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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

APRIL CHRISTINE CABANA, Plaintiff, vs. STRYKER BIOTECH, LLC; STRYKER CORPORATION; MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC, INC.; ALI H. MESIWALA (formerly DOE 41); POMONA VALLEY HOSPITAL MEDICAL CENTER (formerly DOE 61) and DOES 1 through 100, inclusive, Defendants.	Case No.: BC 465 313 Hon. Michael Paul Linfield **FIRST AMENDED COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL** Action Filed: July 13, 2011 Trial Date: May 13, 2013

COMES NOW Plaintiff APRIL CHRISTINE CABANA who alleges as follows:

SUMMARY OF ALLEGATIONS

1. This is a products liability action arising out of injuries caused by the illegal off-label promotion of two medical device manufacturers. To cure her back pain, plaintiff April Cabana underwent a surgery in which her surgeon used a mixture of two products manufactured by defendant Stryker Biotech. The mixed use of these two products (Calstrux and OP-1) had not been approved by the FDA and defendant Stryker knew, or should have known, that mixed use of these two products was ineffective and could lead to unwanted bone growth. Nonetheless, Stryker engaged in extensive and

illegal off-label promotion of the mixed use of these two products. Stryker has since been federally indicted for its illegal promotion of these two products and two of its sales managers have pled guilty to engaging in illegal off-label promotion. The mixed use of these two products eventually resulted in excessive bone growth and migration in Cabana's lower back resulting in nerve compression and severe pain in her lower back and extremities. Cabana eventually had to undergo a second surgery to remove the "bone of unknown origin."

2. In the second surgery, Cabana's surgeon removed the "bone of unknown origin" and, in order to fuse the bone, the surgeon used INFUSE Bone Graft manufactured by defendant Medtronic, Inc. The INFUSE Bone Graft had only been approved for a limited surgical procedure, yet Medtronic illegally promoted it for a number of off-label procedures. The surgeon in this case used the INFUSE Bone Graft in an off-label manner. The surgery failed to remedy Cabana's condition and her pain has only been exacerbated. In July of 2011, the prominent medical journal, *The Spine Journal*, dedicated its entire journal to publishing numerous articles regarding the risks associated with INFUSE Bone Graft. The journal articles discuss Medtronic's failure to accurately report the side effects from its clinical trials; Medtronic's failure to report that many of the authors who studied and promoted INFUSE Bone Graft had significant financial ties to Medtronic; that INFUSE Bone Graft can cause severe problems with nerves and spinal cords; and that off-label use of INFUSE Bone Graft can lead to severe side effects.

3. Cabana underwent two surgeries both of which were expected to cure and remedy her lower back pain, however, neither surgery has been a success and, as a result of these surgeries and the untested, unapproved and off-label use of materials during her surgeries, her condition and pain has worsened necessitating additional curative surgeries and permanent, disabling injury. As a result of defendants' illegal off-label promotion of their respective products and failure to deal honestly with the medical community and the public, Cabana has endured serious physical and emotional pain, and, despite being only 34-years old, has been placed on disability, is unable to be mobile, is unable to work, and can no longer participate in many of the regular activities she once used to enjoy.

THE PARTIES

4. Plaintiff **April C. Cabana** ("Cabana" or "Plaintiff") is a 34-year-old female who is, and at all times relevant hereto was, a resident of San Bernardino County, California.

5. Defendant **Stryker Biotech, LLC** ("Stryker Biotech") and Does 1-10, inclusive, and each of them are and at all relevant times were, limited liability companies doing business in California, including but not limited to manufacturing, marketing, promoting and selling medical products and devices for use on California citizens. Stryker Biotech is, and at all relevant times was, a subsidiary of defendant Stryker Corporation.

6. Defendant **Stryker Corporation** and Does 11-20, inclusive, and each of them are and at all relevant times were, Corporations doing business in California, including but not limited to manufacturing, marketing, promoting and selling medical products and devices for use on California citizens. Defendants Stryker Corporation, Stryker Biotech and Does 1-20, inclusively, will hereinafter be collectively referred to as the "Stryker Defendants."

7. At all relevant times, the Stryker Defendants were engaged in the manufacture, promotion and sale of medical devices for human use, including medical devices for use in healing of fractured or broken bones, including: (a) OP-1 Putty, a putty to promote bone growth in certain spinal fusions; and (b) Calstrux, a bone void filler for surgically created bone defects or bone defects resulting from traumatic injury.

8. Defendant **Medtronic Sofamor Danek USA, Inc**., and Does 21-30, inclusive, and each of them are and at all relevant times were, corporations doing business in California, including but not limited to manufacturing, marketing, promoting and selling medical products and devices for use on California citizens. Medtronic Sofamor Danek USA, Inc. is, and at all relevant times was, a subsidiary of defendant Medtronic, Inc.

9. Defendant **Medtronic, Inc**. and Does 31-40, inclusive, and each of them are and at all relevant times were, corporations doing business in California, including but not limited to manufacturing, marketing, promoting and selling medical products and devices for use on California citizens. Medtronic maintains research, development, manufacturing and/or distribution facilities in

Los Angeles County. Defendants Medtronic Sofamor Danek USA, Inc., Medtronic, Inc. and Does 21-40, inclusively, will hereinafter be collectively referred to as "Medtronic."

10. At all relevant times, Medtronic was engaged in the manufacture, promotion and sale of INFUSE Bone Graft. INFUSE Bone Graft is a surgically implanted medical device containing a genetically engineered protein designed to stimulate bone growth.

11. On July 12, 2011, pursuant to Section 364 of the California Code of Civil Procedure, Cabana, through her undersigned counsel, served her treating surgeon, Ali H. Mesiwala, M.D. ("Dr. Mesiwala"), with a 90-day notice of intention to commence action. Once the 90-day wait period expires without resolution, Cabana intends to amend her complaint to name Dr. Mesiwala as a defendant. Dr. Mesiwala is a resident and citizen of the state of California and has his principal place of business in Pomona, California.

12. On July 12, 2011, pursuant to Section 364 of the California Code of Civil Procedure, Cabana, through her undersigned counsel, served Pomona Valley Hospital Medical Center ("Pomona Hospital"), the hospital where her lumbar spine surgeries were performed, with a 90-day notice of intention to commence action. Once the 90-day wait period expires without resolution, Cabana intends to amend her complaint to name Pomona Valley Hospital as a defendant. Pomona Valley Hospital is a California corporation and has its principal place of business in Pomona, California.

13. The true names and capacities, whether individual, corporate, associate, or otherwise, of the defendants named herein, under the fictitious names of **DOES 1 through 100**, inclusive, are unknown to Cabana, who, therefore, sues said defendants by such fictitious names. Cabana will ask leave of Court to amend this complaint and insert the true names and capacities of said defendants when the same have been ascertained. Cabana is informed and believes and based thereon alleges that each of the defendants designated herein as a "Doe" is legally responsible in some manner for the events and happenings herein alleged, and that Cabana's damages were proximately caused by such defendants. Unless otherwise specified, references herein to "defendants" refer to the Stryker Defendants, Medtronic and DOES 1 through 100, inclusive.

14. At all times herein mentioned, defendants, and each of them, and their aggregates, corporates, associates, and partners, and each of them, were the agent, servant, employee, assignee,

permissive user, successor in interest or joint venture of each other, and were acting within the time, purpose or scope of such agency or employment or permission; and all acts or omissions alleged herein of each such defendant were authorized, adopted, approved, or ratified by each of the other defendants.

ALLEGATIONS

I. FDA AND FDCA REGULATIONS APPLICABLE TO MEDICAL DEVICES

15. At all times herein relevant, the United States Food and Drug Administration ("FDA") was, and is, the federal agency of the United States responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug and Cosmetic Act, ("FDCA"), 21 U.S.C. §§ 301, *et seq*., and ensuring, among other things, that medical devices intended for use in humans are safe and effective for each of their intended uses and that the labeling of such medical devices bears true and accurate information.

16. At all times herein relevant, the FDCA stated that a "device" for use in humans includes "an ... implant ... or other similar or related article ... which is ... intended for use in ... the treatment or prevention of disease of man ... or intended to affect the structure or any function of the body of man ... which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. §321(h).

17. At all times herein relevant, the FDCA required every manufacturer of a new device to obtain approval from the FDA prior to marketing and selling its device in interstate commerce.

18. To obtain such approval, the FDCA assigned all devices into one of three classes of devices, depending on the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of the device for its intended use. Class I devices pose the lowest risk to consumers' health, do not require FDA approval for marketing, and include devices such as tongue depressors; Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents; and Class III devices pose the greatest risk of death or complications and include most implantable surgical devices including several types of implantable orthopedic devices for spine and hip surgery.

19. At all times herein relevant, the FDCA provided four different ways for a manufacturer to obtain approval to introduce the device intended for human use into interstate commerce:

A. *Premarket Approval.* Before a company could market a Class III device, that company is required to submit a premarket approval ("PMA") application to the FDA that provided the FDA with a reasonable assurance that the device was safe and effective for its intended use. 21 U.S.C. §§360e(a)(2) and 360e(d)(2). In order to show safety and effectiveness, the applicant is required to submit proof to the FDA, typically in the form of clinical trial results.

B. *510(k) Approval.* Alternatively, a company could seek a premarket notification, commonly referred to as a "510(k)," to the FDA seeking a determination that the device was "substantially equivalent" to a legally marketed device. 21 U.S.C. §§360c(f) and (i) and 360(k). If the FDA "cleared" the device by determining that the device was substantially equivalent to a device that had already demonstrated safety and efficacy, the company could market the device, which was then considered to be in the same class as the device to which it was compared. 21 U.S.C. §360c(f)(1).

C. *Investigational Device Exemption.* This exemption allows for clinical investigation of devices to determine safety and effectiveness for new uses. 21 U.S.C.§ 360j(g) and 21 C.F.R. §812. Submission, and subsequent approval, of an Investigational Device Exemption ("IDE") permits a device that would otherwise be required to obtain premarket approval to be shipped in interstate commerce for the purpose of conducting clinical investigations.

