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ORIGINAL

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Plaintiff In Pro Per

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Plaintiff In Pro Per

IN THE UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

JENNIFER ANN COOK, and
DAVID CHRISTOPHER COOK,

Plaintiffs,

v.

WILLIAM GRANT STEVENS, M.D., JOHNSON & JOHNSON, ETHICON, INC., and MENTOR WORLDWIDE LLC,

Defendants.

Case No.
CV19-06673-RGK-GJSx

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

(1) Strict Liability (Failure to Warn)
(2) Negligence; Negligence Per Se; Violation of California Health and Safety Code § 24176
(3) Negligence; Negligence Per Se; Violation of California Health and Safety Code § 24176
(4) Loss of Consortium

Plaintiffs hereby bring this Complaint for damages against the Defendants and allege the following:

JURISDICTION

1. Subject matter jurisdiction is proper in this Court under 28 USC §1332, because each Plaintiff has suffered and claims damages of at least $75,000, exclusive of interest and costs, and because no Plaintiff is a citizen of the same state as any Defendant.

VENUE

2. Venue is proper in this District under 28 USC §1391, because a substantial part of the events or omissions giving rise to each Plaintiffs' claims occurred in Los Angeles County,

California.

INTRODUCTION

3. Plaintiffs Jennifer and David Cook, h/w, bring this action against Defendants Johnson & Johnson ("J&J), Ethicon, Inc. ("Ethicon"), and Mentor Worldwide LLC ("Mentor") (hereinafter, collectively referred to as "Manufacturer Defendants"), and each of them in relation to the design, manufacture, marketing, labeling, testing, and distribution of Mentor Worldwide LLC's Siltex Contour Profile Gel Mammary Prostheses and to Mentor's sponsorship of the Contour Profile Gel Continued Access Study,

4. Plaintiffs Jennifer and David Cook, h/w, also bring this action against Defendant William Grant Stevens, M.D. (hereinafter referred to as "Defendant Stevens") in relation to his role as a principal investigator in Mentor's Contour Profile Gel Continued Access Study.

PARTIES

5. Plaintiff Jennifer Ann Cook ("Plaintiff") is an individual residing at 356 Ironhill Trace, Woodstock, Georgia 30189, and is a citizen of the state of Georgia.

6. Plaintiff David Christopher Cook (Mr. Cook) is an individual residing at 356 Ironhill Trace, Woodstock, Georgia 30189, and is a citizen of the state of Georgia.

7. Plaintiffs were married and residing together from January 17, 2012 to present.

8. Defendant William Grant Stevens, M.D. (Defendant Stevens), is an individual and citizen of California, with a principal place of business at 4644 Lincoln Blvd. Suite 552, Marina Del Rey, California 90292.

9. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

10. J&J's corporate family structure includes a multitude of wholly-owned subsidiaries and affiliated companies all over the word, including Ethicon and Mentor.

11. Defendant Ethicon is a subsidiary of Johnson & Johnson. Ethicon is and was at the time the Complaint was filed, a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in New Jersey. Accordingly, Ethicon is a citizen of New Jersey.

12. Defendant Mentor is a limited liability company organized and existing under the laws of the State of Delaware. Mentor's sole member is, and was at the time the Complaint was filed, Ethicon, Inc. Ethicon, Inc. is, and was at the time the Complaint was filed, a corporation organized and existing under the laws of the State of New Jersey with its principal place of business in New Jersey. Accordingly, Ethicon is a citizen of New Jersey. A limited liability company "is a citizen of every state of which its owners/members are citizens." Johnson v.

Columbia Props. Anchorage, L.P., 437 F.3d 894, 899 (9th Cir. 2006). Accordingly, for purposes of section 1332(c)(1), Mentor is a citizen of the State of New Jersey. Defendant Mentor's headquarters is at 33 Technology Drive, Irvine, California 92618.

13. Founded in 1969, Mentor originally sold electronic laboratory instruments to measure activity within the nervous system. After introducing urethral catheters in the 1970s, the company began delving into the plastic surgery field in the mid-1980s.

14. For more than 30 years, Mentor's products have been implanted into millions of women's breast regions.

15. Mentor remains a leading supplier of medical products for the global aesthetic medicine market. The company develops, manufactures, and markets products for aesthetics medical procedures.

