UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RAYMOND CHASSE, JR., Individually and On Behalf of All Others Similarly Situated, Plaintiff	)	
	)	C.A. NO.:_____
v.	)	
STRYKER CORPORATION, HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS, and STRYKER IRELAND, LTD. Defendants	)	

CLASS ACTION COMPLAINT & JURY DEMAND

INTRODUCTION

This is a class action against the Defendants for negligence. The Plaintiff and the members of the Class all underwent total hip replacements using the Defendants' artificial hip device, the Trident System. The Defendants, however, failed to comply with the federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder concerning the Trident System. As a result, the Trident Systems failed, causing audible "squeaking," severe pain and discomfort, and/or the need for complete surgical removal and replacement.

PARTIES

1. Plaintiff Raymond Chasse, Jr. is a natural person and resident of Lynn, Essex County, Massachusetts.

2. Defendant Stryker Corporation is incorporated in Michigan with its principal place of business in Michigan, and is a citizen of Michigan pursuant to 28 U.S.C § 1332(c)(1).

3. Howmedica Osteonics Corporation is incorporated in New Jersey with its principal place of business in New Jersey, and is a citizen of New Jersey pursuant to 28 U.S.C. § 1332(c)(1).

4. Stryker Ireland, Ltd. Is incorporated in Ireland with its principal place of business in Ireland, and is a citizen of Ireland pursuant to 28 U.S.C. § 1332(c)(1).

JURISDICTION AND VENUE

5. The amount in controversy exceeds $75,000, exclusive of interest and costs.

6. This Court has subject matter jurisdiction based on diversity of citizenship pursuant to 28 U.S.C. § 1332(a)(3).

7. Defendants, each of them, have transacted business in Massachusetts; contracted to supply services or things in Massachusetts; caused tortious injury by an act or omission in Massachusetts; and caused tortious injury in Massachusetts by an act or omission outside Massachusetts while regularly doing or soliciting business, or engaging in any other persistent course of conduct, or deriving substantial revenue from goods used or consumed or services rendered, in Massachusetts. Therefore, this Court has personal jurisdiction over the Defendants pursuant to the Massachusetts long arm statute, M.G.L. c. 223A, § 3.

8. Defendants reside in this district within the meaning of the venue statute, and a substantial part of the events or omissions giving rise to the claims set forth in this Complaint occurred in this district. Therefore, this district is a proper venue pursuant to 28 U.S.C. § 1391 (a)(1) and (2).

CLASS ACTION ALLEGATIONS

9. Plaintiff brings this negligence action individually, and on behalf of the following Massachusetts state-wide class of similarly situated individuals, pursuant to Mass. R. Civ. P. 23, described as follows:

> All Massachusetts residents that have undergone total hip arthroplasty since 2003 using the Defendants' Trident System containing Trident Hemispherical Acetabular Shells, and who have experienced a failure of said Trident System as evidenced by the following: an audible "squeaking" emanating from the replaced hip joint area; pain and/or discomfort in the replaced hip joint area; and/or the necessity for revision surgery of the replaced hip joint.

10. The members of the Class are so numerous that joinder of all members is impractical. Plaintiff estimates that there are at least 40 members of the Class who have been uniformly affected by Defendants' negligence. The precise number of class members can be ascertained through Defendants' internal records. Given the composition and size of the class, potential class members may be informed of the pendency of this Class Action by direct mail.

11. There are questions of law and fact common to the Class, including, without limitation:

a. whether Defendants are liable for negligence as a result of their violations of federal statutes and regulations – specifically, the Federal Food, Drug , and Cosmetic Act, and the regulations promulgated thereunder;

b. whether Plaintiff and the Class have suffered and are entitled to damages, and, if so, in what amount; and

c. whether punitive damages or special damages are warranted.

12. Plaintiff's claims are typical of the claims of the Class members. The Defendants' medical device the Trident System, which contained the Trident Hemispherical Acetabular Shell, was implanted into Plaintiff and the members of the Class as part of a total hip

arthroplasty. The Defendants failed to comply with federal requirements concerning said Trident System. The Plaintiff suffered similar injuries as those suffered by the Class members as a result of this negligence by Defendants. The Defendants' negligence has affected Plaintiff and the Class in the exact same way.

13. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff is similarly situated to the Class and has no conflict with the Class members. Plaintiff has retained competent attorneys who are experienced in class action litigation of this type and who are committed to prosecuting this action.

14. The action is properly maintainable as a class action under Mass. R. Civ. P. 23 because the common questions of law and fact set forth above are applicable to the Class and predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this case, especially with respect to considerations of consistency, economy, efficiency, fairness and equity.

FACTUAL ALLEGATIONS

15. Since 2003, each of the Defendants have introduced or delivered for introduction into interstate commerce, received or manufactured medical devices used to perform artificial hip replacement surgery known as the Trident System.

16. The Trident System is an artificial hip replacement device made up of four basic components; and alumina ceramic femoral head (ball), an alumina ceramic insert (socket liner), a metal acetabular shell (socket), and a metal femoral stem (hip stem).

17. As required by law, before commercially distributing the Trident System in the United States, the Defendants submitted an application for premarket approval (PMA) of the device to the Secretary of Health and Human Services and, on February 3, 2003, the Food and

Drug Administration (FDA) completed its review of the Defendants' premarket approval application for the Trident System, and based on the materials submitted by the Defendants, the FDA conditionally approved the Trident System for commercial distribution.

