure.

17. At all times material hereto, the ABG™ II Hip Stem implanted in Plaintiffs were designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

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

19. 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.

20. Based upon these findings and in light of worsening symptoms, Plaintiffs have or will undergo revision surgery for removal of the Hip Stem, or need 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.

PARTIES

21. Plaintiffs are citizens and/or residents of the United States who were implanted with the Rejuvenate® Hip System and/or the ABG™ II Hip System.

22. Defendant Howmedica Osteonics d/b/a Stryker Orthopaedics, is a corporation organized and existing under the laws of New Jersey, with its principal place

of business in Mahwah, New Jersey. Defendant does business throughout the United States, including in the State of Minnesota. Defendant Howmedica Osteonics d/b/a Stryker Orthopaedics is a wholly owned subsidiary of parent corporation, Stryker Corporation.

23. Defendant Stryker Corporation is the parent corporation organized and existing under the laws of Michigan, with its principal place of business in Kalamazoo, Michigan. Defendant does business throughout the world and throughout the United States, including in the State of Minnesota. Stryker holds itself out as "one of the world's leading medical technology companies and is dedicated to helping healthcare professionals perform their jobs more efficiently while enhancing patient care. Stryker provides innovative orthopaedic implants as well as state-of-the-art medical and surgical equipment to help people lead more active and more satisfying lives." www.stryker.com

24. In 2009, sales totaled $6.723 billion, which places Stryker Corporation among the 12 leading medical technology companies in the world.

25. Defendant Stryker Sales Corporation is a corporation organized and existing under the laws of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002 and conducts business throughout the United States, including the State of Minnesota. Stryker Sales Corporation is a wholly owned subsidiary of Stryker Corporation. It employs field representatives throughout the United States. (source: http://www.law360.com/articles/408121/stryker-field-service-reps-win-class-cert-in-flsa-suit)

26. Defendant Stryker Ireland, Limited is a foreign corporation that is also a wholly owned subsidiary of Stryker Corporation. Stryker Ireland has three facilities located in Ireland (two in Cork and one in Limerick) and employs approximately 1,200 people in total. These sites are held out as "centres of excellence" in R&D, Manufacturing and Customer Service. Stryker Ireland's product profile includes: Hip Replacement Systems, Knee Replacement Systems, Bone Cement and Precise Cutting Accessories including Micro Rotary Instruments and Bone Saw Blades. Stryker develops minimally invasive surgical instruments which are used for cutting, drilling, burring and shaping of bone and soft tissue. Upon information and belief, these products are used during Orthopaedic, Ear Nose and Throat (ENT), Spine, Neuro and Plastic Surgery. Much of the research and design and manufacturing of the Devices at issue in this litigation occurred at Stryker Ireland, before moving the operation to Howmedica Osteonic in Mahwah, New Jersey.

27. The Devices manufactured at Stryker Ireland were sold throughout the United States and in the State of Minnesota. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=110699

28. Upon information and belief, at all times herein mentioned, the employees of Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of each of the individual Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such

designations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of Defendants while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

29. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

30. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendants did (and does) business within the State of Minnesota and have had continuous and systematic contacts with the State of Minnesota, and they have consented to jurisdiction in the State of Minnesota. Upon information and belief, Defendants also advertised in this District, made material omissions and representations in this District and breached warranties in this District.

THE STRYKER REJUVENATE MODULAR PRIMARY HIP SYSTEM

31. In February 2009, Defendants released the Rejuvenate® Modular Primary Hip System ("Rejuvenate®"), the latest evolution in the Defendants' OmniFit and Secure-Fit Hip systems, which was approved for market by the FDA on June 3, 2008. The Rejuvenate® Hip is an extension of the Stryker Modular Hip, which was approved for market by the FDA on September 13, 2007.

32. 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.

33. Unlike most prosthetic hip implants, the Rejuvenate® is an artificial hip replacement device consisting of two basic components: (1) a chromium-cobalt neck that is inserted into a (2) titanium stem. The Rejuvenate® system can be used interchangeably with any number of Stryker bearing surface components which comprise the ball or head and an acetabular cup or socket. The bearing surface system or components are unrelated to the method of failure now seen in the Rejuvenate®.

34. According to Defendants' materials, the Rejuvenate® 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, upon information and belief, the Rejuvenate® was marketed to enable surgeons to better personalize the implant to a patient's unique anatomy.

35. The Rejuvenate® is comprised of separate femoral stem and neck components. This offers a variety of sizing options during surgery. The benefit, according to Defendants' Rejuvenate® Total Hip System Surgical Protocol brochure ("Surgical Protocol"), 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 implant.

36. The Surgical Protocol highlights that the Rejuvenate® 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. Upon information and belief, Defendants claim that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

37. TMZF® is an alloy that was designed and patented by Defendants Howmedica Osteonics d/b/a Stryker Corporation and Stryker Corporation and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. Defendants claim in its promotional materials for the Rejuvenate® that its alloy is both stronger and less rigid than other titanium alloys. Defendants also claim that the particular titanium alloy has been tested and proven by Defendants to resist the effects of corrosion and fretting.

38. Despite Defendants' 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. Svensson et al., "Formation of a fulminant soft-tissue pseudo tumor after uncemented hip arthroplasty. A case report." JBJS(A). 1988 Sep;70(8);1238-42.