D. *Humanitarian Device Exemption.* The fourth option to obtain approval was the submission of an application for a Humanitarian Device Exemption ("HDE"). An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device was effective for its intended purpose. The application, however, has to contain sufficient information for the FDA to determine that the device did not pose an unreasonable or

significant risk of illness or injury, and that the probable benefit to health outweighed the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant has to demonstrate that no comparable devices were available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. An HDE approval is accompanied by certain additional requirements:

i. An HDE can only be granted upon a finding by the FDA that the device was designed to treat or diagnose a disease or condition that affected fewer than 4,000 individuals in the United States.

ii. A device approved under an HDE cannot be sold for an amount that exceeded the costs of research and development, fabrication, and distribution of the device; thus, the holder of an HDE is not allowed to make a profit on the sale of an HDE device.

iii. An HDE device can only be used at a medical facility after an institutional review board ("IRB") at or on behalf of the medical facility approved the use of the device for the FDA approved indication; the IRBs acted as a safeguard that the HDE devices were being used properly.

20. The FDCA required that a submission for approval of a device include proposed labeling for the proposed intended uses of the device that includes, among other things, the conditions for therapeutic use. A device manufacturer is not permitted to promote and market a new device until it has an approval, including approval for the proposed labeling. Moreover, if approved, the device manufacturer is permitted to promote the device only for the medical conditions of use specified in the approved labeling. Uses not approved by the FDA are known as "unapproved" or "off-label" uses.

21. Devices that are promoted for uses that have not been approved by the FDA are deemed to be misbranded under the FDCA.

II. THE STRYKER DEFENDANTS' PRODUCTS

A. The OP-1 Products

22. Two of the Stryker Defendants 'products were OP-1 Implant and OP-1 Putty (collectively referred to as "OP-1 products" or "OP-1"). These two devices are part of a class of devices known as Bone Morphogenic Proteins ("BMP"). These proteins have the ability to stimulate, repair and regenerate bone. OP- Implant and OP-Putty stimulates natural bone healing by actively recruiting blood supply and stem cells from surrounding tissue and thereby initiating bone formation. OP-1 Implant was designed for use in long bones, and OP-1 Putty was designed for use in the spine. The difference between the two devices was that OP-1 Implant was intended to be used by itself in the long bones, while OP-1 Putty was comprised of both OP- Implant and a separate vial of 230 mg of carboxymethylcellulose, which were intended to be mixed together to form a putty to be implanted during a spinal fusion surgery.

23. Plaintiff is informed and believes and based thereon alleges that, on October 17, 2001, the FDA, in response to a prior application by the Stryker Defendants, granted a Humanitarian Device Exemption or HDE for **OP-1 Implant**. The HDE was only for "use as an alternative to autograft in recalcitrant long bone non-unions where use of autograft is unfeasible and alternative treatments have failed." A long bone nonunion typically referred to an arm or leg break that did not heal after conventional treatments. "Autograft" referred to bone typically harvested from a patient's hip bone to place and stimulate bone growth in the affected site. Autograft use was unfeasible in certain patients, including elderly patients whose hip and other bones had been weakened from osteoporosis or other conditions. Thus, the medical use (also referred to as "indication") for OP-1 Implant was narrow -- it was for patients with a long bone fracture that did not heal from other treatment and for whom the use of autograft was not feasible.

24. Plaintiff is informed and believes and based thereon alleges that, on April 7, 2004, the FDA, in response to a prior application by the Stryker Defendants, granted an HDE for **OP-1 Putty**. The HDE was only for "use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion." "Posterolateral lumbar spinal fusion"

referred to a specific type of spinal surgery in which vertebrae in the lumbar (lower back) area of the spine are fused together. The HDE, however, was only for "revision" surgery, meaning that the patient had already had a surgery that had not succeeded in fusing the vertebrae. Moreover, the HDE was for "use as an alternative to autograft in compromised patients ... for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion." These compromising factors included osteoporosis, smoking and diabetes. Thus, the "indication" for **OP-1 Putty** was narrow -- it was for patients who needed a spinal lumbar fusion that had not succeeded from previous surgery and for whom the use of autograft was not feasible for a subsequent surgery.

25. Plaintiff is informed and believes and based thereon alleges that the Stryker Defendants represented to the FDA that OP-1 Implant and OP-1 Putty were each designed to treat a condition that affected fewer than 4,000 individuals in the United States.

26. Plaintiff is informed and believes and based thereon alleges that, from in or about 2002 through in or about mid-2004, the Stryker Defendants received feedback from surgeons that OP-1 handled poorly (like wet sand) and did not provide enough product volume.

B. The Calstrux Product

27. Plaintiff is informed and believes and based thereon alleges that, in response to these complaints, the Stryker Defendants developed **Calstrux** (originally named "TCP Putty"), a product with a malleable, "silly-putty" type consistency that the Stryker Defendants intended to be mixed with the OP-1 products as a "carrier" or "extender" to increase the volume and improve the handling qualities of OP-1.

28. Plaintiff is informed and believes and based thereon alleges that, despite intending Calstrux to be used in a mixture with OP-1, the Stryker Defendants submitted to the FDA a Section 510(k) premarket notification of intent to market Calstrux as a bone void filler product. Bone void fillers then on the market were approved to fill voids in bones that resulted from bony defects or injury, and were not approved to be mixed with a bone morphogenic protein like OP-1.

29. Plaintiff is informed and believes and based thereon alleges that, on August 26, 2004, the FDA, in response to a Section 510(k) premarket notification of intent to market a bone void filler product, notified the Stryker Defendants that they could market Calstrux (originally named TCP

Putty). Calstrux was approved as "a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous [bony] defects or osseous defects resulting from traumatic injury."

30. Plaintiff is informed and believes and based thereon alleges that the Stryker Defendants never applied to the FDA for approval of a mixture of OP-1 with Calstrux, nor did the FDA ever approve any such use.

31. Plaintiff is informed and believes and based thereon alleges that the Stryker Defendants never performed any clinical trial in humans to determine whether a mixture of OP-1 with Calstrux was safe or effective.

32. Plaintiff is informed and believes and based thereon alleges that the Stryker Defendants never formulated adequate directions for use for the mixture of OP-1 with Calstrux because the mixture was never approved by the FDA and, accordingly, there was no approved labeling for such a mixture.

C. The Stryker Defendants' Illegal and Fraudulent Promotion of the Mixture of OP-1 and Calstrux

33. Plaintiff is informed and believes and based thereon alleges that, in connection with the company-wide launch of Calstrux in early 2005, the Stryker Defendants presented Calstrux to the sales force as a "carrier" or "extender" for the OP-1 products and noted that the availability of Calstrux should "accelerate" the sales of OP-1.

34. Plaintiff is informed and believes and based thereon alleges that, shortly after Calstrux's introduction to the market, the Stryker Defendants promoted it to surgeons, including Dr. Mesiwala, hospitals, and surgical staff, including the staff at Pomona Valley Hospital, as a product to be used in combination with the OP-1 products, specifically as a "carrier" or "extender."

35. Plaintiff is informed and believes and based thereon alleges that, after the launch of Calstrux, the vast majority of sales of Calstrux by the Stryker Defendants was for mixing with one of the OP-1 products.

36. Plaintiff is informed and believes and based thereon alleges that the Stryker Defendants promoted and caused to be promoted to surgeons, including Dr. Mesiwala, hospitals, and surgical staff,

including the staff at Pomona Valley Hospital, "recipes" or mixing instructions on how to combine Calstrux and OP-1. The Stryker Defendants' employees advised surgeons and/or surgical staff to use various recipes for preparing the mixture of Calstrux and OP-1. Some recommended forming the combination into "cigars," some into "tootsie rolls," some into "logs," some into "bricks," and some into "vienna sausages." The recipes also varied in terms of amount of liquid, type of liquid (e.g., blood versus saline), and ratio of Calstrux to OP-1. As one Stryker sales representative wrote to senior management: "Like any product if we have 30+ people doing something different with regards to mixing, dosing etc. we are going to see different results."

37. Plaintiff is informed and believes and based thereon alleges that, beginning in mid-2005, the Stryker Defendants began to receive reports of adverse events arising from a combination of the OP-1 products and Calstrux. The events included inflammation, drainage and impaired wound healing. Some patients who experienced these adverse events had to be operated on again and, during some of these subsequent operations, surgeons observed that the OP-1/Calstrux mixture had migrated from the surgical site and looked like "oatmeal," "grits" or "white sesame seeds." In some instances, patients, similar to plaintiff April Cabana, suffered from unwanted bone growth in areas to which the combination of OP-1 and Calstrux had migrated. In some instances, such as in this case, this unwanted bone growth had to be removed surgically.

38. Plaintiff is informed and believes and based thereon alleges that, in early 2006, the Stryker Defendants asked a surgeon to prepare an analysis of patients at his hospital who had been treated with a mixture of OP-1 and Calstrux. This report, which was communicated to the Stryker Defendants in or about February 2006, showed that patients who received such a mixture had an adverse event rate higher than the norm. Later that year, this same surgeon communicated to the Stryker Defendants that a mixture of OP- and Calstrux was not effective.

39. Plaintiff is informed and believes and based thereon alleges that, despite knowing the mixture of OP-1 and Calstrux was not approved by the FDA and, despite reports of adverse events, the Stryker Defendants touted Calstrux as the "perfect carrier for OP-" at a sales meeting in January 2006.

40. Plaintiff is informed and believes and based thereon alleges that, on or about February 15, 2006, a senior manager at the Stryker Defendants sent a memorandum about the mixture of OP-1

and Calstrux to other senior managers recounting concerns, including, among others: (a) the adverse events from mixing OP-1 and Calstrux, (b) that a "variety of different 'recipes' are used" by different surgeons; and (c) that Calstrux was being improperly promoted as the "preferred carrier" for OP-1 by the sales force. This senior manager further made a series of recommendations, including among others: (a) "[c]ease recommending, suggesting and preparing for use Calstrux and OP-1 Implant as noted above...", and (b) a "dear doctor" letter advising surgeons about the adverse experiences associated with the mixture of OP-1 and Calstrux.

