BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: STRYKER REJUVENATE AND ABG II HIP IMPLANT PRODUCTS LIABILITY LITIGATION	**MDL No. 2441 ORAL ARGUMENT REQUESTED**

INTERESTED PARTY RESONSE IN OPPOSITION TO MOTION FOR TRANSFER OF ACTIONS TO THE DISTRICT OF MINNESOTA AND IN SUPPORT OF MOTION TO TRANSFER ACTIONS TO THE NORTHERN DISTRICT OF ILLINOIS FOR CONSOLIDATED PROCEEDINGS PURSUANT TO 28 U.S.C. § 1407

Plaintiffs, Brett and Lisa Lincoln ("Plaintiffs"), by and through undersigned counsel respectfully submit this Interested Party Response pursuant to Rules 6.1 and 6.2 of the Rules of Procedure for the Judicial Panel on Multidistrict Litigation ("Panel") in Opposition to Motion For Transfer to the District Of Minnesota and in Support of the Motion to Transfer Actions to the Northern District of Illinois concerning all cases pending in federal courts against Howmedica Osteonics Corporation ("Howmedica") involving Stryker Rejuvenate Modular Hip Stem ("Rejuvenate") and ABG II Modular Hip Stems ("ABG II") pursuant to 28 U.S.C. § 1407. As is more fully set forth below, Plaintiffs herein agree that consolidation and coordination of cases concerning both the Rejuvenate and ABG II will promote convenience and efficiency in pretrial proceedings concerning these products; and support movant Christine Wilkinson's Motion for Transfer to the Northern District of Illinois before the Hon. John W. Darrah as the appropriate District for all of these cases. Alternatively, Plaintiffs would support the consolidation of Rejuvenate and ABG II cases before the Eastern District of Pennsylvania as sought by movant Annalisa Fox.

INTRODUCTION

Plaintiffs Lisa and Brett Lincoln are Massachusetts residents and filed their cause of action before the United States District Court for the District of Massachusetts on April 3, 2013. Plaintiff Lisa Lincoln was implanted with the Stryker ABG II Modular Hip Stem in her right hip on June 3, 2010 at Newton Wellesley Hospital in Newton Massachusetts by Dr. Daniel Snyder. (Compl. At ¶ 9, attached hereto as Exhibit A.). Plaintiff suffered failure of her prosthesis and endured two revision surgeries. On April 12, 2012, Plaintiff underwent revision of the acetabular cup due to her lack of progress recovering from hip replacement surgery. Id.. at ¶ 21. On or about June 30, 2012 Defendant Howmedica announced the voluntary recall of the Rejuvenate and ABG II. Id. at ¶ 41. Like the Rejuvenate, the ABG II was recalled because of "device failure due to heavy metal fretting and corrosion." Id. In or about February 2013, Plaintiff was diagnosed with "metallosis, adverse soft tissue reaction and pseudotumor formation," secondary to failure of the device. Id. ¶ 26. On March 26, 2013, Plaintiff had revision of her ABG II prosthesis at Massachusetts General Hospital by Dr. Young Min-Kwon. Id.

A. REJUVENATE AND ABG II CASES SHOULD BE CONSOLIDATED INTO ONE MDL

Defendants' assertion that ABG II claims should not be consolidated into this MDL is moot. At the time of Defendants filing it may have been true that there were no ABG II cases filed; that is no longer the case. Plaintiff's case involves the recalled ABG II device. Moreover, Plaintiffs know of at least three additional cases that have been filed

in federal court concerning the ABG II device.[1]