39. Upon information and belief, Defendants represented and warranted in its marketing and sale of the Rejuvenate® that the Rejuvenate®'s proprietary materials alleviate these problems.

40. Defendant Howmedica Osteonics holds two patents for modular implant devices. Currently, Defendant has a pending application to patent a modular hip prosthesis similar to the Rejuvenate®.

41. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective Rejuvenate®, either directly or indirectly, to members of the general public within the United States and in the State of Minnesota, including to Plaintiffs.

THE STRYKER ABG™ II MODULAR HIP STEM HISTORY

42. The ABG™ II Hip Stem was approved for market by the FDA on or about November 4, 2009 as an extension of the Stryker Modular Hip, which had been approved for market by the FDA on or about September 13, 2007, and the Rejuvenate® Modular Hip, which had been approved for market by the FDA on or about June 3, 2008.

43. According to Defendants' materials, the ABG™ II Hip Stem 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 options, the ABG™ II was marketed to enable surgeons to better personalize the implant to each patient's unique anatomy.

44. The ABG™ II Hip Stem 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.

45. The ABG™ II Hip Stem combines the material characteristics of TMZF® (Ti-12Mo-6Zr-2Fe) with a coating of 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.

46. 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, Defendants represented and warranted that their proprietary materials alleviated this corrosion and fretting problem.

47. Defendants hold multiple patents for modular implant devices. Currently, Defendant Howmedica has a pending application to patent a modular hip prosthesis similar to the ABG™ II Hip Stem.

URGENT SAFETY NOTICES AND RECALLS

48. In April of 2012, Defendant Stryker Corporation issued an Urgent Field Safety Notice to surgeons and hospitals in the United States regarding the Hip Stems.

49. In this notice, Defendants acknowledged that they 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.

50. This corrosion and fretting was exactly the same failure mechanism that Defendants had warranted would not occur because of the Hip Stem'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.

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

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

53. Almost immediately following the Urgent Field Safety Notice, Defendants issued a voluntary recall of the Stryker Rejuvenate® and ABG™ II in Canada. In the Canadian recall notice, Defendants stated that it was amending the Instructions for Use for the Hip Stem to include warnings that Defendants was on notice of the issues described in the Urgent Field Safety Notice above.

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

THE FEDERAL REQUIREMENTS

55. The Medical Device Amendments of 1976 ("MDA") to the Food Device Cosmetic Act ("FDCA") established the current regulatory framework for medical device approval.

56. The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk to consumers' health, do not require FDA approval for marketing, and include devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. Rejuvenate® and ABG™II are Class III devices.

57. Manufacturers such as Stryker that are seeking to market Class III devices, such as Rejuvenate® and ABG™ II, are required to submit a 510(k) Approval Application ("510(k)") that must be evaluated and approved by the FDA, if they can demonstrate to the FDA that the devices are shown to be "substantially equivalent" to a predicate device the manufacturer previously submitted for approval to the FDA. 21 U.S.C.§ 360e(b)(1)(B).

58. According to the U.S. Supreme Court in Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), the Supreme Court explained that demonstrating that a device qualifies for this, known as the "§ 510(k) process," means that: "[s]ection 510(k)

submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,' 21 CFR § 807.87(e) (2000); and must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "any additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," § 807.87(l). 531 U.S. 341, 346. Here, the Rejuvenate® and the ABG™ II were approved pursuant to this 510(k) process.

59. The FDCA requires Class III medical devices to be demonstrated to be safe and effective for each intended use[2]. Not only is the medical device itself part of the 510(k) approval process, but the labeling and packaging that comes with it.

60. A manufacturer is required to give adequate directions for the use of a medical device such that a "layman can use a device safely and for the purposes for which it is intended,"[3] and conform to section 801.15 requirements governing the appearance of the label.

[2] 21 U.S.C. § 360e(c)(2)(A)(iv) (2012)
[3] 21 C.F.R. § 810.5 (2012)

61. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling[4], and false and misleading labeling is considered 'misbranded"[5], which is prohibited[6].

62. The distribution of a "misbranded" medical device is prohibited pursuant to 21 U.S.C. §§ 331(a), (k) (2012) and 21 U.S.C. § 352(f) (2012).

63. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written including adverse events when the manufacturer has failed to disclose those adverse events to the FDA. Therefore, the labeling becomes inadequate and the product is misbranded.

64. Federal law requires a manufacturer to ensure that any warranty statements it voluntary makes are truthful, accurate, not misleading, and consistent with applicable federal and state law[7].

65. Under the FDCA, medical device manufacturers are prohibited from introducing the adulteration or misbranding of any medical device into interstate commerce[8].

---

[4] 21 U.S.C.§ 321 (n)(2012)
[5] 21 U.S.C.§ 352 (a), q(1) (2012)
[6] 21 U.S.C.§ 331(b).
[7] 21 U.S.C. § 331(b) (effective 2013). It should be noted that the FDA approval letter for Infuse® specifically states that the FDA "…does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." *See* http://www.accessdata.fda.gov/cdrh_docs/pdf/P000058a.pdf

A. The FDA, By Its Regulations and 510(k) Process Prohibits Misleading or False Promotion and Marketing Activities

66. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

67. Generally, to comply with the FDCA and FDA's implementing regulations, and therefore the PMA, such promotional pieces:

a. cannot be false or misleading in any particular; and

b. must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece[9]; and,

c. must be about only approved intended uses[10].

68. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices[11].

69. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about

---

[8] 21 U.S.C. § 331(b) (effective 2013)
[9] 21 U.S.C. § 321(n) (2012); 21 C.F.R. §§ 1.21, 202.1(e)(5)(iii) (2012)
[10] 21 C.F.R. § 801.4 (2012)
[11] *See* 21U.S.C. §352(a), (n), (q), &(4) (2012)

the consequences that can result from use of the product as suggested in a promotional piece[12].

70. "In the case of any restricted device distributed for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e)." [13]

71. Advertisements for restricted devices must include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications…"[14]

72. Restricted device advertisements must not be false or misleading[15] and must reveal facts that are material about the product being advertised, including facts about the consequences that can result from use of the product as suggested in an ad[16].

B. After a Medical Device Is Approved, The Manufacturer Still Has Requirements, Including General Reporting Requirements to the FDA Mandated by Federal Regulations.

73. A medical device manufacturer's obligations do not end with the 510(k) Approval.

74. Even after approval, manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

---

[12] 21 U.S.C.§ 321(n)(2012); 21 C.F.R. §§ 1.21, 202.1 (e)(5)(iii) (2012)
[13] 21 C.F.R. § 502 (q) (2012)
[14] *See* 21 U.S.C. § 352 (r)(2) (2012)
[15] 21 U.S.C. § 352 (q)(1) (2012)
[16] 21 U.S.C. § 321 (n) (2012)

a. May have caused or contributed to death or serious injury; or

b. Has malfunctioned and this device or a similar device [likewise marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur[17].

75. These 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[18].

76. In addition, manufacturers are required to make periodic reports to the FDA regarding approved devices, such reports to include summaries of:

a. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

b. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant[19].

77. Under federal law, a medical device manufacturer has a continuing duty to monitor the product after premarket approval and to discover and report to the FDA any

[17] 21 C.F.R. § 803.50(a) (2012)
[18] Id.
[19] 21 C.F.R. § 814.84 (b)(2) (2012)

complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

78. Following approval, a medical device manufacturer is required to report adverse events associated with the use of the product, i.e. those that may have caused serious injury or death or has malfunctioned and would likely cause or contribute to death or serious injury if recurred[20].

79. The medical device manufacturer is required to report any incidents or information that reasonably suggest that the device (1) "[m]ay have caused or contributed to a death or serious injury" or (2) "[h]as malfunctioned" in a manner that would likely "cause or contribute to a death or serious injury" if it recurred[21].

80. Another general reporting requirement for Class III medical devices after PMA approval is that the manufacturer is obligated to inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know.[22]

81. Further, the FDCA subjects approved devices to reporting requirements[23]. For example, the manufacturer must update the FDA when it learns of investigations or scientific studies concerning its device[24], or incidents where the device used in any manner "[m]ay have caused or contributed to a death or serious injury," either due to

[20] 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012)
[21] 21 C.F.R. § 803.50(a) (2012); 21 C.F.R. §360 i (a) (2012)
[22] 21 C.F.R. § 814.84 (b)(2) (2012)
[23] 21 U.S.C. § 360 I (2012)
[24] 21 C.F.R. § 814.84 (b)(2) (2012)

malfunction or normal operation[25]. The FDA can revoke its approval based on these post-approval reports[26]. The manufacturer must establish internal procedures for reviewing complaints and event reports[27]. 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[28].

82. Medical device manufacturers are required by federal regulation to "establish and maintain" an adverse event database[29]. 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[30].

83. Pursuant to federal regulations, manufacturers must disclose any reportable Medical Device Reporting ("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 five (5) business days after becoming aware of such event or events[31].

---

[25] Id., § 803.50(a) (2012)
[26] 21 U.S.C. §§ 360(e)(1), 360(h)(e) (2012)
[27] 21 C.F.R. § 820.198 (a) (2012)
[28] 21 U.S.C. § 360 (i).
[29] 21 C.F.R. § 803.1(a) (2012)
[30] 21 C.F.R. § 803.52 (2012)
[31] *See* 21 C.F.R. § 806 (2012)

84. Pursuant to federal regulations, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals.

85. FDA regulations require submission of a written report within ten (10) 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[32]. Stryker failed to do so in timely manner.

86. Pursuant to federal regulation, 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.

87. Manufacturers must also meet quality standards in the manufacture of and production of the devices.

[32] *See* 21 C.F.R. § 806 (2012)

88. 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.

89. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary.

90. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance.

C. Post Approval, The FDA, By Its Regulations And PMA Process, Requires A Manufacturer To Follow Good Manufacturing Practices

91. Under 21 C.F.R. § 820.1(a) (2012) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). This part establishes basic requirements applicable to manufacturers of finished medical devices.

92. 21 C.F.R. § 820.5 (2012): "Quality Systems", the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

93. 21 C.F.R. § 820.3(z)(2) (2012): “Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).”

94. 21 C.F.R. § 820.22 (2012): “Quality Audit” states: “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.”