18. The conditional approval letter from the FDA stated "Commercial distribution of a device that is not in compliance with these conditions is a violation of the Food, Drug, and Cosmetics Act," 21 U.S.C. §§ 301 et seq.

19. After the conditional approval, Defendants modified the Trident System through submissions made pursuant to 21 U.S.C. § 510(k) on several occasions including, but not limited to: May 25, 2004 – increasing wall thickness in the Trident "T" Acetabular Shells; July 7, 2006 – two geometrical modifications to the Trident Constrained Acetabular Insert; and August 22, 2006 – introducing larger diameter femoral heads and acetabular components.

20. From October 31, 2006 to November 3, 2006, the FDA conducted an inspection at Defendants' Cork, Ireland manufacturing facility. At the conclusion of the inspection, the FDA issued Form FDA 483, List of Inspectional Observations, notifying the Defendants of numerous violations of federal regulations in their manufacturing and inspection processes for the Trident System.

21. On March 15, 2007, after months of inadequate response by the Defendants to the federal regulatory violations indentified in the Form 483, the FDA issued a Warning Letter to Defendants informing them that the Trident Acetabular Systems were "adulterated" within the meaning of section 21 U.S.C. § 351(h) in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, were not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, 21 C.F.R. Part 820.

22. A medical device, like the Trident System, is "adulterated" under federal law if, among other things, if it fails to meet established performance standards; if it is "prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health"; if its "[m]anufacture, packing, storage, or installation …[is not] in conformity with applicable requirements or conditions; or if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation, are not in conformity with applicable requirements."

See 21 U.S.C. § 351.

23. In addition to the violations of the Food, Drug, and Cosmetics Act relating to the Trident System, in the Warning Letter, the FDA also notified the Defendants about their:

a. Failure to establish and maintain adequate procedures for implementing a corrective and preventative action, as required by 21 CFR 820.100(a);

b. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, including the evaluation of nonconforming product, as required by 21 CFR 820.90(a);

c. Failure to perform root cause investigations or initiate corrective/preventative actions;

d. Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5); and

e. Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2).

24. On January 14, 2005, the Plaintiff underwent left total hip replacement surgery at North Shore Medical Center Salem Hospital in Salem, Massachusetts.

25. During this surgery, a Trident System introduced or delivered for introduction into interstate commerce, received or manufactured by the Defendants was implanted into the

Plaintiff, including a component known as Trident Hemispherical Acetabular Shell bearing the catalog number 502-01-56F, Case Code 9952501, and serial number 1007119CF.

26. On January 21, 2008, the Defendants issued an Urgent Product Recall of Trident PSL and Hemispherical Shells manufactured in their Cork, Ireland facility between January 2000 and December 2007, including Trident Hemispherical Acetabular Shells bearing catalogue number 502-01-56F, the exact component which was implanted into Plaintiff.

27. The FDA determined the removal of the recalled devices from the market and the corrective action taken by Defendants should be classified as Class II Recalls under federal regulation.

28. Defendants' recall of the Trident Hemispherical Acetabular Shell implanted into Plaintiff was designated by the FDA as U.S. Food and Drug Administration Recall #Z-1170-2008.

29. Pursuant to 21 CFR § 7.3(g), "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." "These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall." 21 CFR § 7.40(a).

30. The Trident System implanted into Plaintiff's hip on January 14, 2005 was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated pursuant to it.

31. As a result of Defendants' violations of a purely federal statutory and regulatory standard of care, the Trident System implanted in Plaintiff's left hip on January 14, 2005 failed.

32. In or about January 2012, the Plaintiff began hearing an audible sound, specifically, a "squeaking," emanating from his left hip joint, which worsened over time, and caused public humiliation.

33. In or about May, 2012, the Plaintiff first began experiencing discomfort and pain. Over the next several months, said pain and discomfort worsened and became severe.

34. The audible squeaking, the discomfort, and the pain experienced by Plaintiff necessitated revision surgery.

35. On August 15, 2012, Plaintiff underwent revision surgery due to the failure of the Trident System.

36. It was the duty of the Defendants to comply with the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated pursuant to it, yet notwithstanding this duty, Defendants violated the Act and regulations in one or more of the following ways:

a. By introducing or delivering for introduction into interstate commerce a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

b. By adulterating a device in interstate commerce in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

c. By receiving in interstate commerce a device that was adulterated and delivering the device for pay or otherwise in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

d. By manufacturing a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

e. By manufacturing the Trident Hemispherical Acetabular Shell bearing catalog number 502-01-56F in deviation of the manufacturing specifications approved by the FDA in the Defendants' premarket

approval application in violation of the Federal Food, Drug, and Cosmetic Act, and/or;

f. By manufacturing the Trident System implanted into Plaintiff's left hip in deviation of the manufacturing specifications approved by the FDA in the Defendants' premarket approval application in violation of the Federal Food, Drug, and Cosmetic Act.

37. As a direct and proximate result of one or more of these violations, adulterated Trident Hemispherical Acetabular Shells, including the component bearing catalogue number 502-01-56F and an adulterated Trident System was implanted into Plaintiffs' left hip causing him to be injured and sustain damages, including, but not limited to, and unstable left hip, pain, suffering, disability, loss of a normal life, emotional distress, the need for revision surgery on August 15, 2012**,** medical and other expenses. These losses have been incurred in the past, and will be incurred in the future, and some of these losses are permanent.