16. Defendant Mentor is a wholly-owned subsidiary of Defendant J &J.

17. J & J acquired Mentor Corporation in 2009. Under the terms of the acquisition of Mentor Corporation, Defendant Mentor was expected to operate as a stand-alone business unit reporting through Ethicon, a J & J company.

18. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

19. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiffs. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiffs for the negligent acts and omissions alleged herein.

20. Each of the above-named Defendants directed, authorized and/or ratified the conduct of each and every other Defendant.

21. At all relevant times, Defendants acted in concert with one another in the State of California to negligently and/or fraudulently convey false and misleading information concerning Mentor's Siltex Contour Profile Gel Breast Implants and breast implants generally, and concealed the risks of serious adverse events associated with its breast implants and breast implants generally from Plaintiff, the public, physicians, and other healthcare providers. But for Defendants' actions, Plaintiff would not have suffered the severe injuries and harms which have resulted from implantation of Mentor's Siltex Contour Profile Gel Breast Implants and or other breast implants into Plaintiff's body.

DESCRIPTION OF MENTOR'S SILTEX CONTOUR PROFILE GEL BREAST IMPLANTS AND THE CONTOUR PROFILE GEL CONTINUED ACCESS STUDY

22. Mentor's Siltex Contour Profile Gel Breast Implants (hereinafter "CPG Breast Implants") are Class III medical devices.

23. In order to eventually seek pre-market approval for its CPG Breast Implants, Mentor was required to first provide the FDA with sufficient information regarding the safety and efficacy of the medical device.

24. As part of this process, Mentor requested that it be allowed to use the medical device for clinical testing pursuant to an investigational device exemption ("IDE"). See, 21 U.S.C. § 360j (g). Mentor was prohibited from conducting research concerning the device on human subjects without prior approval by the FDA. See, 21 CFR § 812.20.

25. Investigational devices are subject to complex and comprehensive regulations and detailed procedures intended to ensure that the devices are safe and effective.

26. In connection with Mentor's IDE, the FDA approved the Contour Profile Gel Continued Access Study ("CPG CA Study). The CPG CA Study began in August 2004. Enrollment of subjects in the CPG CA Study was closed in June 2013 and converted to a post approval study.

27. Defendant Stevens was a principal investigator in the CPG CA Study.

BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA

28. Approximately 300,000 total breast implants are placed per year in the U.S. From 2000 to 2016, the number of breast augmentations in the United States rose 37%, and reconstructions after mastectomy rose 39%.

29. Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA-ALCL") is a rare T-cell lymphoma that can develop following breast implants. It is a type of non-Hodgkin's lymphoma, a cancer of the cells of the immune system.

30. The most common presenting symptom for BIA-ALCL is a swollen breast caused by the formation of a delayed unilateral idiopathic seroma occurring between the implant surface and the breast capsule.

31. Upon information and belief, the first case of anaplastic large cell lymphoma (ALCL) in association with silicone breast implants was diagnosed in the early 1990's.

32. In November 2008, JAMA published a retroactive analysis of 11 cases of ALCL between 1994 and 2006 and concluded that the evidence indicated an association between silicone breast prosthesis and ALCL.

33. In 2010, a panel of 10 national experts looked at this 10 plus year history and documented their agreement that the established scientific evidence is that a positive association between breast implants and developing ALCL exists.

34. In 2011, a summary of published studies, evidence and reports was published that identified 27 cases of ALCL and concluded that there was an association between breast implants and ALCL.

35. In January 2011, unbeknownst to Plaintiff, the FDA released a report on BIA-ALCL, listing as its primary finding the following: "[b]ased on the published case studies and epidemiological research, the FDA believes that there is a possible association between breast implants and ALCL." (emphasis added).

36. The FDA further noted that, while it was not prepared to associate a particular type of breast implant with BIA-ALCL, "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell." (italics in original).

37. In March 2015, an analysis identified 173 cases of ALCL. That same month, the French National Cancer Institute announced "There is a clearly established link between the occurrence of this disease and the presence of a breast implant."

38. On May 19, 2016, the World Health Organization ("WHO") gave the disease an official designation as "BIA-ALCL" and classified it as a distinct clinical entity, separate from other categories of ALCL.

39. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel to discuss the association between breast implants and ALCL and provide ongoing advice.

40. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL.