Consolidation of cases involving both Rejuvenate and ABG II into one MDL will promote judicial efficiency and eliminate inconsistent rulings arising out of cases that are fundamentally identical and involve the same alleged misconduct by Defendants. It is important to note, as has been pointed out by movant Robert Davis and movant Annalisa Fox, Defendant Howmedica failed to oppose Plaintiffs' motion to consolidate all causes of action in the state of New Jersey concerning personal injuries secondary to the Rejuvenate and ABG II.[2] It is easy to see why the consolidation motion in New Jersey state court was unopposed. First, it is undisputed that both the Rejuvenate and ABG II are made by the same Defendant. Second, both prosthetics are made of a proprietary alloy patented by Stryker, TMZF. Third, according to the Defendant, both the Rejuvenate and the ABG II fail in the same way -- fretting and corroding. See, Stryker's Frequently Asked Questions attached hereto as Exhibit B. Fourth, fretting and corrosion of the Rejuvenate and ABG II causes the same adverse reactions in patients, specifically, metallosis, necrosis, adverse local tissue reaction and pseudo tumor formation. Id. Fifth, Defendants' recommendations for testing and treatment regardless of which recalled device a patient received are identical. Id. In most, if not all of Defendant's public pronouncements concerning the recall Defendant makes no distinction between the two devices. See, Id. and Stryker Website attached hereto as Exhibit C. Any suggestion by

[1] Plaintiff is aware of three other cases filed in federal court concerning the ABG II. Ruben v. Howmedica Osteonics Corp., et al. 1:13-cv-02144 (N.D.Ill) and Wagner et al. v. Howmedica Osteonics Corp., 2:13-cv-00038-DLB-CJS (E.D. KY); and Teoli v. Howmedica , (D. NJ).

[2] See, Plaintiff Robert Davis' Reply Brief in Support of Plaintiff's Motion for Transfer of Actions Pursuant to 28 U.S.C. 1407 at 4-5; and Plaintiff Annalisa Fox's Interested Party Response To Motion to Transfer and Consolidate Pursuant to 28 U.S.C. 1407 and for Consolidation of related Actions to the Eastern District of Pennsylvania, at 3.

Defendant that inclusion of the ABG II in the Rejuvenate consolidation is not serious.[3] As has been pointed out by others,[4] there were more than 9,000 ABG II devices implanted, Plaintiffs fully expect the number of ABG II cases to grow.

As stated above, causes of action arising out of the Rejuvenate and ABG II are based on common questions of law and fact, and as such should be consolidated into a single MDL which should reasonably be titled "In re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation."

B. THE NORTHERN DISTRICT OF ILLINOIS IS THE APPROPRIATE DISTRICT FOR THIS CONSOLIDATION.

As many movants and interested parties have already pointed out, the Northern District of Illinois is the most suitable forum for this matter.[5]

Selection of an appropriate transferee forum involves a balancing test of several factors based on the specific facts of the actions being considered for consolidation. See, Robert A. Cahn., A Look at the Judicial Panel of Multidistrict Litigation, 72 F.R.D. 211, 214 (1977). Plaintiffs supports movant Christine Wilkinson subsequent filing seeking to consolidate these actions in the Northern District of Illinois because it is centrally located in Chicago which is served by two major airports and will be convenient for all parties and witnesses required enabling the "just and efficient conduct of the case as required by 28 U.S.C. § 1407 (a).

Further, Plaintiffs support movant Christine Wilkinson and plaintiffs Pamelia and

[3] Plaintiff concurs with argument of movant Davis' argument that any delay in consolidating ABG II and Rejuvenate cases with waste judicial resources and respectfully refer the Panel to Plaintiff Robert Davis' Reply Brief at 6.
[4] See, Id. and Plaintiff, Stephanie Teoli's Interested Party Response and Memorandum of Law in Support of Transfer, Coordination, and Consolidation Pursuant to 28 U.S.C. § 1407 at 4.
[5] See, generally, filings of Plaintiffs Pamelia and David Espat; and filings of Plaintiff Christine Wilkinson.

David Espat in their assessment of the qualifications and experience of Judge John W. Darrah as uniquely qualified to efficiently manage this litigation.[6] For all the foregoing reasons, Plaintiffs respectfully request that these proceedings be transferred to the United States District Court for the Northern District of Illinois.