38. This cause of action is based entirely on the contention that the Defendants have violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action; but rather, he is pursuing parallel state common law claims based on the Defendants' violations of the applicable federal regulations.

39. It is well established in Massachusetts that a violation of a statute, ordinance or regulation, although not conclusive, is evidence of negligence on the part of a violator as to all consequences that the statute, ordinance or regulation was intended to prevent. *See Campbell v. Cape & Islands Healthcare Servs.*, 81 Mass. App. Ct. 252, 254 (2012). Moreover, the Massachusetts Supreme Judicial Court has stated that a violation of FDA requirements is evidence of negligence. *See MacDonald v. Ortho Pharmaceutical Corp*., 394 Mass. 131, 140 (1985).

40. Thus, under Massachusetts common law, a money damages remedy exists for negligent violation of the Food, Drug, and Cosmetic Act and regulations promulgated thereunder which proximately cause injuries, and there is no need for the Massachusetts legislature to act in order to create such remedy.

41. The Food, Drug, and Cosmetic Act contains an express preemption provision, 21 U.S.C. § 360k, which in relevant part states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -- (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301 et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301 et seq.]."

42. The cause of action set forth in this Count is not preempted by § 360k, because the violations alleged are all based on an exclusively federal statutory and regulatory standard of care which includes no "requirement which is different from, or in addition to, any requirement applicable under" the Food, Drug, and Cosmetic Act and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

COUNT I

NEGLIGENCE BASED EXCLUSIVELY ON VIOLATIONS OF 21 U.S.C. § 331 (A), (B), AND (C); 21 U.S.C. § 351 (H); AND 21 CFR PART 820

43. The Plaintiff restates and incorporates the allegations contained in the above-numbered paragraphs as if fully set forth herein.

44. The Defendants were required to comply with 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820.

45. The Defendants violated 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820.

46. As a direct and proximate cause of the Defendants' violation of 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820, the Plaintiff and members of the Class suffered harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that the Court enter an order:

a. Certifying this action as a class action pursuant to Mass. R. Civ. P. 23;

b. Ordering Defendants to promptly file with this Court and furnish to Plaintiff's counsel a list of all names and addresses of all Massachusetts residents that have undergone total hip arthroplasty since 2003 using the Defendants' Trident System, or other information from the identity of these residents can be derived, and authorizing Plaintiff's counsel to issue notice at the earliest possible time to these individuals, informing them that this action has been filed, the nature of the action, and their right to "opt-in" to this action as part of the Class, if they experienced a failure of said Trident System as evidenced by the following: an audible "squeaking" emanating from the replaced hip joint area; pain and/or discomfort in the replaced hip joint area; and/or the necessity for revision surgery of the replaced hip joint.

c. For Judgment in favor of the Plaintiff and the Class against each of the Defendants, jointly and severally, for the full amount of all damages and costs recoverable by law;

d. Awarding Plaintiff and the Class punitive damages;

e. Awarding pre-judgment and post-judgment interest and court costs as further allowed by law;

f. Granting Plaintiff and the Class leave to add additional plaintiffs by motion, the filing of written opt-in consent forms, or any other method approved by the Court; and

g. For all additional general and equitable relief which is just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

RAYMOND CHASSE, JR.,
Individually and On Behalf of All Others Similarly Situated,
By his attorney,

/s/ Orestes G. Brown
Orestes G. Brown (BBO#566431)
METAXAS BROWN PIDGEON LLP
900 Cummings Center, Suite 207T
Beverly, MA 01915
978-927-8000
obrown@metaxasbrown.com
mengelhardt@metaxasbrown.com

Dated: September 7, 2012

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RAYMOND CHASSE, JR., Individually and On Behalf of All Others Similarly Situated, Plaintiff	)	
	)	C.A. NO.:_____
v.	)	
STRYKER CORPORATION, HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS, and STRYKER IRELAND, LTD. Defendants	)	

CLASS ACTION COMPLAINT & JURY DEMAND

INTRODUCTION

This is a class action against the Defendants for negligence. The Plaintiff and the members of the Class all underwent total hip replacements using the Defendants' artificial hip device, the Trident System. The Defendants, however, failed to comply with the federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder concerning the Trident System. As a result, the Trident Systems failed, causing audible "squeaking," severe pain and discomfort, and/or the need for complete surgical removal and replacement.

PARTIES

1. Plaintiff Raymond Chasse, Jr. is a natural person and resident of Lynn, Essex County, Massachusetts.

2. Defendant Stryker Corporation is incorporated in Michigan with its principal place of business in Michigan, and is a citizen of Michigan pursuant to 28 U.S.C § 1332(c)(1).

3. Howmedica Osteonics Corporation is incorporated in New Jersey with its principal place of business in New Jersey, and is a citizen of New Jersey pursuant to 28 U.S.C. § 1332(c)(1).

4. Stryker Ireland, Ltd. Is incorporated in Ireland with its principal place of business in Ireland, and is a citizen of Ireland pursuant to 28 U.S.C. § 1332(c)(1).

JURISDICTION AND VENUE

5. The amount in controversy exceeds $75,000, exclusive of interest and costs.

6. This Court has subject matter jurisdiction based on diversity of citizenship pursuant to 28 U.S.C. § 1332(a)(3).

7. Defendants, each of them, have transacted business in Massachusetts; contracted to supply services or things in Massachusetts; caused tortious injury by an act or omission in Massachusetts; and caused tortious injury in Massachusetts by an act or omission outside Massachusetts while regularly doing or soliciting business, or engaging in any other persistent course of conduct, or deriving substantial revenue from goods used or consumed or services rendered, in Massachusetts. Therefore, this Court has personal jurisdiction over the Defendants pursuant to the Massachusetts long arm statute, M.G.L. c. 223A, § 3.