95. 21 C.F.R. § 820.160(a) (2012): “Distribution” states: “Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution.”

96. 21 C.F.R. § 820.170(a) (2012): “Installation” states: “Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.”

97. 21 C.F.R. § 803 (2012), states: “Manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting

("MDR") submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use."

98. 21 C.F.R. § 820.100 (2012) "Corrective and Preventive Action" states: (a) [e]ach manufacturer shall establish and maintain procedures for implementing corrective and preventive action.

99. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; and

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

D. Stryker's Conduct in Violation of the FDCA

100. Stryker violated these FDCA statutes and accompanying regulations by:

a. falsely and misleadingly promoting Rejuvenate® and the ABG™ II Hip Stems;

b. failing to report to the FDA adverse events;

c. failing to timely conduct failure investigations and analysis;

d. failing to timely report any and all information concerning product failures and corrections;

e. failing to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, and device failures necessitating a labeling, manufacturing or device modification;

f. failing to conduct necessary design validation;,

g. selling and distributing a misbranded and adulterated product through interstate commerce; and,

h. failing to immediately disclose the metallosis risk from the fretting and corroding failure of these Hip Stems after implantation in patients.

101. Stryker's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth herein.

102. Stryker's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the use of the Rejuvenate® and ABG™ II Hip Stems; and, generally, and directly caused or significantly contributed to the use of these Defective Devices in Plaintiffs; and Stryker's misconduct in this regard thus caused or contributed to Plaintiffs' injuries and damages.

THE RECALLS

103. 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."[33]

104. Recalls are classified by the FDA in to one of three categories. The designation or category "assigned by the Food and Drug Administration to a particular product recall… indicate[s] the relative degree of health hazard presented by the product being recalled."[34]

105. The FDA categorized the Rejuvenate® and the ABG™ II recall as a "Class II" recall. "A Class II [recall] 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."[35] Classifying the Rejuvenate® recall and the ABG™ II as a "Class II" recall confirms by definition that

[33] See 21 C.F.R. § 7.3 (g) (2012)
[34] *See* 21 C.F.R. § 7.3 (m) (2012).
[35] *Id.*

the devices in question were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

CLAIMS FOR RELIEF

COUNT I - NEGLIGENCE

106. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

107. Defendants designed, manufactured, marketed, detailed, and advertised, both to physicians and consumers, the Rejuvenate® and the ABG ™ II.

108. As a result, Defendants 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. Defendants failed to reasonably execute these duties.

109. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the Rejuvenate® and/ or the ABG™II would be implanted, including Plaintiffs, and is therefore negligent in the following respects:

a. Defendants failed to adequately design and manufacture the Rejuvenate® and/or the ABG™II to insure that neither would corrode, erode, deteriorate, fret, and induce severe metal toxicity in the patient. The flaws include, but are not limited to, the following:

i. The incompatibility of the TMZF® titanium alloy with other components;

ii. Poor design of the taper neck junction between stem and neck such that micro motion was unavoidable:

iii. Poor manufacturing practices such that the taper neck junction between the neck and stem do not "fit" the way they were intended; and,

iv. A combination of the above factors led to rapid, severe heavy metal cast off causing soft tissue and bony necrosis, pain and premature failure of the Rejuvenate® and the ABG™ II.

b. Defendants failed to adequately test the Rejuvenate® and the ABG™ II to insure that it would not corrode, erode, deteriorate and/or induce severe metal toxicity in the patient;

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

d. Defendants made affirmative representations that the Rejuvenate® and the ABG™ II would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer, including Plaintiffs;

e. Defendants trained its sales force to "detail" the Rejuvenate® and the ABG™ II utilizing representations that the Defendants knew or should have known were false, creating in the minds of both

surgeons and consumers that the device would not cause metal toxicity;

f. Defendants specifically marketed the Rejuvenate® and the ABG™ II 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. Defendants marketed the Rejuvenate® and the ABG™ II as a "perfect fit" for younger patients due to its modular design, creating in the minds of physicians and consumers that the Rejuvenate® and the ABG™ II were superior to other available hip implants. In fact, the Rejuvenate® and the ABG™ II were so poorly designed, constructed, and tested, that they had to be recalled from the market approximately three years after the Rejuvenate® was introduced and two years after the ABG™ II was introduced. Defendants failed to manufacture the Rejuvenate® and the ABG ™II to FDA-cleared and/or Defendants' 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;

h. Defendants 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 hip replacement device;

i. Defendants failed to promptly act upon reports of early failure such that the Rejuvenate® and the ABG™ II continued to be implanted in unknowing patients by surgeons well after they should have been recalled or sales should have been suspended;

j. Upon information and belief, Defendants chose as its predicate device a system that had known, disastrous failures, 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,

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

110. Defendants, as manufacturers, suppliers and sellers of these medical devices had superior knowledge and owed a duty of care to their customers and to the patients themselves, in whom these Defective Devices were implanted.

111. Defendants breached their duty of care. The above conduct demonstrates Defendants' failure to exercise reasonable and appropriate care.

112. It was foreseeable that this wrongful conduct and omissions would lead to premature device failure as well as severe, permanent, debilitating injuries to patients, including Plaintiffs.

113. As a direct and proximate result of Defendants' 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 Defendants, as contained in the Prayer For Relief.