C. ALTERNATIVELY, THE EASTERN DISTRICT OF PENNSYLVANIA IS AN APPROPRIATE CHOICE FOR CONSOLIDATION

Should the Judicial Panel of MultiDistrict Litigation find that the Northern District of Illinois is not its choice for this consolidated action, Plaintiffs respectfully suggest that the Eastern District of Pennsylvania is an appropriate location for this litigation.[7]

Dated: This 10th day of April, 2013

Respectfully submitted,

/s/ Walter Kelley_____
Walter Kelley, Esquire
BBO No. 670525
KELLEY BERNHEIM DOLINSKY, LLC
Four Court Street
Plymouth, Massachusetts 02360
(508) 747-8854
walterkelley@duejustice.com

Attorney for Brett and Lisa Lincoln

[6] See, Plaintiff Christine Wilkinson's Subsequent Motion of Plaintiff for the Transfer of Actions to the Northern District of Illinois Pursuant to 28 U.S.C. §1407 For Coordinated And/Or Consolidated Proceedings at ¶ 7; and Plaintiffs Pamelia and David Espat's Memorandum in Opposition to the Motion for Transfer of Actions To the District of Minnesota and In Support of Transfer to the Northern District of Illinois Pursuant to 28 U.S.C. § 1407 For Coordinated Or Pretrial Proceedings at 3.

[7] See, Interested Party Annalise Fox's Motion for Transfer to the Eastern District of Pennsylvania.

CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2013 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will deliver the document to all counsel of record.

BY:__/s/ Walter Kelley_____
KELLEY BERNHEIM DOLINSKY, LLC
Four Court Street
Plymouth, Massachusetts 02360
(508) 747-8854
walterkelley@duejustice.com

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

LISA LINCOLN and BRETT LINCOLN Plaintiffs, v. HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPAEDICS Defendant	CIVIL ACTION NO.: COMPLAINT AND JURY DEMAND

COMPLAINT

COME NOW Plaintiffs, LISA LINCOLN and BRETT LINCOLN, by and through the undersigned counsel, and bring this complaint against Defendant, Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics and alleges as follows:

1. This is an action for damages relating to Defendant's development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the Defective Device sold under the name the ABG II Modular Hip Stem (hereinafter "ABG II Modular Hip Stem" or "Defective Device").

PARTIES, JURISDICTION AND VENUE

2. Plaintiffs, LISA LINCOLN and BRETT LINCOLN, ("Plaintiff"), are residents of Walpole, Norfolk County, Massachusetts.

3. 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, New

Jersey 07430 and conducts business throughout the United States including in the Commonwealth of Massachusetts.

4. The Court has original jurisdiction under 28 U.S.C. § 1332 because it is between citizens of different states and the amount in controversy exceeds $75,000, exclusive of costs and interest. Plaintiff is a citizen and resident of the Commonwealth of Massachusetts. The Defendant is a citizen and resident of the state of New Jersey.

5. Venue is proper in the United States District Court for the District of Massachusetts because the wrongful acts upon which this lawsuit is based occurred, in part, in this District and the Plaintiffs reside in the city of Boston. Venue is proper pursuant to 28 U.S.C. § 1391(c) because Defendant is a corporation that has substantial, systematic, and continuous contacts in this District and is subject to personal jurisdiction in this District.

6. Further, venue is proper in the United States District Court for the District of Massachusetts because it is a judicial district in which a substantial part of the events or omissions giving rise to the claims making the basis of this lawsuit occurred.

THE PRODUCT

7. At all times material hereto, Defendant Stryker/Howmedica (hereinafter referred to collectively as "Defendant" or "Stryker") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Defective Device sold under the name "The ABG II ® System" (hereinafter "ABG II Modular Hip Stem" or "Defective Device"), either directly or indirectly, to members of the general public within the Commonwealth of Massachusetts and elsewhere, including Plaintiff, LISA LINCOLN.