8. Defendants reside in this district within the meaning of the venue statute, and a substantial part of the events or omissions giving rise to the claims set forth in this Complaint occurred in this district. Therefore, this district is a proper venue pursuant to 28 U.S.C. § 1391 (a)(1) and (2).

CLASS ACTION ALLEGATIONS

9. Plaintiff brings this negligence action individually, and on behalf of the following Massachusetts state-wide class of similarly situated individuals, pursuant to Mass. R. Civ. P. 23, described as follows:

> All Massachusetts residents that have undergone total hip arthroplasty since 2003 using the Defendants' Trident System containing Trident Hemispherical Acetabular Shells, and who have experienced a failure of said Trident System as evidenced by the following: an audible "squeaking" emanating from the replaced hip joint area; pain and/or discomfort in the replaced hip joint area; and/or the necessity for revision surgery of the replaced hip joint.

10. The members of the Class are so numerous that joinder of all members is impractical. Plaintiff estimates that there are at least 40 members of the Class who have been uniformly affected by Defendants' negligence. The precise number of class members can be ascertained through Defendants' internal records. Given the composition and size of the class, potential class members may be informed of the pendency of this Class Action by direct mail.

11. There are questions of law and fact common to the Class, including, without limitation:

a. whether Defendants are liable for negligence as a result of their violations of federal statutes and regulations – specifically, the Federal Food, Drug , and Cosmetic Act, and the regulations promulgated thereunder;

b. whether Plaintiff and the Class have suffered and are entitled to damages, and, if so, in what amount; and

c. whether punitive damages or special damages are warranted.

12. Plaintiff's claims are typical of the claims of the Class members. The Defendants' medical device the Trident System, which contained the Trident Hemispherical Acetabular Shell, was implanted into Plaintiff and the members of the Class as part of a total hip

arthroplasty. The Defendants failed to comply with federal requirements concerning said Trident System. The Plaintiff suffered similar injuries as those suffered by the Class members as a result of this negligence by Defendants. The Defendants' negligence has affected Plaintiff and the Class in the exact same way.

13. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff is similarly situated to the Class and has no conflict with the Class members. Plaintiff has retained competent attorneys who are experienced in class action litigation of this type and who are committed to prosecuting this action.

14. The action is properly maintainable as a class action under Mass. R. Civ. P. 23 because the common questions of law and fact set forth above are applicable to the Class and predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this case, especially with respect to considerations of consistency, economy, efficiency, fairness and equity.

FACTUAL ALLEGATIONS

15. Since 2003, each of the Defendants have introduced or delivered for introduction into interstate commerce, received or manufactured medical devices used to perform artificial hip replacement surgery known as the Trident System.

16. The Trident System is an artificial hip replacement device made up of four basic components; and alumina ceramic femoral head (ball), an alumina ceramic insert (socket liner), a metal acetabular shell (socket), and a metal femoral stem (hip stem).

17. As required by law, before commercially distributing the Trident System in the United States, the Defendants submitted an application for premarket approval (PMA) of the device to the Secretary of Health and Human Services and, on February 3, 2003, the Food and

Drug Administration (FDA) completed its review of the Defendants' premarket approval application for the Trident System, and based on the materials submitted by the Defendants, the FDA conditionally approved the Trident System for commercial distribution.

18. The conditional approval letter from the FDA stated "Commercial distribution of a device that is not in compliance with these conditions is a violation of the Food, Drug, and Cosmetics Act," 21 U.S.C. §§ 301 et seq.

19. After the conditional approval, Defendants modified the Trident System through submissions made pursuant to 21 U.S.C. § 510(k) on several occasions including, but not limited to: May 25, 2004 – increasing wall thickness in the Trident "T" Acetabular Shells; July 7, 2006 – two geometrical modifications to the Trident Constrained Acetabular Insert; and August 22, 2006 – introducing larger diameter femoral heads and acetabular components.

20. From October 31, 2006 to November 3, 2006, the FDA conducted an inspection at Defendants' Cork, Ireland manufacturing facility. At the conclusion of the inspection, the FDA issued Form FDA 483, List of Inspectional Observations, notifying the Defendants of numerous violations of federal regulations in their manufacturing and inspection processes for the Trident System.

21. On March 15, 2007, after months of inadequate response by the Defendants to the federal regulatory violations indentified in the Form 483, the FDA issued a Warning Letter to Defendants informing them that the Trident Acetabular Systems were "adulterated" within the meaning of section 21 U.S.C. § 351(h) in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, were not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, 21 C.F.R. Part 820.

22. A medical device, like the Trident System, is "adulterated" under federal law if, among other things, if it fails to meet established performance standards; if it is "prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health"; if its "[m]anufacture, packing, storage, or installation …[is not] in conformity with applicable requirements or conditions; or if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation, are not in conformity with applicable requirements."

See 21 U.S.C. § 351.