41. In the Updated Safety Alert, the FDA recognized the WHO's designation that BIA-ALCL can occur after receiving breast implants and stated that "[a]t this, time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

42. In May 2017, a global analysis of forty governmental databases identified 363 cases of BIA-ALCL with 258 being reported to the FDA.

43. A July 2017 article stated that "[e]xperts have called for a common type of breast implant to be banned after it was revealed two people died and 23 developed the same type of cancer in the UK following breast enlargement surgery." Katie Forster, Calls to ban textured breast implants after two die and 23 develop same type of cancer, The Independent Online, July 10, 2017, available at https://www.independent.co.uk/news/health/breast-implants-cancer-ban-two-die-23-develop-same-type-textured-common-women-enlargement-cosmetic-a7832996.html. In July 2014, the United Kingdom's Medicines and Healthcare

Products Regulatory Agency ("MHRA") issued a Medical Device Alert "to further encourage healthcare professionals to report cases of ALCL in women who have breast implants or who have had them removed."

44. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including nine deaths.

45. A recent JAMA Oncology article concluded that "[b]reast implants are associated with increased risk of breast-ALCL", but the absolute risk has not been determined. Mintsje de Boer, et al., Breast Implants and the Risk of Anaplastic Large-Cell Lymphoma in the Breast. JAMA ONCOL. (published January 4, 2018).

46. On May 9, 2018, Australia's Therapeutic Goods Administration ("TGA") reported 72 cases of ALCL in Australian patients.

47. The natural occurrence of this cancer is 1/300,000. However, FDA recently cited to studies that place the estimated current risk of BIA-ALCL in women with textured implants to be between 1:3,817 and 1:30,000. This is consistent with risks reported in Europe. A December 2016 update from the TGA reported a risk of 1:1,000 to 1:10,000 for textured implants.

48. Upon information and belief, BIA-ALCL is mainly associated with textured breast implants, however, there have been cases of BIA-ALCL in women with smooth implants.

49. Despite Defendants' knowledge of an association between breast implants and ALCL dating back to the 1990's, Manufacturer Defendants purposefully failed to comply with their FDA regulatory obligations and in doing so have exposed many hundreds of thousands of women to life-altering and avoidable cancer.

50. The FDA held public hearings on this issue in March 2019. The FDA told ICIJ in a statement pertaining to the 2019 hearing, "[t]his will help inform FDA as to whether we should take additional actions to protect patient safety including a black box label warning, a ban on textured implants, a patient safety checklist, or other steps." Available at https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface.

51. There are multiple cases of women developing BIA ALCL where their only implant exposure was to a Mentor implant, including a bilateral case of BIA ALCL where the disease was diagnosed approximately two years after implantation.

52. Many plastic surgeons in the United States have publicly denounced the use of textured implants for this reason including, but not limited to, the following plastic surgeons: Eric Swanson, M.D., David A. Hidalgo, M.D., and Mark Clemens, M.D., F.A.C.S.

SPECIFIC ALLEGATIONS

53. On or about August 6, 2010, in Marina del Rey, California, Plaintiff Jennifer Cook consulted with Defendant Stevens regarding the appearance of her breasts.

54. On or about August 6, 2010, Defendant Stevens told Plaintiff that he was a principal investigator in the CPG CA Study and recommended that she participate in the study.

55. As part of the CPG CA Study, Mentor provided a document titled "Informed Consent Participation as a Research Subject in the Continued Access Study of the Mentor Contour Profile Gel Breast Implant (CPG CA Study)" (hereinafter referred to as "Informed Consent").

56. Before Plaintiff consented to the purchase of Mentor CPG Breast Implants and to participation in the CPG CA Study, Defendant Stevens provided her with the Informed Consent explaining the purpose and background of the study and informing her of the risks associated with breast implants and breast augmentation.

57. The Informed Consent contained the following statement: **"There is presently no established scientific evidence that links either silicone gel-filled or saline-filled breast implants with cancer."**

58. As shown above in this Complaint, this was a false statement.

59. On August 6, 2010, Plaintiff read and signed the Informed Consent.

60. At the time Plaintiff read and signed the Informed Consent, she was ignorant of the falsity of the above-representation and believed it to be true. In justifiable reliance on the representation, Plaintiff was induced to purchase CPG Breast Implants and to have them surgically implanted as part of the CPG CA Study and would not have agreed had she known the actual facts.