8. Defendant's Defective Device was placed into the stream of interstate commerce and was implanted in Plaintiff LISA LINCOLN on June 3, 2010.

9. On or about June 3, 2010, Plaintiff underwent right total hip replacement at Newton Wellesley Hospital in Newton, Massachusetts by Daniel Snyder, MD.

10. As a direct and proximate result of Defendant placing the Defective Device into the stream of commerce, Plaintiff LISA LINCOLN has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

11. On June 3, 2008, Defendant received FDA clearance to sell its Rejuvenate System in the United States.

12. On or about November 4, 2009, Defendant received 510 (k) FDA approval for the ABG II Modular Hip Stem as substantially equivalent to the Rejuvenate Modular Hip Stem.

13. Sometime during the first week of July, 2012, the Defendant issued a voluntary worldwide recall of both the Rejuvenate and ABG II modular neck hip stems.

14. The ABG II Modular Hip Stem is a modular hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis. It is indicated for cementless use only.

15. Unlike most prosthetic hip implants, the ABG II and Rejuvenate Modular Hip Stems are artificial hip replacement devices consisting of two basic components: a chrome cobalt neck that is inserted into a titanium stem. The ABG II and Rejuvenate stems can be used with any number of bearing surface components comprised of the ball, or artificial femoral head, and an acetabular cup, or socket.

16. In its application for approval Defendant maintained that the Defective Device was "intended to be used with any currently available compatible Howmedica Osteonics' acetabular components. Compatibility with the modular stems includes: V40 Biolox Delta, Biolox Delta Universal Taper Heads and Sleeves, V40 CoCr Heads, V40 LFIT CoCr Heads, C-Taper Alumina Heads when used with the V40/C-taper Adaptor, C-Taper Delta Heads when used with C-taper Adaptor, UHR Universal Head, Unitrax Heads when used with the Unitrax V40 Modular Adapter."

17. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. Their alloy was designed and patented by Defendant and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. The Defendant claims in its promotional materials for the ABG II and Rejuvenate Modular Hip Stems that their alloy is both stronger and less rigid than other titanium alloys. It also claims that the particular titanium alloy has been tested and proven by Defendant to resist the effects of corrosion and fretting.

18. At all times material hereto, the ABG II Modular Hip Stem implanted in the Plaintiff LISA LINCOLN was designed, manufactured, marketed, distributed and/or supplied by Defendant.

19. After the implantation of the Defective Device, Plaintiff LISA LINCOLN presented to Daniel Snyder, MD in Newton, Massachusetts for examination in or about March, 2012 with complaints of pain and discomfort.

20. Diagnostic workup at that time revealed pseudotumor or pseudobursa behind the acetabular cup, suggesting failure and loosening of the acetabular component without evidence of infection.

21. On or About April 12, 2012, based upon the Plaintiff's symptoms and diagnostic testing and examination, Dr. Snyder recommended and scheduled revision surgery of the acetabular cup at Newton Wellesley Hospital.

22. During removal and replacement of the acetabular cup, Dr. Snyder confirmed presence of pseudotumor and adverse tissue reaction that lead to failure of the device.

23. Next, on or about January 2013, Plaintiff was contacted by Dr. Snyder's office informed of the recall involving the ABG II Modular Hip Stem and asked to come in for blood work to check for cobalt toxicity.

24. In or about February, 2013, MARS MRI revealed the presence of significant fluid collection around the hip prosthesis suggesting pseudotumor and adverse local tissue reaction. Laboratory testing revealed the presence of cobalt at 6.7 ug/l.

25. Based upon these findings and Plaintiff's symptoms, Dr. Snyder recommended Plaintiff see Young-Min Kwon, M.D. of Massachusetts General Hospital and Harvard University Medical School. Dr. Kwon concurred with diagnosis of likely pseudo-tumor and metallosis.