23. In addition to the violations of the Food, Drug, and Cosmetics Act relating to the Trident System, in the Warning Letter, the FDA also notified the Defendants about their:

a. Failure to establish and maintain adequate procedures for implementing a corrective and preventative action, as required by 21 CFR 820.100(a);

b. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, including the evaluation of nonconforming product, as required by 21 CFR 820.90(a);

c. Failure to perform root cause investigations or initiate corrective/preventative actions;

d. Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5); and

e. Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2).

24. On January 14, 2005, the Plaintiff underwent left total hip replacement surgery at North Shore Medical Center Salem Hospital in Salem, Massachusetts.

25. During this surgery, a Trident System introduced or delivered for introduction into interstate commerce, received or manufactured by the Defendants was implanted into the

Plaintiff, including a component known as Trident Hemispherical Acetabular Shell bearing the catalog number 502-01-56F, Case Code 9952501, and serial number 1007119CF.

26. On January 21, 2008, the Defendants issued an Urgent Product Recall of Trident PSL and Hemispherical Shells manufactured in their Cork, Ireland facility between January 2000 and December 2007, including Trident Hemispherical Acetabular Shells bearing catalogue number 502-01-56F, the exact component which was implanted into Plaintiff.

27. The FDA determined the removal of the recalled devices from the market and the corrective action taken by Defendants should be classified as Class II Recalls under federal regulation.

28. Defendants' recall of the Trident Hemispherical Acetabular Shell implanted into Plaintiff was designated by the FDA as U.S. Food and Drug Administration Recall #Z-1170-2008.

29. Pursuant to 21 CFR § 7.3(g), "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." "These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall." 21 CFR § 7.40(a).

30. The Trident System implanted into Plaintiff's hip on January 14, 2005 was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated pursuant to it.

31. As a result of Defendants' violations of a purely federal statutory and regulatory standard of care, the Trident System implanted in Plaintiff's left hip on January 14, 2005 failed.

32. In or about January 2012, the Plaintiff began hearing an audible sound, specifically, a "squeaking," emanating from his left hip joint, which worsened over time, and caused public humiliation.

33. In or about May, 2012, the Plaintiff first began experiencing discomfort and pain. Over the next several months, said pain and discomfort worsened and became severe.

34. The audible squeaking, the discomfort, and the pain experienced by Plaintiff necessitated revision surgery.

35. On August 15, 2012, Plaintiff underwent revision surgery due to the failure of the Trident System.

36. It was the duty of the Defendants to comply with the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated pursuant to it, yet notwithstanding this duty, Defendants violated the Act and regulations in one or more of the following ways:

a. By introducing or delivering for introduction into interstate commerce a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

b. By adulterating a device in interstate commerce in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

c. By receiving in interstate commerce a device that was adulterated and delivering the device for pay or otherwise in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

d. By manufacturing a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

e. By manufacturing the Trident Hemispherical Acetabular Shell bearing catalog number 502-01-56F in deviation of the manufacturing specifications approved by the FDA in the Defendants' premarket

approval application in violation of the Federal Food, Drug, and Cosmetic Act, and/or;

f. By manufacturing the Trident System implanted into Plaintiff's left hip in deviation of the manufacturing specifications approved by the FDA in the Defendants' premarket approval application in violation of the Federal Food, Drug, and Cosmetic Act.

37. As a direct and proximate result of one or more of these violations, adulterated Trident Hemispherical Acetabular Shells, including the component bearing catalogue number 502-01-56F and an adulterated Trident System was implanted into Plaintiffs' left hip causing him to be injured and sustain damages, including, but not limited to, and unstable left hip, pain, suffering, disability, loss of a normal life, emotional distress, the need for revision surgery on August 15, 2012**,** medical and other expenses. These losses have been incurred in the past, and will be incurred in the future, and some of these losses are permanent.

38. This cause of action is based entirely on the contention that the Defendants have violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action; but rather, he is pursuing parallel state common law claims based on the Defendants' violations of the applicable federal regulations.

39. It is well established in Massachusetts that a violation of a statute, ordinance or regulation, although not conclusive, is evidence of negligence on the part of a violator as to all consequences that the statute, ordinance or regulation was intended to prevent. *See Campbell v. Cape & Islands Healthcare Servs.*, 81 Mass. App. Ct. 252, 254 (2012). Moreover, the Massachusetts Supreme Judicial Court has stated that a violation of FDA requirements is evidence of negligence. *See MacDonald v. Ortho Pharmaceutical Corp*., 394 Mass. 131, 140 (1985).

40. Thus, under Massachusetts common law, a money damages remedy exists for negligent violation of the Food, Drug, and Cosmetic Act and regulations promulgated thereunder which proximately cause injuries, and there is no need for the Massachusetts legislature to act in order to create such remedy.

41. The Food, Drug, and Cosmetic Act contains an express preemption provision, 21 U.S.C. § 360k, which in relevant part states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -- (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301 et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301 et seq.]."

42. The cause of action set forth in this Count is not preempted by § 360k, because the violations alleged are all based on an exclusively federal statutory and regulatory standard of care which includes no "requirement which is different from, or in addition to, any requirement applicable under" the Food, Drug, and Cosmetic Act and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

COUNT I

NEGLIGENCE BASED EXCLUSIVELY ON VIOLATIONS OF 21 U.S.C. § 331 (A), (B), AND (C); 21 U.S.C. § 351 (H); AND 21 CFR PART 820

43. The Plaintiff restates and incorporates the allegations contained in the above-numbered paragraphs as if fully set forth herein.