COUNT II – NEGLIGENCE PER SE

114. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

115. Defendants 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 Devices.

116. Defendants failed to comply with federal requirements. Specifically, it is believed that with respect to the Devices, Defendants 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 Defendants, as contained in the Prayer For Relief.

COUNT III

STRICT PRODUCTS LIABILITY-DEFECTIVE DESIGN

117. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

118. This is an action for strict liability based upon design defect against Defendants.

119. Defendants' Devices are 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. Defendants acted unreasonably in its design of the Devices in that Defendants failed to adopt a safer design for the Devices 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.

120. Defendants' Devices do not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

121. The risks of using Defendants' Devices outweigh the benefits of using the Devices.

122. There were numerous safer alternative designs to the Devices 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 Devices left the control of Defendants by the application of existing or reasonably achievable scientific knowledge.

123. The design defects in Defendants' Devices 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 Defendants, as contained in the Prayer for Relief.

COUNT IV

STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT

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

125. This is an action for strict liability based on a manufacturing defect.

126. The Devices were designed for implantation into the human body and to last for fifteen or more years. The Devices was also designed to be compatible with human tissue and bone.

127. The Devices 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.

128. The Devices installed in the hips of Plaintiffs herein were not compatible with human tissue and bone. Through a process of fretting and corrosion, the Devices released heavy metals into the bodies of Plaintiffs' herein causing severe and permanent destruction of bone and tissue. Defendants failed to manufacture the Devices in a manner that prevented fretting and corrosion, and, in fact, manufactured the product such that it caused fretting and corrosion.

129. The Devices implanted in the hips of Plaintiffs herein contained manufacturing defects.

130. The manufacturing defects in the Devices 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 Defendants, as contained in the Prayer For Relief.

COUNT V

STRICT PRODUCTS LIABILITY - FAILURE TO WARN

131. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

132. The Devices 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 Defendants. Defendants acted unreasonably in failing to provide such warning or instruction prior to July 2012.

133. The warnings that accompanied the Devices 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 Defendants.

134. Moreover, the Devices left the Defendants' control without an adequate warning or instruction, and created an unreasonably dangerous condition in that Defendants, 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 Devices left the Defendants' control, Defendants became aware of, or in the exercise of ordinary care should have known, that the Devices posed a substantial risk of harm to patients, including Plaintiffs herein, yet Defendants failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

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

COUNT VI

BREACH OF EXPRESS WARRANTY

135. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

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

137. 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 Devices (but which contained material misrepresentations and utterly failed to warn of the risks of the Devices); (iii) verbal assurances made by Defendants' consumer relations personnel to

the public about the safety of the Devices that also downplayed the risks associated with implantation of the Devices; and (iv) false and misleading written information supplied by Defendants.

138. The most prominent representation made by Defendants was on websites where Defendants expressly warranted that the design, testing, and materials utilized in the Devices would prevent fretting and corrosion.

139. Plaintiffs herein further allege that all of the aforementioned written materials are known to Defendants and in their possession, and it is Plaintiffs' reasonable belief that these materials shall be produced by Defendants and be made of record once Plaintiffs are afforded the opportunity to conduct discovery.

140. When Defendants made these express warranties, Defendants knew the purposes for which Devices were to be used and warranted the Devices to be in all respects safe and proper for such purposes.

141. Defendants 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.

142. Defendants' representations and promises regarding the Devices had the natural tendency to induce those in need of prosthetic hip implants, including Plaintiffs herein, to purchase the Devices in reliance thereon.

143. The Devices do not conform to Defendants' representations in that the Devices are not safe and produce serious side effects.

144. As such, the Devices did not conform to Defendants' promises, descriptions, or affirmations of fact and were not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.

145. Defendants therefore breached their express warranties to Plaintiffs herein in violation of applicable state statutes and common law, by manufacturing, marketing, and selling the Devices to Plaintiffs herein and causing damages as will be established at trial.

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

COUNT VII

BREACH OF WARRANTY AS TO MERCHANTABILITY

146. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

147. At all times material, Defendants were merchants with respect to the Devices.

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

149. The Devices were not fit for their ordinary purposes.

150. Plaintiffs herein were foreseeable users of the Devices.

151. The Devices were being used in the intended manner at the time of the injuries sustained by Plaintiffs herein.

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

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

COUNT VIII

BREACH OF IMPLIED WARRANTIES

153. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

154. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Devices.

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

156. Defendants were aware that consumers, including Plaintiffs herein, would use the Devices as hip implants; which is to say that Plaintiffs herein were foreseeable users.

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

158. The Devices were expected to reach and did in fact reach consumers, including Plaintiffs herein, without substantial changes in the condition in which the Devices were manufactured and sold by Defendants.

159. Defendants breached various implied warranties with respect to the Devices in the following manner:

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

161. Defendants represented that the Devices were safe, and/or safer than other alternative hip implants and fraudulently concealed information which demonstrated that the Devices were not safer than alternatives available on the market; and

162. Defendants represented that the Devices were more efficacious than other alternative devices and fraudulently concealed information, regarding the true efficacy of the Devices.