61. On or about August 10, 2010, Plaintiff was implanted with CPG Breast Implants. The surgery was performed in Marina del Rey, California.

62. A few days after the CPG Breast Implants were surgically implanted, Plaintiff experienced complications and Defendant Stevens indicated that the CPG Breast Implants needed to be removed and replaced.

63. In continued reliance on the representations in the Informed Consent, including the representations about the absence of any established scientific evidence linking breast implants and cancer, on or about August 27, 2010, plaintiff agreed to the purchase of Allergan breast implants and had surgery to remove the CPG Breast Implants and replace them with the newly purchased Allergan breast implants.

64. At the time of Plaintiff's surgery to remove and replace her implants with Allergan breast implants, Plaintiff continued to be ignorant of the falsity of the above-referenced representation in the Informed Consent.

65. Plaintiff would not have agreed to the replacement of her CPG Breast Implants with Allergan breast implants or breast implants of any other type had she known the true facts about the scientific evidence linking breast implants to cancer.

66. On August 2, 2017, while living in Alhambra, California, Plaintiff was informed that she had been diagnosed with BIA-ALCL.

67. Plaintiff was 45 years old at the time of her diagnosis with BIA-ALCL.

68. Prior to Plaintiff's development of BIA-ALCL, Plaintiff enjoyed an active, full life.

69. Plaintiff and Mr. Cook have a son, David Jr., who was 4 years old at the time of Plaintiff's diagnosis.

70. Plaintiff has endured pain and other injuries from this terrible disease.

71. As a result of Plaintiff's diagnosis of BIA-ALCL, Plaintiff had surgery to remove her breast implants and the lymphoma near them. Plaintiff also had seven rounds of brentuximab, a type of systemic immunotherapy, administered to her body to try to eliminate the disease.

COUNT I

Products Liability (Failure to Warn)

(Against Manufacturer Defendants J&J, Ethicon, and Mentor)

72. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

73. At all relevant times, Manufacturer Defendants had a duty to Plaintiff to use reasonable care in formulating, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting CPG breast implants.

74. Manufacturer Defendants formulated, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted CPG Breast Implants, including the product that was implanted into Plaintiff.

75. Manufacturer Defendants had a duty under parallel state law, including California law, to exercise reasonable care to provide adequate and truthful warnings about the risks and dangers of CPG Breast Implants that were known or knowable to Manufacturer Defendants at the time of distribution.

76. Manufacturer Defendants breached their duty in that they affirmatively misled and failed to warn Plaintiff and Dr. Stevens by not reporting the risk of serious defects and life-altering complications described herein that Manufacturer Defendants knew or should have known were associated with CPG Breast Implants prior to the time of Plaintiff's implantation, including the actual level of risk, the actual state of scientific evidence as to the link between breast implants and cancer, and the adverse events similar to the injuries suffered by Plaintiff.

77. Specifically, upon information and belief, Manufacturer Defendants breached these duties and violated federal and state law by, inter alia: receiving and failing to warn of or report adverse events to the FDA or the public; receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding the scientific evidence linking breast implants to cancer, and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about CPG Breast Implants.

78. Despite the fact that evidence existed that CPG Breast Implants were dangerous and likely to place users at serious risk to their health, Manufacturer Defendants affirmatively misrepresented and failed to disclose and warn of the health hazards and risks associated with CPG Breast Implants. Instead, Manufacturer Defendants manufactured, marketed, tested, sold, advertised, and promoted CPG Breast

Implants while defrauding, failing to warn, or otherwise ensure the safety of its users in violation of state law, including California law, and FDA regulations.

79. In addition, the Manufacturer Defendants failed to take necessary actions such as communicating newly acquired safety information in annual/progress reports, unilaterally updating its labeling and the Informed Consent, or timely submitting MDRs to advise users of CPG Breast Implants of the defects and risks described above.

80. Manufacturer Defendants had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. California Health & Safety Code, §§ 111440 ("it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded"), 111445 ("it is unlawful for any person to misbrand any drug or device.").

81. Under parallel federal law, Manufacturer Defendants had the ability and duty to timely disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. 21 U.S.C. § 331 ("the following acts and the causing thereof are prohibited: (a) the introduction . .. of any device that is. . . misbranded, (b) the.. . misbranding of any. . . device . . . .