44. The Defendants were required to comply with 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820.

45. The Defendants violated 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820.

46. As a direct and proximate cause of the Defendants' violation of 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820, the Plaintiff and members of the Class suffered harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that the Court enter an order:

a. Certifying this action as a class action pursuant to Mass. R. Civ. P. 23;

b. Ordering Defendants to promptly file with this Court and furnish to Plaintiff's counsel a list of all names and addresses of all Massachusetts residents that have undergone total hip arthroplasty since 2003 using the Defendants' Trident System, or other information from the identity of these residents can be derived, and authorizing Plaintiff's counsel to issue notice at the earliest possible time to these individuals, informing them that this action has been filed, the nature of the action, and their right to "opt-in" to this action as part of the Class, if they experienced a failure of said Trident System as evidenced by the following: an audible "squeaking" emanating from the replaced hip joint area; pain and/or discomfort in the replaced hip joint area; and/or the necessity for revision surgery of the replaced hip joint.

c. For Judgment in favor of the Plaintiff and the Class against each of the Defendants, jointly and severally, for the full amount of all damages and costs recoverable by law;

d. Awarding Plaintiff and the Class punitive damages;

e. Awarding pre-judgment and post-judgment interest and court costs as further allowed by law;

f. Granting Plaintiff and the Class leave to add additional plaintiffs by motion, the filing of written opt-in consent forms, or any other method approved by the Court; and

g. For all additional general and equitable relief which is just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

RAYMOND CHASSE, JR.,
Individually and On Behalf of All Others Similarly Situated,
By his attorney,

/s/ Orestes G. Brown
Orestes G. Brown (BBO#566431)
METAXAS BROWN PIDGEON LLP
900 Cummings Center, Suite 207T
Beverly, MA 01915
978-927-8000
obrown@metaxasbrown.com
mengelhardt@metaxasbrown.com

Dated: September 7, 2012

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RAYMOND CHASSE, JR., Individually and On Behalf of All Others Similarly Situated, Plaintiff	)	
	)	C.A. NO.:_____
v.	)	
STRYKER CORPORATION, HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS, and STRYKER IRELAND, LTD. Defendants	)	

CLASS ACTION COMPLAINT & JURY DEMAND

INTRODUCTION

This is a class action against the Defendants for negligence. The Plaintiff and the members of the Class all underwent total hip replacements using the Defendants' artificial hip device, the Trident System. The Defendants, however, failed to comply with the federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder concerning the Trident System. As a result, the Trident Systems failed, causing audible "squeaking," severe pain and discomfort, and/or the need for complete surgical removal and replacement.

PARTIES

1. Plaintiff Raymond Chasse, Jr. is a natural person and resident of Lynn, Essex County, Massachusetts.

2. Defendant Stryker Corporation is incorporated in Michigan with its principal place of business in Michigan, and is a citizen of Michigan pursuant to 28 U.S.C § 1332(c)(1).

3. Howmedica Osteonics Corporation is incorporated in New Jersey with its principal place of business in New Jersey, and is a citizen of New Jersey pursuant to 28 U.S.C. § 1332(c)(1).

4. Stryker Ireland, Ltd. Is incorporated in Ireland with its principal place of business in Ireland, and is a citizen of Ireland pursuant to 28 U.S.C. § 1332(c)(1).

JURISDICTION AND VENUE

5. The amount in controversy exceeds $75,000, exclusive of interest and costs.

6. This Court has subject matter jurisdiction based on diversity of citizenship pursuant to 28 U.S.C. § 1332(a)(3).

7. Defendants, each of them, have transacted business in Massachusetts; contracted to supply services or things in Massachusetts; caused tortious injury by an act or omission in Massachusetts; and caused tortious injury in Massachusetts by an act or omission outside Massachusetts while regularly doing or soliciting business, or engaging in any other persistent course of conduct, or deriving substantial revenue from goods used or consumed or services rendered, in Massachusetts. Therefore, this Court has personal jurisdiction over the Defendants pursuant to the Massachusetts long arm statute, M.G.L. c. 223A, § 3.

8. Defendants reside in this district within the meaning of the venue statute, and a substantial part of the events or omissions giving rise to the claims set forth in this Complaint occurred in this district. Therefore, this district is a proper venue pursuant to 28 U.S.C. § 1391 (a)(1) and (2).

CLASS ACTION ALLEGATIONS

9. Plaintiff brings this negligence action individually, and on behalf of the following Massachusetts state-wide class of similarly situated individuals, pursuant to Mass. R. Civ. P. 23, described as follows:

> All Massachusetts residents that have undergone total hip arthroplasty since 2003 using the Defendants' Trident System containing Trident Hemispherical Acetabular Shells, and who have experienced a failure of said Trident System as evidenced by the following: an audible "squeaking" emanating from the replaced hip joint area; pain and/or discomfort in the replaced hip joint area; and/or the necessity for revision surgery of the replaced hip joint.

10. The members of the Class are so numerous that joinder of all members is impractical. Plaintiff estimates that there are at least 40 members of the Class who have been uniformly affected by Defendants' negligence. The precise number of class members can be ascertained through Defendants' internal records. Given the composition and size of the class, potential class members may be informed of the pendency of this Class Action by direct mail.

11. There are questions of law and fact common to the Class, including, without limitation:

a. whether Defendants are liable for negligence as a result of their violations of federal statutes and regulations – specifically, the Federal Food, Drug , and Cosmetic Act, and the regulations promulgated thereunder;

b. whether Plaintiff and the Class have suffered and are entitled to damages, and, if so, in what amount; and

c. whether punitive damages or special damages are warranted.