163. In reliance upon Defendants' implied warranties, Plaintiffs herein used the Devices as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

164. Defendants breached their implied warranty to Plaintiffs in that the Devices were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of the following statutes:

a. Ala. Code §§ 7-2-314, *et seq.*;

b. Alaska. Stat. §§ 45.02.314, *et seq.*;

c. Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*;

d. Ark. Code Ann. §§ 4-2-314, *et seq.*;

e. Cal. Comm. Code §§ 2314, *et seq.*;

f. Colo. Rev. Stat. §§ 4-2-314, *et seq.*;

g. Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*;

h. Del. Code Ann. tit. 6, §§ 2-314, *et seq.*;

i. D.C. Code Ann. §§ 28:2-314, *et seq.*;

j. Fla. Stat. Ann. §§ 672.314, *et seq.*;

k. O.C.G.A. §§ 11-2-314, *et seq.*;

l. Haw. Rev. Stat. §§ 490:2-314, *et seq.*;

m. Id. Code §§ 28-2-314, *et seq.*;

n. Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*;

o. Indiana Code Ann. §§ 26-1-2-314, *et seq.*;

p. Iowa Code Ann. §§ 554.2314, *et seq.*;

q. Kan. Stat. Ann. §§ 84-2-314, *et seq.*;

r. Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*;

s. La. Civ. Code Ann. art. 2520, *et seq.* (and is liable for redhibition under this statute);

t. Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*;

u. Md. Code Ann., Com. Law §§ 2-314, *et seq.*;

v. Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*;

w. Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*;

x. Minn. Stat. Ann. §§ 336.2-314, *et seq.*;

y. Miss. Code Ann. §§ 75-2-314, *et seq.*;

z. Mo. Rev. Stat. Ann. §§ 400.2-314, *et seq.*;

aa. Mont. Code Ann. §§ 30-2-314, *et seq.*;

bb. Neb. Rev. Stat. §§ 2-314, *et seq.*;

cc. Nev. Rev. Stat. §§ 104.2314, *et seq.*;

dd. N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*;

ee. N.J. Stat. Ann. §§ 12A:2-314, *et seq.*;

ff. N.M. Stat. Ann. § 55-2-314, *et seq.*;

gg. N.Y. U.C.C. Law §§ 2-314, *et seq.*;

hh. N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*;

ii. N.D. Cent. Code §§ 41-02-31, *et seq.*;

jj. Ohio Rev. Code Ann. §§ 1302.27, *et seq.*;

kk. Okl. Stat. Tit. 12A, §§ 2-314 *et seq.*;

ll. Or. Rev. Stat. §§ 72.3140, *et seq.*;

mm. 13 Pa. Stat. Ann. §§ 2314 *et seq.*;

nn. R.I. Gen. Laws §§ 6A-2-314, *et seq.*;

oo. S.C. Code Ann. §§ 36-2-314, *et seq.*;

pp. S.D. Codified Laws §§ 57A-2-314, *et seq.*;

qq. Tenn. Code Ann. §§ 47-2-314, *et seq.*;

rr. Tex. Bus. & Com. Code Aim. §§ 2.314, *et seq*.;

ss. Utah Code Ann. §§ 70A-2-314, *et seq*.;

tt. Va. Code Ann. §§ 8.2-314, *et seq*.;

uu. Vt. Stat. Ann. §§ 9A-2-314, *et seq*.;

vv. Wash. Rev. Code §§ 62A.2-314, *et seq*.;

ww. W. Va. Code §§ 46-2-314, *et seq*.;

xx. Wis. Stat. Ann. §§ 402.314, *et seq*.; and,

yy. Wyo. Stat. Ann. §§ 34.1-2-314, *et seq*.

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

166. 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, 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 Defendants, as contained in the Prayer For Relief.

COUNT IX

VIOLATION OF MINNESOTA DECEPTIVE ACTS AND PRACTICES, UNFAIR TRADE PRACTICES, CONSUMER PROTECTION, MERCHANDISING PRACTICES AND FALSE ADVERTISING ACTS

167. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

168. By reason of the conduct as alleged herein, and by inducing consumers and their physicians to use the Rejuvenate® and/or the ABG™ II through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts, including but not limited to fraudulent statements, concealments and misrepresentations identified herein and above, Defendants violated the provisions of Minn. Stat. §§325F.67, 325F.69, 325D.13, and 325D.44.

169. As a direct and proximate result of Defendants' statutory violations, Plaintiffs were implanted with a Rejuvenate® Hip Stem and/or an ABG ™II Hip Stem, which would not have occurred had Defendants not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts to induce Plaintiffs and their physicians to use the Devices.

WHEREFORE, by reason of such violations and pursuant to Minn. Stat. § 8.31, subd. 3a, and §§325D.44, 325F.67, and 325F.68-70, Plaintiffs are entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and to recover any and all consequential damages

recoverable under the law including, but not limited to, both past and future medical expenses; past wage loss; loss of future earning capacity; and, past and future pain, suffering, disability, and emotional distress. Plaintiffs are entitled to seek compensatory damages, attorneys' fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. § 8.31, subd. 3a, and §§ 325D.44, 325F.67, and 325F.68-70.

COUNT X

VIOLATION OF CONSUMER FRAUD AND/OR UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

170. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

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

172. Defendants are on notice that such claims may be asserted by individual Plaintiffs herein.

173. Plaintiffs purchased and used the Devices for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

174. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs, Plaintiffs' physicians, hospitals and medical centers would not have purchased and/or paid for the Devices, and would not have incurred related medical costs and injuries.

175. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs, Plaintiffs' physicians and hospitals for the Devices that would not have been purchased had Defendants not engaged in unfair and deceptive conduct.

176. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

177. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

178. Advertising goods or services with the intent not to sell them as advertised; and,

179. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

180. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Devices. Each aspect of Defendants' conduct combined to artificially create sales of the Devices.

181. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Devices.

182. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Devices, and would not have incurred related medical costs.

183. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

184. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

185. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of:

a. Ala. Code §§ 8-19-1 *et seq.*;

b. Alaska Stat. §§ 45.50.471 *et seq.*;

c. Ariz. Rev. Stat. Ann. §§ 44-1522 *et seq.*;

d. Ark. Code Ann. §§ 4-88-101 *et seq.*;

e. Cal. Civ. Code §§ 1770 *et seq.* and Cal. Bus. & Prof. Code §§ 17200 et seq.;

f. Colo. Rev. Stat. §§ 6-1-105 *et seq.*;

g. Conn. Gen. Stat. §§ 42-110a *et seq.*;

h. Del. Code Ann. tit. 6, §§ 2511 *et seq.* and §§ 2531 *et seq.*;

i. D.C. Code Ann. §§ 28-3901 *et seq.*;

j. Fla. Stat. Ann. §§ 501.201 *et seq.*;

k. O.C.G.A. §§ 10-1-372 *et seq.*;

l. Haw. Rev. Stat. §§ 480-1 *et seq.*;

m. Id. Code Ann. §§ 48-601 *et seq.*;

n. Ill. Comp. Stat. Ann ch. 815, 505/1 *et seq.*;

o. Ind. Code Ann. §§ 24-5-0.5-1 *et seq.*;

p. Iowa Code Ann. §§ 714.16 *et seq.*;

q. Kan. Stat. Ann. §§ 50-623 *et seq.*;

r. Ky. Rev. Stat. Ann. §§ 367.170 *et seq.*;

s. La. Rev. Stat. Ann. §§ 51:1401 *et seq.*;

t. Me. Rev. Stat. Ann. tit. 5, §§ 205A *et seq.*;

u. Md. Code Ann., Com. Law §§ 13-101 *et seq.*;

v. Mass. Gen. Laws Ann. Ch. 93A *et seq.*;

w. Mich. Comp. Laws §§ 445.901 *et seq.*;

x. Minn. Stat. §§ 325D.43 *et seq.* and §§ 325F.67 *et seq.*;

y. Miss. Code Ann. §§ 75-24-1 *et seq.*;

z. Mo. Ann. Stat. §§ 407.010 *et seq.*;

aa. Mont. Code Ann. §§ 30-14-101 *et seq.*;

bb. Neb. Rev. Stat. §§ 59-1601 *et seq.*;

cc. Nev. Rev. Stat. §§ 598.0903 *et seq.*;

dd. N.H. Rev. Stat. Ann. §§ 358-A:1 *et seq.*;

ee. N.M. Stat. Ann. §§ 57-12-1 *et seq.*;

ff. N.Y. Gen. Bus. Law §§ 349 *et seq.* and §§ 350-e *et seq.*;

gg. N.C. Gen. Stat. §§ 75-1.1 *et seq.*;

hh. N.D. Cent. Code §§ 51-12-01 *et seq.* and §§ 51-15-01 *et seq.*;

ii. Ohio Rev. Code Ann. §§ 1345.01 *et seq*.;

jj. Okla. Stat. tit. 15 §§ 751 *et seq*.;

kk. Or. Rev. Stat. §§ 646.605 *et seq*.;

ll. 73 Pa. Stat. §§ 201-1 *et seq*.;

mm. R.I. Gen. Laws. §§ 6-13.1-1 *et seq*.;

nn. S.C. Code Ann. §§ 39-5-10 *et seq*.;

oo. S.D. Codified Laws §§ 37-24-1 *et seq*.;

pp. Tenn. Code Ann. §§ 47-18-101 *et seq*.;

qq. Tex. Bus. & Com. Code Ann. §§17.41 *et seq*.;

rr. Utah Code Ann. §§ 13-11-1 *et seq*.;

ss. Vt. Stat. Ann. tit. 9, §§ 2451 *et seq*.;

tt. Va. Code Ann. §§ 59.1-196 *et seq*.;

uu. Wash. Rev. Code. §§ 19.86.010 *et seq*.;

vv. W. Va. Code §§ 46A-6-101 *et seq*.;

ww. Wis. Stat. Ann. §§ 100.20 *et seq*.; and

xx. Wyo. Stat. Ann. §§ 40-12-101 *et seq*.

186. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

187. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Devices were fit to be used for the purpose for which they were intended, when in fact the Devices were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

188. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

189. Defendants had actual knowledge of the defective and dangerous condition of the Products and failed to take any action to cure such defective and dangerous conditions.

190. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which Hip Stem to use.

191. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

192. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

193. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses and other damages

and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

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

COUNT XI

NEGLIGENT MISREPRESENTATION

194. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

195. Specific defects in the Rejuvenate® and/or ABG™II as specified above in this Complaint rendered it defective and unreasonably dangerous.