26. Plaintiff saw Dr. Kwon on February 22, 2013. Based upon her examination of the Plaintiff and available diagnostic testing, Dr. Kwon concurred with diagnosis of likely pseudo-tumor and metallosis of the hip. Dr. Kwon recommended that Plaintiff undergo revision of the Defective Device. Accordingly, Plaintiff will undergo revision surgery on March 26, 2013 at Massachusetts General Hospital in Boston, Massachusetts.

27. Plaintiff has endured extensive rehabilitation in Massachusetts since undergoing partial revision of her hip prosthesis in April, 2012 and is expected to endure further rehabilitation upon removal of the ABG II Modular Hip Stem.

THE STRYKER MODULAR HIP STEM HISTORY

28. In February 2009, STRYKER released its Rejuvenate Modular Hip Neck Stem, 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 neck stem is an extension of the Stryker Modular Hip, which was approved for market by the FDA on September 13, 2007.

29. The ABG II Modular Hip Stem is an extension and the substantial equivalent of the Stryker Modular Hip receiving 510(k) approval from the FDA on November 4, 2009.

30. According to STRYKER'S materials, the Rejuvenate and ABG II Modular Hip Neck Stems were 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 a patient's unique anatomy.

31. The ABG II and Rejuvenate Modular Hip Stem are comprised of separate femoral stem and neck components and offer a variety of sizing options intra-operatively. 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 a patient's hip replacement.

32. The ABG II and Rejuvenate Modular Hip Stems combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fc) with a plasma sprayed coating of commercially pure Ti and PureFix HA for the stem and CoCr for the neck. STRYKER claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

33. Despite STRYKER'S claims, this material combination has been reported to cause corrosion. Since the 1980's medical and scientific literature has reported corrosion to be a problem when Ti and CoCr have been used at modular junctions. In its marketing and sale of the device, Stryker represented and warranted that its proprietary materials alleviate this problem.

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

URGENT SAFETY NOTICES AND RECALLS

35. In April, 2012, Defendant issued an Urgent Field Safety Notice to surgeons and hospitals in the United States.

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

37. This corrosion and fretting was exactly the same failure mechanism that Defendant had warranted would not occur because of the ABG II and Rejuvenate'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 device design since the 1980's.

38. The Notice went on to describe symptoms and findings identical to those experienced by Plaintiff.

39. Among those specifically mentioned in the Notice were tissue necrosis, metallosis, adverse soft tissue reaction and pseudo-tumor formation.

40. Almost immediately following the Notice, Defendant issued a voluntary recall of the Stryker Rejuvenate and ABGII in Canada. In the recall notice, Defendant stated that it was

amending the Instructions for Use for the device to include warnings that Defendant was on notice of the issues described in the Notice above.

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

THE FEDERAL REQUIREMENTS

42. 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).

43. 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).

44. 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).

45. The classification of the product withdrawals and corrections of the Defendant's devices (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 devices.

46. 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.

47. 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.

48. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury.

49. 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).

50. 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 device may have caused or contributed to death or serious injury, or 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.

51. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in 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.

52. Pursuant to federal regulation. manufacturers must report to FDA in 5 business days after becoming aware of 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. Sec 21 CFR §803.53.

53. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and 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 ACI 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 and 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 arc subject to the correction or removal. and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

54. 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. Manufacturers must also meet quality standards in manufacture and production. 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. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

55. Pursuant to federal regulation, 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 the device. 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."

56. Specifically, it is believed that with respect to the Rejuvenate Modular Hip Stem, Defendant failed to timely report adverse events, failed to timely conduct failure investigations and analysis, 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

57. Plaintiffs re-allege and incorporate by reference the allegations set forth above.

58. Defendant designed, manufactured, marketed, detailed, and advertised both to physicians and consumers the ABG II Modular Hip Stem.

59. 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.