82. Manufacturer Defendants had the ability and the duty under state law, including Cal. Health Safety Code § 24176, to report new evidence and studies regarding the risks of breast implants and cancer to the FDA and IRB.

83. Under parallel federal law, Manufacturer Defendants had the ability and duty to report new evidence and studies regarding the risks of breast implants and cancer to the FDA and IRB. 21 CFR 812 and 21 CFR parts 50 and56.

84. Manufacturer Defendants had the duty under state law, including Cal. Health Safety Code § 24176, to update and revise the language in the Informed Consent so that it was not false and misleading as to the risk of cancer from exposure to breast implants.

85. Under parallel federal law, Manufacturer Defendants had the ability and duty to update and revise the language in the Informed Consent provided to principal investigators and Plaintiff to ensure its labeling and product were not misbranded. 21 U.S.C. § 331 ("the following acts and the causing thereof are prohibited: (a) the introduction . .. of any device that is. . . misbranded, (b) the.. . misbranding of any. . . device. . . .

86. Under parallel federal law, Manufacturer Defendants also had the ability and duty to update and revise the language in the Informed Consent provided to principal investigators and Plaintiff to ensure it did not violate FDA regulations requiring that a sponsor assure the FDA that the CPG CA Study would be conducted in

compliance with the informed consent and IRB regulations. 21 CFR 812 and 21 CFR parts 50 and 56.

87. Had Manufacturer Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned Plaintiff, physicians, including Plaintiff's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to Plaintiff, the public, including Plaintiff's physician, regarding the dangers of CPG Breast Implants that were known or knowable to Defendants at the time of distribution.

88. Had Manufacturer Defendants timely and adequately reported the scientific evidence and research studies linking breast implants to cancer to the FDA, it would have effectively warned Plaintiff, physicians, including Plaintiff's physician, of that scientific evidence through discussion of that evidence that would have followed in the literature and at meetings. Thus, additional information would have been available to the Plaintiff, the public, including Plaintiff's physician, regarding the dangers of CPG Breast Implants that were known or knowable to Defendants at the time of distribution.

89. Had Manufacturer Defendants timely and adequately reported the adverse events and the scientific evidence and research studies linking breast implants to cancer to the FDA, it would have required Manufacturer Defendants and Defendant Stevens

to correct the false statement in the Informed Consent regarding the existence of those events and evidence before the Informed Consent was signed by and relied upon by Plaintiff.

90. If Defendant Stevens been adequately warned of the serious risks and adverse events and the scientific evidence and research studies linking breast implants to cancer, Defendant Stevens would have warned the Plaintiff of those risks including in the Informed Consent and Plaintiff would not have agreed to or used CPG Breast Implants or any other breast implant.

91. If Manufacturer Defendants had updated and revised the language in the Informed Consent provided to principal investigators so that it no longer contained misleading and literally false information regarding the established scientific evidence linking breast implants to cancer, Plaintiff would not have agreed to participate in the CPG CA Study or agreed to implantation of CPG Breast Implants or any other breast implant.

92. As a proximate and legal result of Manufacturer Defendants' failure to comply with FDA regulations, Manufacturer Defendants breached their duty of care to Plaintiff under parallel state law and caused Plaintiff past and future suffering, including severe physical injuries which are permanent and continuing in nature and which required and will require medical treatment including hospitalization, severe

emotional distress, mental anguish, economic loss, and other injuries, for which she is entitled to compensatory and other damages in an amount to be proven at trial.

COUNT II

Negligence, Negligence Per Se, and Violation of California Health and Safety Code § 24176

(Against Manufacturer Defendants J&J, Ethicon, and Mentor)

93. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

94. Manufacturer Defendants owed a duty in all their several undertakings, including the communication of information concerning CPG Breast Implants and other breast implants, and to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

95. Manufacturer Defendants, in the course of their business and profession, knowingly and negligently disseminated inaccurate and misleading information to Plaintiff and physicians, including principal investigators in the CPG CA Study, concerning the properties and effects of CPG Breast Implants and breast implants generally, with the intent and expectation that Plaintiff and physicians would rely

on that information including in decisions in recommending and surgically implanting CPG Breast Implants and other breast implants in patients.