196. At all relevant times, Defendants were engaged in the business of selling Rejuvenate® and/or ABG™II for resale or use, and in fact did sell the Devices used by Plaintiffs' implanting surgeons. In the course of marketing Rejuvenate® and/or ABG™II, Stryker made untrue representations of material facts and omitted material information to Plaintiffs, Plaintiffs' physicians, and the public at large. Stryker made these misrepresentations and omissions to guide physicians in their purchase and use of Rejuvenate® and/or ABG™II.

197. Plaintiffs and Plaintiffs' physicians would not have purchased and implanted the Device or Devices in the hip implant surgery had they known of the true safety risks related to Rejuvenate® and/or ABG™II.

198. Defendants were negligent in making the untrue misrepresentations and omitting material information because Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their Devices.

199. Plaintiffs and Plaintiffs' physicians would reasonably be expected to use Rejuvenate® and/or ABG™II Hip Stems. Defendants intended to induce Plaintiff and Plaintiff's physicians to rely on their misrepresentations and omissions to use either or both of these devices in hip implant operations in lieu of using safer, alternative hip stems and hip systems.

200. Plaintiffs and Plaintiffs' physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to Rejuvenate® and/or ABG™II in deciding to implant these Devices as Hip Stems.

201. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiffs have suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

202. Plaintiffs have been injured and suffer injuries to the body and mind, the exact nature of which are not completely known to date.

203. Plaintiffs have sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown.

204. Plaintiffs will be required to incur additional medical expenses in the future to care for themselves and each of them as a result of the injury and damages each has suffered.

205. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

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

COUNT XII

LOSS OF CONSORTIUM

206. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

207. At all times material, certain Plaintiffs were married to spouses. As a result of the injuries and damages sustained by certain Plaintiffs, Plaintiffs' spouses have suffered the loss of care, comfort, society and affections from Plaintiffs.

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

COUNT XIII

UNJUST ENRICHMENT

208. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

209. Stryker enjoys enormous revenues from sales of the Defective Devices during the period the Defective Devices were on the market in the United States.

210. It is unjust to allow Stryker to earn revenues and retain the benefits and profits from these Defective Devices while Plaintiffs suffered injuries and damages as specified herein.

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

COUNT XIV

WRONGFUL DEATH

211. Plaintiffs reallege and incorporate by reference the allegations set forth above as if set forth herein and further allege as follows:

212. Plaintiff alleges, on information and belief, that Decedent's sudden, premature, and untimely death was the result of the defective Rejuvenate® and/or ABG™II Hip Stems.

213. As alleged throughout this Complaint and as reincorporated herein, Plaintiff alleges that Decedent would not have received the Rejuvenate® and/or ABG™II Hip Stems but for the intentional and negligent tortious conduct of Defendants; similarly, as alleged throughout this Complaint and as incorporated herein, Plaintiff alleges the Defendants are strictly liable for the Decedent's death and all injuries and damages flowing from Decedent's death, for the reasons alleged in this Complaint;

214. Plaintiff seeks to recover damages for all legally compensable injuries relating to Decedent's wrongful death.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and request:

1. Awarding compensatory damages;
2. Awarding pre-judgment and post-judgment interest to Plaintiffs;
3. Awarding all statutory damages and relief;
4. Awarding the costs and the expenses of this litigation to Plaintiff;
5. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law;
6. Granting Plaintiffs equitable relief in the nature of disgorgement; Restitution to remedy Stryker's unjust enrichment; and,
7. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims in this Complaint so triable.

Dated: __1/14/2014____ Respectfully submitted,

Plaintiffs' Lead Counsel Committee

MEYERS & FLOWERS

/s/ Peter J. Flowers
Peter J. Flowers
225 W. Wacker Drive, Suite 1515
Chicago, IL 60606
Phone: (312) 214-1017
Email: pjf@meyers-flowers.com

Lead Counsel Committee Chairperson

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

/s/Wendy R. Fleishman
Wendy R. Fleishman
250 Hudson Street, 8th Floor
New York, NY 10013
Phone: (212) 355-9500
Email: wfleishman@lchb.com

CORY WATSON CROWDER & DEGARIS, PC

/s/ Annesley DeGaris
Annesley H. DeGaris
2131 Magnolia Avenue
Birmingham, AL 35205
Phone: (205) 328-2200
Email: adegaris@cwcd.com

WEISMAN, KENNEDY & BERRIS CO., L.P.A.

/s/ Eric Kennedy
R. Eric Kennedy
1600 Midland Building
101 Prospect Avenue West
Cleveland, OH 44115
Phone: (216) 781-1111
Email: ekennedy@weismanlaw.com

LEVIN PAPANTONIO, P.A.

/s/ Ben W. Gordon, Jr.
Ben W. Gordon
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
Phone: (850) 435-7090
Email: bgordon@levinlaw.com

ZIMMERMAN REED P.L.L.P.

/s/ Genevieve M. Zimmerman
Genevieve M. Zimmerman (MN#330292)
1100 IDS Center
80 South 8th Street
Minneapolis, MN 55402
Phone: (612) 341-0400
Fax: (612) 341-0844
Email:
Genevieve.Zimmerman@zimmreed.com