60. Defendant failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted 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:

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

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

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

iv. 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 induce severe metal toxicity in the patient;

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;

e. Defendant trained its sales force to detail the device utilizing representations that the Defendant 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. 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 this device as a "perfect fit" for younger patients due to its modular design, creating in the minds of physicians and consumers that the device was superior to other available hip implants when, in fact, the device 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 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;

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 device continued to be implanted in unknowing patients by surgeons well after it should have been recalled;

k. Defendant chose as its predicate device a system that had known disastrous failures, had to be redesigned and is the subject of protracted litigation;

l. Defendant was on actual notice prior to marketing the Rejuvenate and ABG II Modular Hip Stems that its TMZF titanium alloy performed poorly when mated with its chrome cobalt components. Defendant knew when it introduced the ABG II Modular Hip Stem to the market that the Stryker Accolade device, that was also a TMZF product, was having corrosion, fretting and failure issues at the taper neck junction between the neck and chrome cobalt head ball. Nevertheless, Defendant either suppressed or ignored the reports and marketed the ABG II Modular Hip Stem anyway, knowing that these two dissimilar metals were performing poorly in the market.

61. 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, debilitating injuries that were permanent.

62. As a direct an proximate result of the Defendant's negligence, Plaintiff suffered severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for

the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of earning capacity. These damages have occurred in the past and will continue into the future.

COUNT II -BREACH OF EXPRESS WARRANTY

63. Plaintiffs re-allege and incorporate by reference the allegations set forth above as if set forth herein.

64. Through their public statements, their descriptions of the ABG II Modular Hip Stem and their promises relating to the ABG II Modular Hip Stem, Defendant expressly warranted among other things that the ABG II Modular Hip Stem 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 acetabular devices; and was more suitable for younger adults that other devices given its purported longevity.

65. 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 ABG II Modular Hip Stem, but which contained material misrepresentations and utterly failed to warn of the risks of the ABG II Modular Hip Stem; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the ABG II Modular Hip Stem and the down playing of the risks associated with the ABG II Modular Hip Stem; (iv) false and misleading written information supplied by Defendant.

66. The most prominent representation made by Defendant was on its website where it expressly warranted that the design, testing and materials utilized in the ABG II Modular Hip Stem would prevent fretting and corrosion

67. Plaintiff further alleges that all of the aforementioned written materials are known to Defendant and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendant and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

68. When Defendant made these express warranties, Defendant knew the purpose for which ABG II Modular Hip Stem was to be used and warranted it to be in all respects safe and proper for such purpose.

69. 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.

70. The ABG II Modular Hip Stem does not conform to Defendant's representations in that it is not safe and produces serious side effects.

71. As such, the ABG II Modular Hip Stem 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.

72. Defendant, therefore, breached its express warranties to Plaintiff in violation of Massachusetts statutory and common law by manufacturing, marketing and selling the ABG II Modular Hip Stem to Plaintiff causing damages as will be established at trial.

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

COUNT III -BREACH OF IMPLIED WARRANTY

Plaintiff re-alleges and incorporates by reference the allegations set forth above as if set forth herein.

73. Through their public statements, their descriptions of the ABG II Modular Hip Stem and their promises relating to the ABG II Modular Hip Stem, Defendant impliedly warranted among other things that the ABG II Modular Hip Stem 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 acetabular devices; and was more suitable for younger adults than other devices given its purported longevity.

74. These implied 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 ABG II Modular Hip Stem, but which contained material misrepresentations and utterly failed to warn of the risks of the ABG II Modular Hip Stem; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the ABG II Modular Hip Stem and the down playing of the risks associated with the ABG II Modular Hip Stem; (iv) false and misleading written information supplied by Defendant.

75. Plaintiff further alleges that all of the aforementioned written materials are known to Defendant and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendant and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

76. When Defendant made these implied warranties, Defendant knew the purpose for which ABG II Modular Hip Stem was to be used and impliedly warranted it to be in all respects safe and proper for such purpose.

77. 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.

78. The ABG II Modular Hip Stem does not conform to Defendant's representations in that it is not safe and produces serious side effects.