41. Plaintiff is informed and believes and based thereon alleges that, after learning about the recommendation to send a "dear doctor" letter to physicians and IRBs about the adverse experiences associated with the mixture of OP-1 and Calstrux, William Heppner, the National Sales Director at Stryker Biotech and others in sales management argued against that disclosure in part because disclosure would: (a) harm sales of OP-1; (b) anger surgeons who had been misled because "many surgeons are just handed the product prior to implantation and think its all OP-1"; and (c) cause IRBs, whose mission was to protect patients, to cease all OP-1 usage at medical facilities at which they had previously approved the use of OP-1.

42. Plaintiff is informed and believes and based thereon alleges that, on or about March 1, 2006, a Vice-President of the Stryker Defendants provided training to the sales force and sales management in which he explained that the promotion of a mixture of OP-1 and Calstrux could expose the company and individual employees to criminal prosecution and fines.

43. Plaintiff is informed and believes and based thereon alleges that, on or about March 3, 2006, the president of Stryker Biotech, Mark Philip, decided and instructed his employees that no "dear doctor" letter would be sent to surgeons advising them about adverse experiences with the mixture of OP-1 and Calstrux.

44. Plaintiff is informed and believes and based thereon alleges that, despite knowing that the off-label promotion of the mixture of OP-1 and Calstrux was illegal, the Stryker Defendants continued to promote or cause the promotion of the mixture of OP-1 and Calstrux to surgeons, including Dr. Mesiwala, hospitals, and surgical staff, including the staff at Pomona Valley Hospital.

45. Plaintiff is informed and believes and based thereon alleges that, beginning on a date unknown, but no later than in or about February 2006, the Stryker Defendants devised and intended to devise a scheme and artifice to defraud physicians, hospitals and patients and to obtain money by means of false and fraudulent pretenses, representations, and promises concerning material facts, and by concealing material facts.

46. Plaintiff is informed and believes and based thereon alleges that the purpose of the scheme and artifice to defraud was for the Stryker Defendants to obtain many millions of dollars in sales from OP-1 and Calstrux, all through the deliberate manipulation of health care professionals with false, deceptive, incomplete and misleading information into using OP-1 for unapproved uses, including the unapproved use of a mixture of OP-1 and Calstrux.

47. Plaintiff is informed and believes and based thereon alleges that it was part of the scheme and artifice to defraud that the Stryker Defendants developed and launched Calstrux as a product to be mixed with the OP- products, as a "carrier" or "extender" for the OP-1 products, despite knowing they had never sought FDA approval for such use, that the FDA had not approved the mixture of OP- and Calstrux, and that no clinical trials to evaluate the safety or efficacy of the mixture of OP-1 and Calstrux had ever been performed.

48. Plaintiff is informed and believes and based thereon alleges that it was further part of the scheme and artifice to defraud that the Stryker Defendants trained their sales representatives that Calstrux was an "extender" for the OP-1 products, and provided them with instructions as to how to mix the two products.

49. Plaintiff is informed and believes and based thereon alleges that it was a further part of the scheme and artifice to defraud that the Stryker Defendants' sales force, including representatives of affiliated companies and distributors, misled surgeons, including Dr. Mesiwala, and surgical staff, including the staff at Pomona Valley Hospital, regarding the mixture of OP-1 and Calstrux in a variety of different ways in different circumstances, including by one or more of the following: (a) failing to disclose that there were adverse events arising from a combined use of Calstrux and OP-1; (b) failing to disclose that the mixture of OP-1 and Calstrux was not FDA approved; (c) failing to disclose that the mixture of OP-1 and Calstrux had never been clinically studied in humans; (d) affirmatively misrep-

resenting the nature of the FDA "approval" by referring to the HDE as a "steppingstone" to full approval, or telling surgeons that there was no difference between an HDE and a PMA in terms of the ability to use the product "off-label"; and (e) affirmatively misrepresenting the mixture of Calstrux and OP-1 was simply OP-1 when presented to the surgeon, and/or failing to disclose that the mixture of OP-1 and Calstrux was not simply OP-1 knowing that the surgeon so assumed.

50. Plaintiff is informed and believes and based thereon alleges that it was a further part of the scheme and artifice to defraud that the Stryker Defendants misled its sales force by suggesting, without proper clinical testing, or any scientific testing, that the adverse events associated with a mixture of OP-1 and Calstrux could be solved by merely using a "drier" mix or by using smaller sizes of Calstrux (e.g., 5cc or 10cc as opposed to 15cc).

51. Plaintiff is informed and believes and based thereon alleges that it was a further part of the scheme and artifice to defraud that the Stryker Defendants encouraged their sales force to sell a mixture of OP-1 and Calstrux through one or more of the following mechanisms: bonuses, commissions, sales quotas, employee reviews, field training and feedback.

52. It was a further part of the scheme and artifice to defraud that the Stryker Defendants' sales representatives and sales managers, although not medical doctors or registered nurses, attended surgeries and directed the mixing of the Calstrux and OP-1 at surgery. When the Stryker Defendants' employees could not attend surgeries, they sometimes provided or caused to be provided written mixing instructions to surgeons or surgical staff.

53. It was a further part of the scheme and artifice to defraud that the Stryker Defendants promoted or caused to be promoted a mixture of OP-1 and Calstrux through pricing proposals to hospitals and medical facilities, including those that offered combined discounted prices for purchasing OP-1 with Calstrux as an "extender."

54. It was also part of the scheme and artifice to defraud that the Stryker Defendants hired outside surgeon/consultants to promote unapproved uses of OP-1, including the mixture of OP-1 and Calstrux, through lectures at restaurants.

55. It was also part of the scheme or artifice to defraud that the Stryker Defendants, hired outside surgeon/consultants to promote unapproved uses of OP-1, including the mixture of OP-1 and

Calstrux, through making sales calls with the Stryker Defendants' sales force on physicians at their offices.

56. It was a further part of the scheme and artifice to defraud that, in or about October 2006, in an effort to conceal the Stryker Defendants' role in promoting the mixture of OP-1 and Calstrux to surgeons, the Stryker Defendants' instructed their sales force to return to hospitals and surgical offices to retrieve copies of written mixing instructions that had been left behind.

D. Stryker Biotech Is Criminally Indicted For Its Off-Label Promotion Activities and Two of Its Sales Managers Plead Guilty to Illegally Promoting the Mixture of OP-1 and Calstrux in Violation of the FDCA

57. By February 2009, two Stryker Biotech sales representatives had pled guilty to illegally promoting the mixture of OP-1 and Calstrux in violation of the FDCA.

58. On October 28, 2009, the U.S. Department of Justice issued an indictment against Stryker Biotech and its President arising out of Stryker Biotech's illegal off-label promotion of OP-1 and Calstrux to surgeons in various states, including California.

III. THE MEDTRONIC INFUSE BONE GRAFT PRODUCT

59. Plaintiff is informed and believes and based thereon alleges that surgeons have, for decades, employed spinal fusion—a surgical technique in which one or more of the vertebrae of the spine are united together ("fused") so that motion no longer occurs between them—to treat a number of conditions, including treatment of a fractured vertebra, spinal deformities (spinal curves or slippages), back pain from instability, or abnormal or excessive movement between vertebrae. Similar to the concept of welding, spinal fusion surgery joins vertebrae together to eliminate or reduce movement between vertebrae through the use of bone grafts.

60. Plaintiff is informed and believes and based thereon alleges that, in a bone graft procedure, the graft—usually bone or bone-like material—is placed around the vertebrae during surgery. Over the following months, a physiological mechanism similar to that which occurs when a fractured bone heals causes the graft to join, or "weld," the vertebrae together. The goal of spinal fusion is to obtain a solid fusion of the vertebrae.

61. Plaintiff is informed and believes and based thereon alleges that, for years, autologous bone graft has been considered the "gold standard" in spinal fusion surgery. In an autologous bone

graft, or "autograft," the surgeon procures bone graft material from another part of the patient's body, typically from the patient's pelvis or iliac crest, and implants the bone graft in the site where fusion is desired. As the harvested bone exhibits all the properties necessary for bone growth—including osteogenic, osteoconductive and osteoinductive properties—successful fusions occur at significantly higher rates in autograft procedures.

62. Plaintiff is informed and believes and based thereon alleges that, as an alternative to autograft, patients can undergo an allograft procedure, in which bone is taken from the cadavers of deceased people who have donated their bone to so called "bone banks." Although healing and fusion is not as predictable as with the patient's own bone, an allograft eliminates the need for the harvest procedure required in an autograft.

63. Plaintiff is informed and believes and based thereon alleges that studies revealing the ability for biologically manufactured protein to generate bone growth in laboratory animals represented a potential to provide a third surgical option to traditional bone graft procedures. If fusion could be accomplished through the use of biologically manufactured proteins, patients could forego the harvest surgery required in an autograft, but could still benefit from the superior fusion rates associated with autograft procedures.

64. Plaintiff is informed and believes and based thereon alleges that, attempting to seize on this potentially lucrative opportunity to develop an alternative spinal fusion procedure, Medtronic, via a company buyout, acquired the exclusive rights to recombinant human bone morphogenetic protein-2 ("rhBMP-2") for spinal applications. rhBMP-2 is in a similar class as Stryker's OP-1 product,[1] and is a genetically engineered version of a naturally occurring protein that stimulates bone growth, developed as a commercially viable bone morphogenetic protein ("BMP") technology.

65. Plaintiff is informed and believes and based thereon alleges that, on January 12, 2001, Medtronic filed the INFUSE Bone Graft PMA and was granted expedited review status by the FDA.

[1] Stryker's OP-1 product is a recombinant human bone morphogenetic protein-7 ("rhBMP-7").

A. INFUSE Bone Graft Was Only Approved for A Very Specific Spinal Procedure -- Anterior Lumbar Interbody Fusion Utilizing All Components

66. Plaintiff is informed and believes and based thereon alleges that, on July 2, 2002, the FDA approved INFUSE Bone Graft, a medical device containing an absorbable collagen sponge that is treated with rhBMP-2, for certain limited uses.

67. Plaintiff is informed and believes and based thereon alleges that the FDA's limited use approval of INFUSE Bone Graft was based on concerns about potential adverse events that already had been reported with the product at the time of approval. As a result, the FDA approved INFUSE Bone Graft for a small percentage of overall spinal fusion surgeries, with the device label specifying the limited surgical application to be used.