96. When Manufacturer Defendants disseminated information to Plaintiff, physicians, principal investigators, and/or patients concerning the properties and effects of CPG Breast Implants and breast implants generally, they knew or should have known that Plaintiff, physicians, principal investigators, and/or patients would reasonably rely on that information in their decisions concerning participation in the CPG CA Study, the use of CPG breast implants, and breast implants generally.

97. Manufacturer Defendants disseminated false information, in that they provided Plaintiff and Defendant Stevens with the Informed Consent which stated that there was no scientific evidence linking breast implants with cancer when the knew or should have known that the information was, in fact, false and misleading.

98. Manufacturer Defendants had no reasonable grounds for believing these representations were true when they were made or at the time Plaintiff signed the Informed Consent; in fact, Manufacturer Defendants knew or should have known the representations to be false.

99. Manufacturer Defendants' breach of their duties under state law parallel to their violations of federal law; FDA regulations and state law independently requires, that any representations regarding the device and its risks in the Informed Consent

must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

100. Manufacturer Defendants disseminated the false information, as referenced above, to Plaintiff, principal investigators in the CPG CA Study, and physicians with the intention that Plaintiff, principal investigators, physicians and their patients would rely on that information and to induce Plaintiff to participate in the CPG CA study, and to induce physicians and patients to surgically implant CPG Breast Implants and other breast implants. In negligently or willfully supplying the false and misleading information, Manufacturer Defendants negligently or willfully failed to exercise reasonable care to ensure that the information disseminated to Plaintiff, principal investigators in the CPG CA Study, physicians, and patients concerning the properties and effects of CPG Breast Implants and breast implants generally was accurate and not false or misleading.

101. By failing to ensure representations regarding CPG Breast Implants and breast implants generally were truthful, accurate, and not misleading, Manufacturer Defendants have violated FDA regulations and parallel state law.

102. Manufacturer Defendants expected or should have expected that Plaintiff and patients, in reliance on false information, who were implanted with CPG Breast Implants and other breast implants would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to CPG Breast Implants and

other breast implants, causing them to undergo future removal surgeries including future implant replacement surgeries.

103. Manufacturer Defendants expected or should have expected that Plaintiff, in reliance on false information about breast implants generally might rely on that false information in deciding to replace CPG Breast Implants with implants from another manufacturer in a situation where complications arose days after placement of the CPG Breast Implants and required removal and replacement surgery.

104. Plaintiff and/or Plaintiff's physician did in fact reasonably rely on Manufacturer Defendants' negligent and/or willful misrepresentations as Manufacturer Defendants intended.

105. As a proximate and foreseeable result of Manufacturer Defendants' misrepresentations and failure to exercise reasonable care, Plaintiff suffered and will continue to suffer severe physical injuries which are permanent and continuing in nature and which required and will require medical treatment including hospitalization, severe emotional distress, mental anguish, economic loss, and other injuries, for which she is entitled to compensatory and other damages in an amount to be proven at trial.

106. WHEREFORE, Plaintiff prays for judgment against Manufacturer Defendants as hereinafter set forth.

COUNT III

Negligence, Negligence Per Se, and Violation of California Health and Safety Code § 24176

(Against Defendant Stevens)

107. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

108. Defendant Stevens owed a duty in all his several undertakings, including the communication of information concerning CPG Breast Implants and other breast implants in connection with the CPG CA Study, and to exercise reasonable care to ensure that he did not, in those undertakings, create unreasonable risks of personal injury to others.

109. Defendant Stevens, in the course of his role as principal investigator in the CPG CA Study, negligently disseminated inaccurate and misleading information to Plaintiff concerning the properties and effects of CPG Breast Implants and breast implants generally, with the intent and expectation that Plaintiff would rely on that information including in decisions to participate in the CPG CA Study and in decisions to agree to the implantation of CPG Breast Implants and other breast implants.

110. When Defendant Stevens disseminated information to concerning the properties and effects of CPG Breast Implants and breast implants generally, he

knew or should have known that Plaintiff would reasonably rely on that information in her decisions concerning participation in the CPG CA Study, the use of CPG Breast Implants, and breast implants generally.

111. Defendant Stevens disseminated false information, in that he provided Plaintiff with the Informed Consent which stated that there was no scientific evidence linking breast implants with cancer when he should have known that the information was, in fact, false and misleading.

112. Defendant Stevens had no reasonable grounds for believing these representations were true when they were made or at the time Plaintiff signed the Informed Consent; in fact, Defendant Stevens should have known the representations to be false.