79. As such, the ABG II Modular Hip Stem 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.

80. Defendant, therefore, breached its implied warranties to Plaintiff in violation of Massachusetts law by manufacturing, marketing and selling the ABG II Modular Hip Stem to Plaintiff causing damages including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting 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 damage and losses will continue in the future.

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

COUNT IV– LOSS OF CONSORTIUM

81. Plaintiffs incorporate by reference all of the paragraphs of this Complaint as if fully set forth herein

82. At all times material, Brett Lincoln was married to Lisa Lincoln.

83. As a result of the injuries and damages sustained by his spouse, Lisa Lincoln has suffered the loss of his spouse's care, comfort, society and affections.

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

PRAYER FOR RELIEF

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

a. Awarding compensatory damages resulting from Defendant's violation of Massachusetts law;

b. Awarding compensatory damages resulting from Defendant's breach of implied and express warranty, negligence and for loss of consortium;

c. Awarding actual damages to the Plaintiffs incidental to Plaintiff's purchase and use of The ABG II Modular Hip Stem in an amount to be determined at trial;

d. Awarding pre-judgment and post-judgment interest to the Plaintiffs as provided by law;

e. Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law; and

f. Granting all such other relief as the Court deems necessary, just and proper.

PLAINTIFF DEMANDS TRIAL BY JURY ON ALL COUNTS.

Respectfully submitted,
By her attorney,
Kelley Bernheim Dolinsky, LLC

/s/ Walter Kelley
Walter Kelley, Esq.
BBO# 670525
4 Court Street
Plymouth, MA 02360
Tel: (508) 747-8854
Fax: (508) 747-8857
walterkelley@duejustice.com

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Patient Follow-Up FAQs

Q: Why were these products voluntarily withdrawn from the market?

A: While modular neck hip stems provide surgeons with an option to correct certain aspects of a patient's anatomy and hip biomechanics, we decided to voluntarily recall these modular-neck stem hip systems because there is a potential for fretting and corrosion at the modular-neck junction which may lead to adverse local tissue reactions.

Q: Why is Stryker updating the recall notice?

A: Stryker is suggesting that surgeons consider performing a clinical examination, such as blood work and cross sectional imaging, on all patients who received a Rejuvenate or ABG II modular-neck hip stem regardless of whether a patient is experiencing pain and/or swelling. For further information regarding patient follow-up please refer to the Product Recall Update.

Q: Why is Stryker suggesting that I contact all my patients, including asymptomatic patients?

A: In working with the medical community to better understand this matter, we have received reports of patients with mild or no symptoms that have tested positive for elevated metal ion levels or been diagnosed with adverse local tissue reaction.

Q: Are monolithic stems included in this voluntary recall?

A: No. Monolithic stems are not part of this voluntary recall.

Q: What is the appropriate patient follow-up?

A: The following information is applicable to patients with ABG II Modular and Rejuvenate Modular Hip Systems:

- Surgeons should consider performing a clinical examination, such as blood work (including infection screen and metal ion levels) and cross sectional imaging, regardless of whether a patient is experiencing pain and/or swelling.
- Repeat follow-up examination, such as blood work and cross section imaging, should be considered even in the presence of normal initial findings.
- When following up with patients, surgeons should continue to evaluate their patients for aseptic loosening and periprosthetic sepsis.
- If the surgeon's workup reveals an adverse response to metal wear debris, the surgeon should consider proceeding with a revision of the femoral component to a device without a modular neck.

Q: Is Stryker communicating to patients impacted by this recall?

A: Stryker is communicating directly with surgeons and hospitals who have appropriate patient contact information. Stryker has created a sample patient letter to assist surgeons with patient communications. This sample letter can be found on stryker.com/ModularNeckStems or provided by your sales representative. Please advise patients to contact 1-888-317-0200 (US & Canada only) or visit www.aboustryker.com/ModularNeckStems for additional information.