68. Plaintiff is informed and believes and based thereon alleges that, as presented in Medtronic's original PMA and eventually approved by the FDA in July 2002, the initially-approved INFUSE Bone Graft product consisted of two components (1) the LT-CAGE® Lumbar Tapered Fusion Device Component, a thimble-sized hollow metal cylinder which keeps the two vertebrae in place and provides a frame that contains and directs the development of new bone growth; and (2) the INFUSE Bone Graft Component, which includes (a) an absorbable collagen sponge ("ACS") that acts as a carrier and scaffold for the active ingredient in INFUSE Bone Graft, and (b) rhBMP-2, the actual active ingredient that is reconstituted in sterile water and applied to the ACS. Although these two components are sold separately, the initial approved labeling for the product indicates that the INFUSE Bone Graft must be used with the LT-CAGE component.

69. Plaintiff is informed and believes and based thereon alleges that the labeling also directs the specific manner in which both components are to be used in a fusion procedure.

70. Plaintiff is informed and believes and based thereon alleges that, according to the label sought by Medtronic in the PMA and subsequently approved by the FDA, INFUSE Bone Graft can only be used in an Anterior Lumbar Interbody Fusion ("ALIF") procedure, involving a single-level fusion in the L4-S1 region of the lumbar spine. ALIF is performed by approaching the spine from the

front through an incision in the abdomen and is primarily used to treat pain resulting from disc collapse.[2]

71. Plaintiff is informed and believes and based thereon alleges that there are numerous other lumbar spine surgical procedures for which INFUSE had not been approved but for which it was promoted and/or utilized. These other lumbar procedures included: (a) Posterior Lumbar Interbody Fusion ("PLIF"), a procedure that is used to treat nerve compression and back pain resulting from a number of causes, involves approaching the spine from the back. PLIF, however, is a more sensitive surgical approach and procedure because the spinal canal and nerves are posterior to the vertebral body, and because a surgeon must manipulate the dural sac (the membranous sac that encases the spinal cord within the vertebral column) to perform the PLIF procedure; (b) Posterolateral Fusion which is similar to the PLIF procedure, but instead of removing the disc space and replacing it with a bone graft, the disc space remains intact and the bone graft is placed between the transverse processes in the back of the spine. This allows the bone to heal and stabilizes the spine by fusing the transverse process of one vertebra to the transverse process of the next vertebra; and (c) Transforaminal Lumbar Interbody Fusion ("TLIF"), which is also similar to the PLIF procedure, and is a technique utilized when an inter-body fusion is performed via a posterior approach. TLIF allows the surgeon to perform a fusion from a posterior approach without disturbing the dural sac by approaching the spine via a more lateral, or sideways, approach.

72. Plaintiff is informed and believes and based thereon alleges that, not only was the application of INFUSE Bone Graft with the LT-CAGE in an ALIF single-level fusion **the only** procedure and indication used in the pivotal study that formed the basis of Medtronic's PMA submission, but the use of rhBMP-2 in other applications revealed instances of adverse events. In particular, a Medtronic-sponsored trial examining the application of rhBMP-2 using the PLIF procedure was halted in December 1999 when heterotopic bone growth—defined as any bone growth that occurs in areas of

[2] While the product's label remains substantially the same as that approved by the FDA in 2002, the FDA has made minor amendments to the label through post-approval supplements. For example, on July 29, 2004, the FDA approved a supplement expanding the indicated spinal region from L4-S1 to L2-S1 and later granted approval for uses in certain oral maxillofacial surgeries.

the body where such growth is not desired—developed in a number of patients. A doctor who participated in the study reported that one of the patients he treated required two extra surgeries to clear the excessive bone growth from the spinal canal. The complications observed in the PLIF trial were particularly serious given the potential of neural impingement (or nerve pinching) from such bony overgrowth in that procedure, potentially triggering the very sort of pain that a fusion procedure attempts to eliminate; the very type of pain that Plaintiff continues to suffer.

73. Plaintiff is informed and believes and based thereon alleges that complications such as those noted in the PLIF trial result from INFUSE Bone Graft's very mechanism of action. In such cases, INFUSE Bone Graft can stimulate bone growth where new bone is not desired and can lead to excessive bone growth in the target area, and swelling. There is insufficient scientific evidence concerning the proper dosages of rhBMP-2 for use in different procedures or the expected responses to the protein in different biological environments. Indeed, many adverse events associated with the use of INFUSE Bone Graft result from off-label use of the product by surgeons who do not fully understand the powerful nature of this protein, nor have defendants, or any of them, provided any clinical or other scientific evidence to support the usages recommended by Medtronic.

74. Plaintiff is informed and believes and based thereon alleges that, at the FDA Advisory Committee panel hearing on January 10, 2002 concerning FDA approval of Medtronic's INFUSE Bone Graft, the panel members stressed concerns regarding potential off-label use of the product and asked Medtronic presenters repeated questions about how the Company would seek to guard against off-label applications of the product.

75. Plaintiff is informed and believes and based thereon alleges that, at the conclusion of the hearing, the FDA Advisory Panel again reiterated concerns regarding the potential for off-label use, specifically admonishing the Company to guard against procedures other than the specific ALIF procedure provided in the labeled application. Panel member Dr. John Kirkpatrick noted his concern that procedures other than ALIF—especially the PLIF procedure—could result in harm to patients. According to Dr. Kirkpatrick, the use of the tapered LT-CAGE—which is difficult to implant in a posterior approach—would, if required, "prevent a majority of surgeons from applying this from a Posterior Lumbar Interbody Fusion perspective."

76. Plaintiff is informed and believes and based thereon alleges that, even at the time of its FDA approval, Medtronic and its senior management, were well aware of the concern regarding off-label uses of INFUSE Bone Graft and the potential dangers posed by them.

77. Plaintiff is informed and believes and based thereon alleges that, subsequent medical studies confirmed the fears of the FDA Advisory Panel that use of INFUSE Bone Graft outside of the studied application sought in the PMA could present severe risks to patient safety. Although the adverse outcomes reported in medical journals and other sources were known to Medtronic, the dangers posed by the increasing off-label use of INFUSE Bone Graft and their impact on the sustainability of the valuable revenue stream generated by off-label sales of the product were concealed by Medtronic from surgeons, including Cabana's surgeon, hospitals, including Pomona Valley Hospital, and operating room staff.

78. Plaintiff is informed and believes and based thereon alleges that numerous medical studies published since the introduction of INFUSE Bone Graft have shown that its use in procedures not approved by the FDA can lead to serious, and even deadly, adverse events. A May 15, 2006 medical article in *Spine* entitled "Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue" observed that these complications often result from the product's mechanism of action. As the authors stated, "rhBMP-2 may stimulate bone growth in areas in which bone is not desired, especially as the material 'leaks' into such spaces. . . . Although this phenomenon has not been thoroughly studied, it implies that the release of rhBMP-2 into the soft tissues stimulates a rapid, potentially life-threatening, inflammatory reaction."

79. Plaintiff is informed and believes and based thereon alleges that a number of other published articles and other studies likewise noted the serious risks posed by off-label use of INFUSE Bone Graft in more detail prior to its use in Cabana's surgery.

B. Medtronic Illegally Promoted INFUSE Bone Graft for Un-approved and off-label Uses

80. Plaintiff is informed and believes and based thereon alleges that, at all times herein relevant, notwithstanding these reports and the FDA Advisory Panel's earlier concerns, as set forth

below, Medtronic's senior management concealed the Company's surreptitious effort to promote the widespread off-label use of INFUSE Bone Graft.

81. Plaintiff is informed and believes and based thereon alleges that Medtronic provided millions of dollars in undisclosed payments to doctors (including so-called "Key Opinion Leaders") who published articles in medical journals, delivered presentations at continuing medical education courses, and appeared at consulting engagements addressing off-label applications of INFUSE Bone Graft. In turn, Medtronic's sales force would direct other doctors to these consultants and Key Opinion Leaders or their written work to further drive off-label sales of the INFUSE Bone Graft.

82. Under applicable FDCA and FDA regulations, device and drug manufacturers such as Medtronic are prohibited from actively promoting products for uses not approved by the FDA. Indeed, federal law provides for significant penalties for manufacturers that promote their products in ways inconsistent with a product's labeling. Severe penalties for off-label promotion were designed to ensure that the FDA's careful, deliberate consideration of a product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process.

83. Any application of INFUSE Bone Graft outside of its FDA approved usage is considered off-label. Examples of off-label uses of the INFUSE Bone Graft include: when the rhBMP-2 is applied without using the LT-CAGE or with a substitute cage; use of INFUSE Bone Graft in a PLIF, a Posterolateral Fusion, TLIF or any other procedure besides an ALIF using the LT-CAGE; or use of INFUSE Bone Graft in an ALIF procedure that involves a multiple-level fusion.

84. Plaintiff is informed and believes and based thereon alleges that, despite the prohibition against off-label promotion, Medtronic actively promoted off-label use of INFUSE Bone Graft by, among other things, providing doctors with information about other doctors using the product off-label (including those "Key Opinion Leaders" targeted and paid by the Company as "consultants") and by having Medtronic sales force personnel in the hospital operating rooms at the time of the off-label surgeries to provide doctors with information and instruction during the actual surgeries.

85. Plaintiff is informed and believes and based thereon alleges that, as a result of its illegal off-label promotion, sales of Medtronic's INFUSE Bone Graft have soared and have totaled billions of dollars. INFUSE Bone Graft's sales for the last fiscal year alone exceeded $900 million.

86. The Medical community is finally beginning to learn of the serious risks associated with INFUSE Bone Graft. This month (July 2011), one of the leading journals on spine surgery, *The Spine Journal*, dedicated its entire journal to publishing various articles regarding the risks associated with INFUSE Bone Graft, including articles on Medtronic's failure to accurately report the side effects from its clinical trials; Medtronic's failure to report that many of the authors who studied and promoted INFUSE Bone Graft had financial ties to Medtronic with the median range of $12 to $16 million per study; INFUSE Bone Graft can cause severe problems with nerves and spinal cords; off-label use of INFUSE Bone Graft can lead to severe side effects; and that Medtronic and its paid consultants/study authors downplayed the risks associated with INFUSE Bone Graft, over-emphasized its benefits and over-emphasized the risks associated with other conventional procedures.