12. Plaintiff's claims are typical of the claims of the Class members. The Defendants' medical device the Trident System, which contained the Trident Hemispherical Acetabular Shell, was implanted into Plaintiff and the members of the Class as part of a total hip

arthroplasty. The Defendants failed to comply with federal requirements concerning said Trident System. The Plaintiff suffered similar injuries as those suffered by the Class members as a result of this negligence by Defendants. The Defendants' negligence has affected Plaintiff and the Class in the exact same way.

13. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff is similarly situated to the Class and has no conflict with the Class members. Plaintiff has retained competent attorneys who are experienced in class action litigation of this type and who are committed to prosecuting this action.

14. The action is properly maintainable as a class action under Mass. R. Civ. P. 23 because the common questions of law and fact set forth above are applicable to the Class and predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this case, especially with respect to considerations of consistency, economy, efficiency, fairness and equity.

FACTUAL ALLEGATIONS

15. Since 2003, each of the Defendants have introduced or delivered for introduction into interstate commerce, received or manufactured medical devices used to perform artificial hip replacement surgery known as the Trident System.

16. The Trident System is an artificial hip replacement device made up of four basic components; and alumina ceramic femoral head (ball), an alumina ceramic insert (socket liner), a metal acetabular shell (socket), and a metal femoral stem (hip stem).

17. As required by law, before commercially distributing the Trident System in the United States, the Defendants submitted an application for premarket approval (PMA) of the device to the Secretary of Health and Human Services and, on February 3, 2003, the Food and

Drug Administration (FDA) completed its review of the Defendants' premarket approval application for the Trident System, and based on the materials submitted by the Defendants, the FDA conditionally approved the Trident System for commercial distribution.

18. The conditional approval letter from the FDA stated "Commercial distribution of a device that is not in compliance with these conditions is a violation of the Food, Drug, and Cosmetics Act," 21 U.S.C. §§ 301 et seq.

19. After the conditional approval, Defendants modified the Trident System through submissions made pursuant to 21 U.S.C. § 510(k) on several occasions including, but not limited to: May 25, 2004 – increasing wall thickness in the Trident "T" Acetabular Shells; July 7, 2006 – two geometrical modifications to the Trident Constrained Acetabular Insert; and August 22, 2006 – introducing larger diameter femoral heads and acetabular components.

20. From October 31, 2006 to November 3, 2006, the FDA conducted an inspection at Defendants' Cork, Ireland manufacturing facility. At the conclusion of the inspection, the FDA issued Form FDA 483, List of Inspectional Observations, notifying the Defendants of numerous violations of federal regulations in their manufacturing and inspection processes for the Trident System.

21. On March 15, 2007, after months of inadequate response by the Defendants to the federal regulatory violations indentified in the Form 483, the FDA issued a Warning Letter to Defendants informing them that the Trident Acetabular Systems were "adulterated" within the meaning of section 21 U.S.C. § 351(h) in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation, were not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, 21 C.F.R. Part 820.

22. A medical device, like the Trident System, is "adulterated" under federal law if, among other things, if it fails to meet established performance standards; if it is "prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health"; if its "[m]anufacture, packing, storage, or installation …[is not] in conformity with applicable requirements or conditions; or if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation, are not in conformity with applicable requirements."

See 21 U.S.C. § 351.

23. In addition to the violations of the Food, Drug, and Cosmetics Act relating to the Trident System, in the Warning Letter, the FDA also notified the Defendants about their:

a. Failure to establish and maintain adequate procedures for implementing a corrective and preventative action, as required by 21 CFR 820.100(a);

b. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, including the evaluation of nonconforming product, as required by 21 CFR 820.90(a);

c. Failure to perform root cause investigations or initiate corrective/preventative actions;

d. Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5); and

e. Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2).

24. On January 14, 2005, the Plaintiff underwent left total hip replacement surgery at North Shore Medical Center Salem Hospital in Salem, Massachusetts.

25. During this surgery, a Trident System introduced or delivered for introduction into interstate commerce, received or manufactured by the Defendants was implanted into the

Plaintiff, including a component known as Trident Hemispherical Acetabular Shell bearing the catalog number 502-01-56F, Case Code 9952501, and serial number 1007119CF.

26. On January 21, 2008, the Defendants issued an Urgent Product Recall of Trident PSL and Hemispherical Shells manufactured in their Cork, Ireland facility between January 2000 and December 2007, including Trident Hemispherical Acetabular Shells bearing catalogue number 502-01-56F, the exact component which was implanted into Plaintiff.

27. The FDA determined the removal of the recalled devices from the market and the corrective action taken by Defendants should be classified as Class II Recalls under federal regulation.

28. Defendants' recall of the Trident Hemispherical Acetabular Shell implanted into Plaintiff was designated by the FDA as U.S. Food and Drug Administration Recall #Z-1170-2008.

29. Pursuant to 21 CFR § 7.3(g), "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." "These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall." 21 CFR § 7.40(a).

30. The Trident System implanted into Plaintiff's hip on January 14, 2005 was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated pursuant to it.

31. As a result of Defendants' violations of a purely federal statutory and regulatory standard of care, the Trident System implanted in Plaintiff's left hip on January 14, 2005 failed.

32. In or about January 2012, the Plaintiff began hearing an audible sound, specifically, a "squeaking," emanating from his left hip joint, which worsened over time, and caused public humiliation.