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Q: Who should surgeons contact with clinical questions regarding Rejuvenate Modular or ABG II?

A: All requests for clinical information relating to Rejuvenate Modular or ABG II should be directed to Dr. Jon Hopper, Stryker's Vice President, Global Medical Director, at 201-972-9140 or jon.hopper@stryker.com.

Q: Where should I report any claims of deficiency related to quality, reliability, safety or effectiveness of any product?

A: If you experience any adverse events related to any product, please contact your Stryker sales representative or call 1-866-OR-ASSIST to report any such events.

Q: What should I say to my patients? Can I refer them somewhere?

A: To help address patient questions, Stryker has established a dedicated patient call center at 1-888-317-0200 (US & Canada only) and has posted web resources at www.AboutStryker.com/ModularNeckStems.

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EXHIBIT C

Modular-Neck Stems

Rejuvenate Modular / ABG II Modular-Neck Stem Voluntary Recall

Information about the Voluntary Recall:

In June 2012, Stryker initiated a voluntary recall of its Rejuvenate and ABG II modular-neck hip stems. While modular-neck hip stems provide surgeons with an option to correct certain aspects of a patient's anatomy and hip biomechanics, we decided to voluntarily recall these modular-neck hip systems due to the potential for fretting and corrosion at the modular-neck junction which may result in ALTR (adverse local tissue reactions), as well as possible pain and/or swelling at or around the hip.

Surgeons should consider performing a clinical examination, such as blood work and cross section imaging on all patients who received a Rejuvenate or ABG II modular-neck hip stem regardless of whether a patient is experiencing pain and/or swelling. Repeat follow-up examination, such as blood work and cross section imaging, should be considered even in the presence of normal initial findings. For further information regarding patient follow-up please refer to the Product Recall Update.

Frequently Asked Questions Related to Patient Follow-up - PDF

Information about Reimbursement:

As part of our commitment to support patients and surgeons affected by this matter, Stryker will be reimbursing patients for testing, treatment, revision surgery, if necessary, and other costs relating to this voluntary recall. Beginning immediately, Stryker is partnering with Broadspire Services, Inc., a leading third-party claims administrator, to manage requests for reimbursement of costs relating to the voluntary recall of the Rejuvenate and ABG II modular-neck hip stems.

Frequently Asked Questions Related to Claims & Reimbursement - PDF

Information for Patients:

Stryker suggests that patients who have received a Rejuvenate or ABG II modular-neck hip stem contact their surgeon to schedule a follow-up appointment even if they are not experiencing symptoms such as pain and/or swelling at or around their hip.

In an effort to provide you and your office staff with support, we have established a Stryker Patient Care Line which can be reached at 1-888-317-0200, 8am – 9pm EST, Monday through Saturday. Please advise your office staff to refer patients with questions regarding the voluntary recall and claims to the Stryker Patient Care Line.

The patient website has been updated to reflect this information.

Click here to visit the patient website

Additionally the following resources have been developed to assist you and your office staff in communications with patients:

Office Manager Talking Points - PDF
Sample Patient Letter - PDF
Sample Treated Patient Letter - PDF

Clinical Information:

Click here to view the following:

Evaluation of Painful Total Hip Replacements Modular Metal Taper Junctions,R. Michael Meneghini, MD - PDF
Rejuvenate Modular Extraction Protocol - PDF
ABG II Modular Extraction Protocol - PDF

Please feel free to contact us with other questions related to these matters:

Clinical matters Contact:
Dr. Jon Hopper, Stryker's Vice President, Global Medical Director,
at 201-972-9140 or jon.hopper@stryker.com
Regulatory matters Contact:
Colleen O'Meara, Manager, Divisional Regulatory Compliance,
at 201-972-2100 or colleen.omeara@stryker.com

Product Questions Contact:
Jonathan Sacks, Director, Global Femoral Brands,
at 201-831-6398 or jonathan.sacks@stryker.com

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