IV. APRIL CABANA'S SURGERIES

A. Cabana's September 26, 2008 Surgery

87. Cabana's surgeon, Dr. Mesiwala, diagnosed her with "L5-S1 degenerative disk disease with discogenic pain." On September 26, 2008, Dr. Mesiwala performed a surgical procedure known as Transaxial Anterior Lumbar Interbody Fusion which is a procedure utilized to fuse the fifth lumbar vertebral body with the sacrum (sacralisation) L5-S1. During this procedure, the center of the diseased disc is removed, and bone growth material is inserted in its place with the intention that it would stimulate bone growth over time in order to "fuse."

88. To achieve fusion, Dr. Mesiwala performed an off-label procedure by mixing Calstrux bone-filler with the OP-1 Putty.

89. Plaintiff is informed and believes and based thereon alleges that the Stryker Defendants, through their sales representatives and paid Key Opinion Leaders, directly and indirectly promoted, trained and encouraged Dr. Mesiwala to engage in the off-label procedure of mixing Calstrux with OP-1 Putty.

90. Dr. Mesiwala never informed Cabana that he would be using the OP-1 and Calstrux Stryker products, he never informed her that he would be engaging in an off-label procedure of mixing these two products; never informed her that mixture of the OP-1 Putty and Calstrux was deemed to be ineffective and that it would lead to more risks and adverse events; never informed her that mixture of

the OP-1 Putty and Calstrux could result in unwanted bone growth and migration of the bone to sensitive nerve areas exacerbating her pain and necessitating the need of additional surgeries; never informed her that OP-1 Putty had only received a very limited FDA approval under the Humanitarian Device Exception; never informed her that use of the OP-1 Putty was so limited that it required the Hospital's IRB approval; never informed her that use of these products could cause severe, debilitating, permanent lower back pain; never informed her of available alternative methods of surgery and having failed to inform her of these, and other material facts and risks, he never actually obtained her informed consent to perform the procedures that he performed.

91. Shortly after her September 2008 surgery, Cabana began to experience severe intolerable lower back pain and presented herself to Dr. Mesiwala and other physicians for multiple post-surgical follow-ups. She was assured by Dr. Mesiwala and these other physicians that it was normal for her to have lower back pain following the surgery and that the surgery and fusion were successful.

92. A CT-scan and MRI subsequently revealed a "bone of unknown origin" in Cabana's lower back which was putting pressure on her nerve and causing her pain, and Dr. Mesiwala informed her that he would need to perform another surgery. Dr. Mesiwala never informed Cabana that the "bone of unknown origin" was probably caused by the leakage and migration of the Calstrux and OP-1 mixture nor did he ever inform her that anything from the previous surgery was or could have been responsible for the "bone of unknown origin."

93. Following review of the CT scan and MRI, on July 13, 2009, Dr. Mesiwala once again performed surgery on Cabana – this time to remove the bone of unknown origin for the purpose of relieving her severe, debilitating lower back pain and suffering.

B. Cabana's July 13, 2009 Surgery

94. In the July 13, 2009 surgery, Dr. Mesiwala, removed the Stryker bone graft that was migrating through her foramen. He still chose to accomplish fusion through bone morphogenic protein, though instead of using the Stryker products (which had failed), he used Medtronic's INFUSE Bone Graft.

95. However, Dr. Mesiwala used the INFUSE Bone Graft in an off-label manner. Instead of performing an *anterior* procedure, Dr. Mesiwala opted for a *posterior* procedure. The FDA had not approved the Medtronic INFUSE Bone Graft to be used in a posterior procedure.

96. Plaintiff is informed and believes and based thereon alleges that Medtronic, through its sales representatives and paid Key Opinion Leaders directly and indirectly promoted, trained and encouraged Dr. Mesiwala to use the INFUSE Bone Graft in an off-label manner, including utilizing it in posterior procedures.

97. Among other things, Dr. Mesiwala never informed Cabana that he would be using the Medtronic INFUSE Bone Graft; he never informed her that this product had only received limited FDA approval for certain specific procedures; never informed her that he would be using the INFUSE Bone Graft in a posterior procedure that had never been tested or approved by the FDA; never informed her that a INFUSE Bone Graft clinical trial utilizing the posterior procedure had been halted due to the serious adverse events that had been experienced; never informed her that use of the INFUSE Bone Graft could result in unwanted bone growth and migration of the bone to sensitive nerve areas exacerbating her pain; never informed her that use of the INFUSE Bone Graft could cause severe, debilitating, permanent lower back pain; never informed her of available alternative methods of surgery, and having failed to inform her of these facts and risks, he never actually obtained her informed consent to perform the procedures that he performed.

98. Cabana has never recovered from her two surgeries and continues to have daily severe disabling pain in her lower back and nerve pain throughout her right leg.

C. Cabana's Discovery of Stryker's Wrongdoing

99. The first time Cabana discovered that her lower back and leg pain may have been caused and exacerbated by a medical device was in October 2010 when she received and reviewed her medical records from the September 26, 2008 surgery. During the course of litigation arising out of an auto accident, Ms. Cabana's former lawyer had sought and made multiple requests for these medical records, however, the hospital failed to timely produce these records claiming they were missing. As of January 22, 2010, the hospital had yet to produce the medical records. The records were eventually

produced by the hospital to Cabana's former counsel at some point prior to May 28, 2010. Cabana's auto-accident litigation, thereafter settled on June 1, 2010.

100. When Cabana reviewed these medical records in October 2010, she discovered for the first time that Dr. Mesiwala had used the Stryker OP-1 and Calstrux products. Not knowing what these products were, she performed a Google search on or about October 31, 2010, and, for the first time, learned that the combination of these two products were not FDA approved and further learned that these products were associated with leakage and unwanted bone growth. It was at this point, **October 2010**, that she first suspected that her post-September 2008 back pains were caused by the wrong doing of a third party, including the medical device manufacturer, Stryker, and possibly her surgeon, Dr. Mesiwala. Prior to this point, she had always been reasonably led to believe by, among others, her treating surgeon Dr. Mesiwala that her on-going and escalating back pain was caused by her underlying medical condition.

PLAINTIFF'S CAUSES OF ACTION

FIRST CAUSE OF ACTION
NEGLIGENCE AGAINST THE STRYKER DEFENDANTS

101. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

102. On September 26, 2008, Cabana underwent lumbar spine surgery in which her surgeon utilized, as a bone-filler, a mixture of Calstrux and OP-1 Putty. OP-1 Putty had received a very narrow and limited Humanitarian Device Exception by the FDA and the mixture of OP-1 Putty and Calstrux had never been approved by the FDA. As a means of enhancing sales, the Stryker Defendants (the manufacturers of Calstrux and OP-1 Putty) illegally promoted these products beyond the legal and limited uses for which they had been approved.

103. The Stryker Defendants, through sales representatives and paid Key Opinion Leaders, among other things, illegally provided surgeons with instructions on how to mix these two products and utilize them in off-label procedures in violation of federal laws. The Stryker Defendants, however, failed to inform physicians, hospitals and the public regarding the limited uses for which these products had been approved, and that the mixture of these two products could lead to unwanted bone

growth, leakage and other serious medical complications which would require additional surgeries to remedy.

104. The mixture of the OP-1 Putty and Calstrux that was used in Cabana's surgery eventually failed, leaked and led to unwanted bone growth into her nerve resulting in severe exacerbated intolerable and disabling pain and suffering.

105. Cabana's injuries and exacerbated pain described herein were caused by the negligence and misrepresentations of the Stryker Defendants through their representatives, sales representatives, paid Key Opinion Leaders, agents, servants and/or employees acting within the course and scope of their employment who were negligently, carelessly and recklessly researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing Calstrux and OP-1 Putty, and including among other things:

(a) Negligently, carelessly and recklessly engaging in the illegal off-label promotion of these products by recommending to physicians and instructing them that they should mix Calstrux with OP-1 Putty;

(b) Negligently, carelessly and recklessly failing to disclose that the mixture of these two products had not been approved by the FDA;

(c) Negligently, carelessly and recklessly failing to disclose to physicians that the mixture of these two products can result in serious side effects including but not limited to unwanted bone growth and migration of the bone;

(d) Negligently, carelessly and recklessly failing to fully disclose the results of the testing and other information in their possession regarding the possible adverse reactions associated with the off-label mixture of Calstrux and OP-1 Putty;

(e) Negligently, carelessly and recklessly failing to disclose the lack of clinical or other scientific evidence to support any particular ratio in the mixture of Calstrux and OP-1 Putty;

(f) Negligently, carelessly and recklessly representing that the mixture of these two products was safe when, in fact, it was unsafe;

(g) Negligently, carelessly and recklessly promoting OP-1 Putty beyond the narrow and limited Humanitarian Device Exception for which it was approved;

(h) Negligently, carelessly and recklessly failing to adequately warn the medical community, the general public, plaintiff's surgeon and plaintiff of the dangers, contra-indications, and side effects from the use, mixed use, and off-label use of these two products;

(i) Negligently, carelessly and recklessly failing to act as a reasonably prudent drug manufacturer.

106. Before Cabana was administered a mixture of Calstrux and OP-1 Putty, the Stryker Defendants, based upon the state of knowledge as it existed at the time, knew or should have known that the mixture of these two products could be dangerous and unsafe, and knew or should have known that its mixed use could result in migration and unwanted bone growth which would cause patients severe continuous pain, would require additional remedial surgeries and could lead to irremediable side effects.

107. As a direct and proximate result of the acts and conduct of the Stryker Defendants, Plaintiff has been injured in her health, strength and activity, and has suffered, continues to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, some of which injuries may be permanent, all to her damage in an amount in excess of the jurisdictional minimum of the Court.

108. As a further direct and proximate result of the acts and conduct of the Stryker Defendants, Plaintiff has lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

109. As a further direct and proximate result of the acts and conduct of Defendants, and each of them, Plaintiff has incurred medical, hospital and related expenses, and on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

SECOND CAUSE OF ACTION
NEGLIGENCE AGAINST MEDTRONICS

110. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

111. On July 13, 2009, Cabana underwent a second lumbar spine surgery. Her surgeon, Dr. Mesiwala, performed a *posterior* fusion using the Medtronic INFUSE Bone Graft. INFUSE Bone Graft had only received limited approval by the FDA to be used in an Anterior Lumbar Interbody Fusion ("ALIF") and had not been approved for a *posterior* procedure. However, as a means of enhancing sales, Medtronic (the manufacturers of INFUSE Bone Graft) illegally promoted it beyond the legal and limited uses for which it had been approved.