33. In or about May, 2012, the Plaintiff first began experiencing discomfort and pain. Over the next several months, said pain and discomfort worsened and became severe.

34. The audible squeaking, the discomfort, and the pain experienced by Plaintiff necessitated revision surgery.

35. On August 15, 2012, Plaintiff underwent revision surgery due to the failure of the Trident System.

36. It was the duty of the Defendants to comply with the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated pursuant to it, yet notwithstanding this duty, Defendants violated the Act and regulations in one or more of the following ways:

a. By introducing or delivering for introduction into interstate commerce a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

b. By adulterating a device in interstate commerce in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

c. By receiving in interstate commerce a device that was adulterated and delivering the device for pay or otherwise in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

d. By manufacturing a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;

e. By manufacturing the Trident Hemispherical Acetabular Shell bearing catalog number 502-01-56F in deviation of the manufacturing specifications approved by the FDA in the Defendants' premarket

approval application in violation of the Federal Food, Drug, and Cosmetic Act, and/or;

f. By manufacturing the Trident System implanted into Plaintiff's left hip in deviation of the manufacturing specifications approved by the FDA in the Defendants' premarket approval application in violation of the Federal Food, Drug, and Cosmetic Act.

37. As a direct and proximate result of one or more of these violations, adulterated Trident Hemispherical Acetabular Shells, including the component bearing catalogue number 502-01-56F and an adulterated Trident System was implanted into Plaintiffs' left hip causing him to be injured and sustain damages, including, but not limited to, and unstable left hip, pain, suffering, disability, loss of a normal life, emotional distress, the need for revision surgery on August 15, 2012**,** medical and other expenses. These losses have been incurred in the past, and will be incurred in the future, and some of these losses are permanent.

38. This cause of action is based entirely on the contention that the Defendants have violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action; but rather, he is pursuing parallel state common law claims based on the Defendants' violations of the applicable federal regulations.

39. It is well established in Massachusetts that a violation of a statute, ordinance or regulation, although not conclusive, is evidence of negligence on the part of a violator as to all consequences that the statute, ordinance or regulation was intended to prevent. *See Campbell v. Cape & Islands Healthcare Servs.*, 81 Mass. App. Ct. 252, 254 (2012). Moreover, the Massachusetts Supreme Judicial Court has stated that a violation of FDA requirements is evidence of negligence. *See MacDonald v. Ortho Pharmaceutical Corp*., 394 Mass. 131, 140 (1985).

40. Thus, under Massachusetts common law, a money damages remedy exists for negligent violation of the Food, Drug, and Cosmetic Act and regulations promulgated thereunder which proximately cause injuries, and there is no need for the Massachusetts legislature to act in order to create such remedy.

41. The Food, Drug, and Cosmetic Act contains an express preemption provision, 21 U.S.C. § 360k, which in relevant part states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -- (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301 et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301 et seq.]."

42. The cause of action set forth in this Count is not preempted by § 360k, because the violations alleged are all based on an exclusively federal statutory and regulatory standard of care which includes no "requirement which is different from, or in addition to, any requirement applicable under" the Food, Drug, and Cosmetic Act and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

COUNT I

NEGLIGENCE BASED EXCLUSIVELY ON VIOLATIONS OF 21 U.S.C. § 331 (A), (B), AND (C); 21 U.S.C. § 351 (H); AND 21 CFR PART 820

43. The Plaintiff restates and incorporates the allegations contained in the above-numbered paragraphs as if fully set forth herein.

44. The Defendants were required to comply with 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820.

45. The Defendants violated 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820.

46. As a direct and proximate cause of the Defendants' violation of 21 U.S.C. § 331(A), (B), and (C) and 21 CFR Part 820, the Plaintiff and members of the Class suffered harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that the Court enter an order:

a. Certifying this action as a class action pursuant to Mass. R. Civ. P. 23;

b. Ordering Defendants to promptly file with this Court and furnish to Plaintiff's counsel a list of all names and addresses of all Massachusetts residents that have undergone total hip arthroplasty since 2003 using the Defendants' Trident System, or other information from the identity of these residents can be derived, and authorizing Plaintiff's counsel to issue notice at the earliest possible time to these individuals, informing them that this action has been filed, the nature of the action, and their right to "opt-in" to this action as part of the Class, if they experienced a failure of said Trident System as evidenced by the following: an audible "squeaking" emanating from the replaced hip joint area; pain and/or discomfort in the replaced hip joint area; and/or the necessity for revision surgery of the replaced hip joint.

c. For Judgment in favor of the Plaintiff and the Class against each of the Defendants, jointly and severally, for the full amount of all damages and costs recoverable by law;

d. Awarding Plaintiff and the Class punitive damages;

e. Awarding pre-judgment and post-judgment interest and court costs as further allowed by law;

f. Granting Plaintiff and the Class leave to add additional plaintiffs by motion, the filing of written opt-in consent forms, or any other method approved by the Court; and

g. For all additional general and equitable relief which is just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

RAYMOND CHASSE, JR.,
Individually and On Behalf of All Others Similarly Situated,
By his attorney,

/s/ Orestes G. Brown
Orestes G. Brown (BBO#566431)
METAXAS BROWN PIDGEON LLP
900 Cummings Center, Suite 207T
Beverly, MA 01915
978-927-8000
obrown@metaxasbrown.com
mengelhardt@metaxasbrown.com

Dated: September 7, 2012