112. A proximate cause of Cabana's injuries and damage is the negligence and misrepresentations of Medtronic through its agents, sales representatives, paid Key Opinion Leaders, servants and/or employees acting within the course and scope of their employment, negligently, carelessly and recklessly researching, , selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing INFUSE Bone Graft, and including among other things:

(a) Negligently and carelessly engaging in the illegal off-label promotion of INFUSE Bone Graft by recommending to physicians, including Plaintiff's physicians, and instructing them to use it in procedures for which it had not been approved;

(b) Negligently, carelessly and recklessly promoting the off-label use of INFUSE Bone Graft by instructing, promoting and directing the use of the product without the mandatory LT-CAGE component;

(c) Negligently, carelessly and recklessly failing to disclose that usage of INFUSE Bone Graft in posterior procedures had not been approved by the FDA;

(d) Negligently, carelessly and recklessly failing to disclose to physicians that the promoted off-label use of INFUSE Bone Graft can result in serious side effects;

(e) Negligently, carelessly and recklessly failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions associated with the off-label use of INFUSE Bone Graft;

(f) Negligently, carelessly and recklessly representing that the off-label use of INFUSE Bone Graft was safe when, in fact, it was unsafe;

(g) Negligently, carelessly and recklessly promoting INFUSE Bone Graft beyond the narrow and limited uses for which it was approved;

(h) Negligently, carelessly and recklessly failing to adequately warn the medical community, the general public, plaintiff's surgeon and plaintiff of the dangers, contra-indications, and side effects from the off-label use of INFUSE Bone Graft;

(i) Negligently, carelessly and recklessly failing to act as a reasonably prudent drug manufacturer.

113. Before Cabana was given the INFUSE Bone Graft through a posterior procedure, Medtronic, based upon the state of knowledge as it existed at the time, knew or should have known that such a use could be dangerous and unsafe, and knew or should have known that such a use could result in migration, unwanted bone growth, inflammation, enhanced pain and other serious side effects.

114. As a direct and proximate result of the acts and conduct of Medtronic, Plaintiff has been injured in her health, strength and activity, and has suffered, continues to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, some of which injuries may be permanent, all to her damage in an amount in excess of the jurisdictional minimum of the Court.

115. As a further direct and proximate result of the acts and conduct of the - Defen-dants, Plaintiff has lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some of which losses may be permanent, all in an amount excess of the jurisdictional minimum of the Court.

116. As a further direct and proximate result of the acts and conduct of Defendants, and each of them, Plaintiff has incurred medical, hospital and related expenses and, on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

THIRD CAUSE OF ACTION
STRICT LIABILITY AGAINST STRYKER DEFENDANTS

117. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

118. At all times herein mentioned, the Stryker Defendants placed Calstrux and OP-1 Putty on the market.

119. At all times herein mentioned, the mixture of Calstrux with OP-1 Putty was defective, unsafe and ineffective, and the Stryker Defendants knew or should have known that it was unsafe and ineffective when used in an off-label manner as promoted, instructed and supplied by the Stryker Defendants, and as utilized in Cabana's September 26, 2008 surgery.

120. At all times herein mentioned, the Stryker Defendants knew that the products would be used and mixed without inspection for and knowledge of defect.

121. At all times herein mentioned, the Stryker Defendants had specific knowledge of the risks involved in the off-label mixed use of OP-1 and Calstrux when used in a surgery such as the September 26, 2008 surgery performed on Cabana.

122. At all times herein mentioned, Cabana and her agents and physicians relied upon the misrepresentations of the Stryker Defendants, and each of them, in utilizing the product in an off-label manner as promoted and instructed by the Stryker Defendants.

123. At all times herein mentioned, the mixture of Calstrux with OP-1 produced serious side effects, including unwanted bone growth and migration, and the Stryker Defendants knew or should have known that said products could be unsafe because of said side effects.

124. Cabana was administered a mixture of Calstrux and OP-1 Putty in a manner that had been illegally promoted and used in a manner intended by the Stryker Defendants.

125. The Stryker Defendants promoted the off-label mixture and administration of Calstrux and OP-1 Putty with the knowledge of its risk to patients.

126. The off-label mixture of OP-1 Putty and Calstrux, as given to Cabana, was ineffective, defective and dangerous when manufactured, designed, promoted, and instructed by the Stryker Defendants, who are strictly liable for the injuries arising from its use.

127. The risk attendant to the use of Calstrux and OP-1 greatly outweighed the benefit to be expected from the off-label and unapproved mixed use of Calstrux and OP-1 as promoted by the Stryker Defendants.

128. The mixed use of Calstrux and OP-1 failed to perfom in a manner that reasonable consumer would expect it to perform.

129. Cabana is informed and believes and thereon alleges that the Stryker Defendants knew that the OP-1 Putty and Calstrux manufactured, designed, and sold by them, when used off-label in the manner described above and as promoted and instructed by the Stryker Defendants, was defective and dangerous in the manner hereinbefore described; that is, said defendants knew that, because said use was dangerous and defective when so used off-label, the product could not be safely used for the purpose intended; that each said defendant, knowing that said product when used off-label was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including Cabana, when they placed the product on the market without warning of the defect, and knew when so placed that it would be used without inspection for defect when so used.

130. By placing said product on the market and promoting said off-label use, the Stryker Defendants impliedly represented it was safe for the purpose intended, and intended that doctors and patients in the general public should rely on their misrepresentations. Cabana and her doctors did rely on each of said misrepresentations, all to her damage as hereinabove alleged. In doing the things aforementioned, the Stryker Defendants are guilty of malice, oppression, and fraud, and Cabana is therefore entitled to recovery exemplary or punitive damages in a sum according to proof at trial.

FOURTH CAUSE OF ACTION
(*WITHDRAWN*)

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
AGAINST STRYKER DEFENDANTS

131. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

132. At all times herein mentioned, the Stryker Defendants utilized journal articles, advertising media, sales representatives and paid Key Opinion Leaders to urge the use, purchase, and

utilization of a mixture of Calstrux and OP-1 and expressly warranted to physicians and other members of the general public that such a use and mixture was safe and effective.

133. The Stryker Defendants knew, or in the exercise of reasonable diligence should have known, that such use and mixture had the serious side effects set forth herein.

134. Plaintiff is informed and believes and based thereon alleges that her treating surgeon, Dr. Mesiwala, and her other physicians and medical professionals, relied on the Stryker Defendants' express warranty representations regarding the safety and efficacy of mixing OP-1 and Calstrux, but such a mixture was not effective, safe, and proper for its intended use as warranted in that such mixture failed, migrated, lead to unwanted bone growth and was dangerous when put to its promoted use.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY AGAINST MEDTRONIC

135. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

136. At all times herein mentioned, Medtronic utilized journal articles, advertising media, sales representatives and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of the INFUSE Bone Graft and expressly warranted to physicians and other members of the general public and medical community that such off-label uses, including uses in posterior procedures was safe and effective.

137. Medtronic knew or, in the exercise of reasonable diligence, should have known that such off-label uses had the serious side effects set forth herein.

138. Cabana is informed and believes and based thereon alleges that her treating surgeon, Dr. Mesiwala, and her other physicians and medical professionals, relied on Medtronic's express warranty representations regarding the safety and efficacy of off-label use of INFUSE Bone Graft, but such off-label uses, including uses in posterior procedures, was not effective, safe, and proper for the use as warranted in that such it failed, migrated, lead to unwanted bone growth and was dangerous when put to its promoted use.

SEVENTH CAUSE OF ACTION
FOR FRAUD AGAINST THE STRYKER DEFENDANTS

139. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

140. As a pharmaceutical company, the Stryker Defendants had an affirmative continuing duty to warn the public and medical community regarding risks they knew, learned or should have known associated with their medical devices and pharmaceutical products.

141. The Stryker Defendants concealed adverse information and provided inaccurate or misleading information which was material to treating surgeons' treatment decisions, which misled surgeons and patients who were relying on those surgeons' professional judgment, including Cabana and her treating surgeon. This misleading information, along with omissions of material facts related to Calstrux and OP-1 Putty's safety and effectiveness, caused health care providers, patients and the general public, including Cabana and her surgeon, to be misled about Calstrux and OP-1 Putty's risks and benefits and deprived surgeons from making a proper risk/benefit assessment as to the use of and mixed use of Calstrux and OP-1 Putty.

142. Through internal adverse event reports, the Stryker Defendants knew that the off-label mixed use of Calstrux with OP-1 Putty was not effective and could lead to serious side effects, including but not limited to unwanted bone growth and migration. Notwithstanding, the Stryker Defendants failed to take any measures whatsoever to alert surgeons or the public regarding these risks and, instead, continued to promote the mixed use of Calstrux and OP-1 Putty as safe and effective.

143. Plaintiff is informed and believes and based thereon alleges that, despite knowing that the mixture of OP-1 and Calstrux was illegal, the Stryker Defendants, through their sales representatives and Key Opinion Leaders, promoted the mixed use of Calstrux and OP-1 Putty to Dr. Mesiwala and the staff and physicians at Pomona Valley Hospital and concealed that the mixed use of Calstrux and OP-1 Putty is ineffective and that it could result in unwanted bone growth and migration.

144. Plaintiff is informed and believes and based thereon alleges that, when the representations and/or omissions set forth herein were made by the Stryker Defendants, the Stryker Defendants knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or

omissions were made by the Stryker Defendants with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing surgeons and hospitals (including Dr. Mesiwala and Pomona Valley Hospital) to use, recommend, and approve the mixed use of Calstrux and OP-1 for surgical patients.

145. Plaintiff is informed and believes and based thereon alleges that, at the time the aforesaid representations and/or omissions were made by the Stryker Defendants, Cabana and her medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied upon the Stryker Defendants assertions, promulgated through aggressive sales tactics as set forth herein, that the mixed use of Calstrux/OP-1 Putty was safe and effective when, in fact, it was neither.

146. Plaintiff is informed and believes and based thereon alleges that, in direct and indirect reliance upon said representations and/or omissions, Dr. Mesiwala used a mixture of Calstrux and OP-1 Putty. Had Dr. Mesiwala (or Pomona Valley Hospital) been made aware of the inefficacy and serious risks associated with the mixed use of Calstrux and OP-1 Putty, he would not have mixed Calstrux and OP-1 Putty.

147. Had Cabana known of the actual dangers of and inefficacy of the mixed use of Calstrux and OP-1 Putty, she would not have consented to its use in her surgery.

148. Plaintiff is informed and believes and based thereon alleges that the Stryker Defendants' motive in failing to advise surgeons, the medical community and Hospital IRB's of these risks and inefficacies was for financial gain and fear that, if they provided proper and adequate information, Calstrux and OP-1 Putty would lose sales and market share.

149. Plaintiff is informed and believes and based thereon alleges that, at all times herein mentioned, the actions of the Stryker Defendants, their agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Cabana in particular and to the public generally in that the Stryker Defendants did willfully and knowingly promote the off-label mixture of OP-1 Putty and Calstrux with the specific knowledge that it would be used by surgeons without adequate instructions and without adequate knowledge regarding their efficacy, risks and side effects.

150. Plaintiff is informed and believes and based thereon alleges that, at all times relevant herein, the Stryker Defendants' conduct was malicious, fraudulent, and oppressive toward Cabana in particular and the public generally, and the Stryker Defendants conducted themselves in a willful, wanton, and reckless manner. Despite the Stryker Defendants' specific knowledge regarding Calstrux/OP-1 Putty's risks as set forth above, the Stryker Defendants deliberately recommended the off-label mixed use of these products and promoted them as being safe and effective.

151. In doing the things aforementioned, the Stryker Defendants are guilty of malice, oppression, and fraud, and Cabana is therefore entitled to recovery exemplary or punitive damages in a sum according to proof at trial.

EIGHTH CAUSE OF ACTION
FOR FRAUD AGAINST MEDTRONIC

152. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

153. As a pharmaceutical company, Medtronic had an affirmative continuing duty to warn the public and medical community regarding risks it knew, learned, or should have known about associated with its medical devices and pharmaceutical products.

154. Medtronic concealed adverse information and provided inaccurate or misleading information which was material to treating surgeons' treatment decisions, which misled surgeons and patients who were relying on those surgeons' professional judgment, including Cabana and her treating surgeon. This misleading information, along with omissions of material facts related to INFUSE Bone Graft's safety and effectiveness, caused health care providers, patients and the general public, including Cabana and her surgeon, to be misled about INFUSE Bone Graft's risks and benefits and deprived surgeons from making a proper risk/benefit assessment as to the use and off-label use of INFUSE Bone Graft.

155. Through internal adverse event reports, Medtronic knew that the off-label use of INFUSE Bone Graft was not effective and could lead to serious side effects, including but not limited to unwanted bone growth, inflammation, and other serious side effects. Medtronic failed to take any measures whatsoever to alert surgeons or the public regarding these risks and instead continued to promote the off-label use of INFUSE Bone Graft as safe and effective.

156. Plaintiff is informed and believes and based thereon alleges that, despite knowing that the off-label promotion of INFUSE Bone Graft was illegal, Medtronic, through its sales representatives and Key Opinion Leaders, promoted the off-label use of INFUSE Bone Graft to Dr. Mesiwala and the staff and physicians at Pomona Valley Hospital and concealed that the off-label use of INFUSE Bone Graft could result in unwanted bone growth and other serious side effects.

157. Plaintiff is informed and believes and based thereon alleges that, when the above representations and/or omissions were made by Medtronic, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Medtronic with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing surgeons and hospitals (including Dr. Mesiwala and Pomona Valley Hospital) to use and recommend the off-label use of INFUSE Bone Graft.

158. Plaintiff is informed and believes and based thereon alleges that, at the time the afore-said representations and/or omissions were made by Medtronic, Cabana and her medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied upon Medtronic's assertions, promulgated through aggressive sales tactics as set forth herein, that the off-label use of INFUSE Bone Graft was safe and effective when, in fact, it was neither.

159. Plaintiff is informed and believes and based thereon alleges that, in direct and indirect reliance upon said representations and/or omissions, Dr. Mesiwala used INFUSE Bone Graft in an off-label posterior procedure. Had Dr. Mesiwala been made aware of the inefficacy and serious risks associated with such use, he would not have used it.

160. Had Cabana known of the actual dangers of and inefficacy of the off-label use of INFUSE Bone Graft, she would not have consented to its use in her surgery.

161. Plaintiff is informed and believes and based thereon alleges that Medtronic's motive in failing to advise surgeons and the medical community of these risks and inefficacies was for financial gain and fear that, if it provided proper and adequate information, the INFUSE Bone Graft would lose sales and market share.

162. Plaintiff is informed and believes and based thereon alleges that, at all times herein mentioned, the actions of Medtronic, its agents, servants, and/or employees was wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Cabana in particular and to the public generally in that Medtronic did willfully and knowingly promote the off-label use of INFUSE Bone Graft with the specific knowledge that it would be used by surgeons without adequate instructions and without adequate knowledge regarding its efficacy, risks and side effects.

163. Plaintiff is informed and believes and based thereon alleges that, at all times relevant herein, Medtronic's conduct was malicious, fraudulent, and oppressive toward Cabana in particular and the public generally, and Medtronic conducted itself in a willful, wanton, and reckless manner. Despite its specific knowledge regarding risks as set forth above, Medtronic deliberately recommended the off-label use of INFUSE Bone Graft and promoted it as being safe and effective.

164. In doing the things aforementioned, Medtronic is guilty of malice, oppression, and fraud, and Cabana is therefore entitled to recovery exemplary or punitive damages in a sum according to proof at trial.

NINTH CAUSE OF ACTION
NEGLIGENCE PER SE AGAINST THE STRYKER DEFENDANTS AND MEDTRONIC

165. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

166. Medtronic and the Stryker Defendants violated applicable federal statutes and regulations relating to medical devices.

167. Defendants' violations of these federal statutes and regulations caused Cabana's injuries.

168. Cabana's injuries resulted from an occurrence the laws and regulations were designed to prevent.

169. Cabana was one of the class of persons whom these statutes and regulations were meant to protect.

170. Medtronic and the Stryker Defendants' violation of these statutes or regulations constitute negligence per se.

TENTH CAUSE OF ACTION
MEDICAL MALPRACTICE AGAINST DOES 41-60
(PHYSICIANS/SURGEONS)

171. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

172. At all times herein mentioned, defendants Does 41-60 were physicians and surgeons licensed to practice medicine and perform surgery under the laws of the State of California, and were engaged in the practice of medicine in California.

173. At all times herein mentioned, Cabana visited defendants Does 41-60 in their offices and employed them to diagnose and treat her back and spinal pain. Defendants Does 41-60 undertook to diagnose Cabana's illness and to treat and care for her.

174. Defendants Does 41-60 negligently failed to exercise the proper degree of knowledge and skill in examining, diagnosing, treating, operating, and caring for Cabana as herein described.

175. As a direct and proximate result of the negligence of defendants Does 41-60,which includes, among other things, two negligently performed surgeries on September 26, 2008 and July 13, 2009, Cabana has been injured in her health, strength and activity, and has suffered, continues to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, some of which injuries may be permanent, all to her damage in an amount in excess of the jurisdictional minimum of the Court.

176. As a further direct and proximate result of the acts and conduct of defendants Does 41-60, and each of them, Cabana has lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some of which losses may be permanent, all in an amount excess of the jurisdictional minimum of the Court.

177. As a further direct and proximate result of the acts and conduct of defendant Does 41-60, and each of them, Cabana has incurred medical, hospital and related expenses, and, on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

ELEVENTH CAUSE OF ACTION
MEDICAL MALPRACTICE AGAINST DOES 61-80
(HOSPITAL STAFF)

178. At all times herein mentioned, defendant Does 61-80 were the staff, nurses, physicians, technicians, IRB members, agents, contractors and employees of a Hospital operating in the State of California, and who were acting within the course and scope of their authority as such agents and employees.

179. On or about September 2008 and July 2009, Cabana entered the hospital for the purpose of surgery on her lower back. At that time, defendant Does 61-80, and each of them, undertook to provide Cabana with such care and attendance as Cabana might require while she was a patient at the hospital.

180. While Cabana was a patient in the hospital, defendant Does 61-80, and each of them, negligently and carelessly failed to exercise the proper degree of knowledge and skill in examining, diagnosing, treating, operating, and caring for Cabana as herein described.

181. As a direct and proximate result of the negligence of defendants Does 61-80,which includes, among other things, two negligently performed surgeries on September 26, 2008 and July 13, 2009, Cabana has been injured in her health, strength and activity, and has suffered, continues to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, some of which injuries may be permanent, all to her damage in an amount in excess of the jurisdictional minimum of the Court.

182. As a further direct and proximate result of the acts and conduct of defendants Does 61-80, and each of them, Cabana has lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some of which losses may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

183. As a further direct and proximate result of the acts and conduct of defendant Does 61-80, and each of them, Cabana has incurred medical, hospital and related expenses, and, on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

TWELFTH CAUSE OF ACTION
VIOLATION OF THE PROTECTION OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTATION ACT AGAINST POMONA HOSPITAL

184. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

185. California has passed the Protection of Human Subjects in Medical Experimentation Act (codified at Health & Safety Code Section 24170 *et seq*.) which generally provides that a patient should not be experimented on or enrolled in a medical research project without his or her express written consent.

186. The purpose of the Protection of Human Subjects in Medical Experimentation Act is to "provide minimum statutory protection for the citizens of this state with regard to human experimentation and to provide penalties for those who violate such provisions." Cal. Health & Safety Code § 24171. The Act further provides for the imposition of statutory damages (in addition to other common law remedies) against anyone who violates the Act. See Cal. Health & Safety Code § 24176.

187. Plaintiff is informed and believes and based thereon alleges that Pomona Hospital's IRB approved a "research project" wherein physicians and staff at the hospital would test the safety and efficacy of the Humanitarian Use Device OP-1 Putty on patients. Internal Pomona Hospital documents which were produced to plaintiff's counsel on or about May 30, 2012 reveal that the hospital was *randomizing* patients to various treatment options and testing whether the implementation of experimental and humanitarian devices such as OP-1 Putty are safe and effective for use in patients. Specifically, in a February 4, 2009 letter from the Vice-Chairperson of Pomona Hospital's IRB to plaintiff's surgeon regarding the OP-1 Putty research project, the Pomona Hospital IRB Vice-Chairperson questions "should the research project and randomization be continued."

188. Plaintiff is informed and believes and based thereon alleges that the OP-1 Putty research project was in existence from July, 2006 until January 25, 2012 when it was finally terminated and patient accrual was discontinued. During its existence, a total of at least 17 patients were recruited in Pomona Hospital's OP-1 Putty "research project."

189. Plaintiff is informed and believes and based thereon alleges that, unbeknownst to her, she was one of the first handful of patients/test subjects to be enrolled in the OP-1 Putty "research project." However, contrary to federal and state laws, including but not limited to the California

Protection of Human Subjects in Medical Experimentation Act, plaintiff was never informed that (a) she was being enrolled into Pomona Hospital's OP-1 Putty "research project"; (b) that a Humanitarian Use Device (OP-1 Putty) whose efficacy had never been established would be implanted in her; (c) that the OP-1 Putty would be mixed with other substances, including Calstrux, by hospital nurses (at the direction of Stryker's sales representative, Brian Whalen, who was present during the OP-1 Putty research surgeries/procedures) and implanted in her in an off-label manner wherein its safety and efficacy had never been established; (d) and, indeed, plaintiff was never even informed that OP-1 Putty would be used during her surgery or that her surgery was part of a larger "research project" taking place at the hospital. In sum, plaintiff entered the hospital expecting to receive a routine back surgery and was instead (and unbeknownst to her) turned into an unwitting guinea-pig in the hospital's OP-1 Putty "research project."

190. As a result of her unwitting participation in Pomona Hospital's OP-1 Putty "research project," plaintiff developed unwanted bone growth in her lumbar spine which leaked and migrated onto her nerve channels necessitating an additional curative surgery. Plaintiff has never recovered from these injuries and will need additional curative surgeries.

191. The first time plaintiff discovered that her lower back and leg pain may have been caused and exacerbated by a medical device was in October 2010 when she received and reviewed her medical records from the September 26, 2008 surgery. When Cabana reviewed these medical records in October 2010, she discovered for the first time that her surgeon had used the OP-1 Putty and Calstrux products. Not knowing what these products were, she performed a Google search on or about October 31, 2010, and, for the first time, learned that the combination of these two products were not FDA approved and further learned that these products were associated with leakage and unwanted bone growth. It was at this point, **October 2010**, that she first suspected that her post-September 2008 back pain was caused by the wrongdoing of a third party, including the medical device manufacturer, Stryker, and possibly her surgeon and the hospital. Prior to this point, she had always been reasonably led to believe by, among others, her treating surgeon Dr. Mesiwala, that her ongoing and escalating back pain was caused by her underlying medical condition.

192. The first time plaintiff discovered that she had been enrolled in Pomona Hospital's OP-1 Putty "research project" was in **June 2012** when co-defendant Stryker produced some of Pomona Hospital's internal IRB records which revealed the existence of the secret "research project."

193. Had Cabana known that she would be implanted with an experimental or humanitarian device (OP-1 Putty) she would not have consented to its use.

194. Had Cabana known that she would be enrolled in Pomona Hospital's "research project" for OP-1 Putty, she would never have consented to her surgery and would never have consented to participating in any medical "research project."

195. Plaintiff is informed and believes and based thereon alleges that Pomona Hospital's motive in failing to seek her informed consent and to demand that physicians and hospital personnel obtain her written informed consent regarding the surgery was for fear that, if they had truthfully informed patients about the "research project," the hospital would not be able to recruit patients and would have to pay patients to participate as opposed to charging patients for being used as unwitting guinea pigs.

196. Plaintiff is informed and believes and based thereon alleges that, at all times herein mentioned, the actions of Pomona Hospital, its agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete and conscious disregard for the rights and safety of Cabana in particular and to the public generally in that Pomona Hospital did willfully and knowingly approve a research project without mandating that physicians and hospital staff obtain the patient/subject's express written consent, did willfully and knowingly allow patients to be recruited as unwitting guinea pigs for its OP-1 Putty "research project," and failed to inform patients that they were being enrolled in the hospital's medical research project involving the implantation of dangerous, untested and unapproved medical devices.

197. Plaintiff is informed and believes and based thereon alleges that, at all times relevant herein, Pomona Hospital's conduct was malicious, fraudulent, and oppressive toward Cabana in particular and the public generally, and Pomona Hospital conducted itself in a willful, wanton, and reckless manner.

198. In doing the things aforementioned, Pomona Hospital is guilty of malice, oppression, and fraud, and Cabana is therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

199. In addition to the imposition of compensatory and exemplary damages as requested herein, Plaintiff also seeks the imposition of statutory damages against Pomona Hospital as provided by Section 24176 of the California Health & Safety Code.

THIRTEENTH CAUSE OF ACTION
FOR FRAUD AGAINST POMONA HOSPITAL

200. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

201. As a hospital, Pomona Hospital owed its patient Cabana a fiduciary duty to ensure her safety and well-being and an affirmative duty to reveal to her all pertinent information regarding her care and treatment at the hospital.

202. Pomona Hospital concealed from Cabana that she was being enrolled in the hospital's OP-1 Putty "research project" and provided inaccurate or misleading information to her regarding her surgical procedure (experimentation). Cabana's lack of knowledge of the experimental nature of her surgery and the fact that she was being enrolled in a medical research project was material to Cabana's decision to grant consent to her surgery. Pomona Hospital's concealment and misleading information, along with omissions of material facts related to the medical "research project" and the OP-1 Putty experimental surgery, caused Cabana to be misled about the risks and benefits of her surgical procedure and deprived Cabana of her ability to make an informed decision and provide informed consent regarding her surgery.

203. Plaintiff is informed and believes and based thereon alleges that, when the representations and/or omissions set forth herein were made by Pomona Hospital, Pomona Hospital knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Pomona Hospital with the intent of defrauding and deceiving patients and with the intent of inducing patients to become unwitting guinea pigs in Pomona Hospital's "research project."

204. Plaintiff is informed and believes and based thereon alleges that, at the time the aforesaid representations and/or omissions were made by Pomona Hospital, Cabana was unaware of the falsity of said representations and/or omissions and reasonably relied upon Pomona Hospital's assertions, representations and omissions.

205. Plaintiff is informed and believes and based thereon alleges that, in direct and indirect reliance upon said representations and/or omissions, Cabana consented to her September 26, 2008 surgery. Had Cabana been made aware of the experimental nature of her surgery or the fact that she was being enrolled in Pomona Hospital's OP-1 Putty research project, she would not have consented to the surgery or being enrolled in a research project.

206. Plaintiff is informed and believes and based thereon alleges that Pomona Hospital's motive in failing to advise patients regarding their unwitting enrollment in the "research project" was for fear that, if patients knew the true state of affairs, they would not agree to being part of the "research project" or consent to the experimental surgery.

207. Plaintiff is informed and believes and based thereon alleges that, at all times herein mentioned, the actions of Pomona Hospital, its agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete and conscious disregard to the rights and safety of Cabana in particular and to the public generally in that Pomona Hospital did willfully and knowingly approve a research project without mandating that physicians and hospital staff obtain the patient/subject's express written consent, did willfully and knowingly allow patients to be recruited as unwitting guinea pigs for its OP-1 Putty "research project," and failed to inform patients that they were being enrolled in the hospital's medical research project involving the implantation of dangerous, untested and unapproved medical devices.

208. Plaintiff is informed and believes and based thereon alleges that, at all times relevant herein, Pomona Hospital's conduct was malicious, fraudulent, and oppressive toward Cabana in particular and the public generally, and Pomona Hospital conducted itself in a willful, wanton, and reckless manner.

209. In doing the things aforementioned, Pomona Hospital is guilty of malice, oppression, and fraud, and Cabana is therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

FOURTEENTH CAUSE OF ACTION
NEGLIGENCE PER SE AGAINST POMONA HOSPITAL

210. Cabana repeats and alleges every allegation set forth above as if fully set forth herein.

211. Pomona Hospital violated applicable federal and state statutes and regulations relating to performing human medical experiments and utilizing humanitarian use devices such as OP-1 Putty as part of experiments and medical "research projects." The applicable federal and state statutes included but are not limited to (a) California's Human Subjects in Medical Experimentation Act (codified at Health & Safety Code Section 24170 *et seq*), including Sections 24172 and 24173 of the Act; and (b) applicable portions of federal and FDA regulations in 21 Code of Federal Regulations, Part 50, including but not limited to 21 C.F.R. §§ 50.20, 50.25 and 50.27.

212. Pomona Hospital's violations of these and other similar federal and state statutes regulations and guidance documents caused Cabana's injuries.

213. Cabana's injuries resulted from an occurrence the laws and regulations were designed to prevent.

214. Cabana was one of the class of persons these statutes and regulations were meant to protect.

215. Pomona Hospital's violation of these statutes or regulations constitutes negligence per se.

PRAYER

WHEREFORE, Cabana prays for judgment against defendants as follows:

1. For general damages in a sum exceeding this Court's jurisdictional minimum;

2. For specific damages according to proof;

3. For economic and non-economic damages in a sum exceeding this Court's jurisdictional minimum;

4. For punitive and exemplary damages against the Medtronic Defendants, the Stryker Defendants and Pomona Hospital according to proof;

5. For prejudgment interest and post-judgment interest as allowed by law;

6. For the costs of suit herein incurred; and

7. For such other and further relief as this Court may deem just and proper.

Dated: September 14, 2012

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

Bijan Esfandiari, Esq.

Attorneys for Plaintiff

JURY DEMAND

Cabana hereby respectfully requests a jury trial as to all claims.

Dated: September 14, 2012

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

Bijan Esfandiari, Esq.

Attorneys for Plaintiff