113. Defendant Stevens was negligent in his role as a principal investigator of the CPG CA Study in failing to take steps to ensure that the information in the Informed Consent was current, truthful, accurate, and not misleading.

114. Defendant Stevens breached his duty under state law, including California Health Safety Code § 24176 which required that any representations regarding the device and its risks in the Informed Consent must be truthful, accurate, and not misleading.

115. Defendant Stevens disseminated the false information, as referenced above, to Plaintiff in connection with the CPG CA Study with the intention that Plaintiff

would rely on that information and to induce Plaintiff to participate in the CPG CA study, and to induce her to surgically implant CPG Breast Implants and other breast implants. In negligently supplying the false and misleading information, Defendant Stevens negligently failed to exercise reasonable care to ensure that the information disseminated to Plaintiff concerning the properties and effects of CPG Breast Implants and breast implants generally was accurate and not false or misleading.

116. By failing to ensure that representations regarding CPG Breast Implants and breast implants generally were current, truthful, accurate, and not misleading, Defendant Stevens violated state law, including California Health Safety Code § 24176.

117. Defendant Stevens expected or should have expected that Plaintiff, in reliance on false information, who was implanted with CPG Breast Implants and other breast implants would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to CPG Breast Implants and other breast implants, causing her to undergo future removal surgeries including possible future implant replacement surgeries.

118. Defendant Stevens expected or should have expected that Plaintiff, in reliance on false information about breast implants generally might rely on that false information in deciding to replace CPG Breast Implants with implants from

another manufacturer in a situation where complications arose days after placement of the CPG Breast Implants and required removal and replacement surgery.

119. Plaintiff did in fact reasonably rely on Defendant Stevens' negligent misrepresentations, including the misrepresentations in the Informed Consent, as Defendant Stevens intended.

120. As a proximate and foreseeable result of Defendant Stevens misrepresentations and failure to exercise reasonable care, Plaintiff suffered and will suffer severe physical injuries which are permanent and continuing in nature and which required and will require medical treatment including hospitalization, severe emotional distress, mental anguish, economic loss, and other injuries, for which she is entitled to compensatory and other damages in an amount to be proven at trial.

121. WHEREFORE, Plaintiff prays for judgment against Defendant Stevens as hereinafter set forth.

COUNT IV

Loss of Consortium

(Against Manufacturer Defendants and Defendant Stevens)

122. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

123. As a result of the injuries and damages caused to Plaintiff by Manufacturer Defendants' and Defendant Stevens' tortious conduct, Plaintiff was unable to perform activities she had previously commonly performed for the household, for the family, and for her own support. Consequently, Mr. Cook was required to, inter alia, perform additional activities and upkeep around the house and support Plaintiff by performing activities she previously performed for her own needs and maintenance.

124. As a result of Manufacturer Defendants' and Defendant Stevens' tortious conduct in relation to the CPG Breast Implants and the CA CPG Study and the development of Plaintiff's BIA-ALCL, Mr. Cook effectively lost the companionship and accompaniment of his wife.

125. As a further result of Manufacturer Defendants' and Defendant Stevens' tortious conduct in relation to the CPG Breast Implants and the CA CPG Study and

the injuries they caused to Plaintiff and the resulting demands placed upon Mr. Cook, Mr. Cook has suffered lost wages and income.

126. As a direct and proximate result of the injuries caused to Plaintiff by Manufacturer Defendants' and Defendant Stevens' tortious conduct, Mr. Cook suffered and will continue to suffer the loss of his wife's consortium, companionship, society, intimacy, affection, services and support, and suffered and will continue to suffer economic damages, including lost wages and income.

127. WHEREFORE, Plaintiffs pray for judgment against Manufacturer Defendants and Defendant Stevens as hereinafter set forth.

REQUEST FOR RELIEF

128. WHEREFORE Plaintiffs pray for judgment against Manufacturer Defendants and Defendant Stevens, as appropriate to each cause of action alleged and as appropriate to the standing of each plaintiff, as follows:

a. Economic and non-economic damages in an amount in excess of $75,000 for each plaintiff, exclusive of interest and costs, as provided by law and to be supported by evidence at trial;

b. For compensatory damages according to proof;

c. Past and future medical expenses;

d. Past and future lost wages and loss of earning capacity;

e. Past and future emotional distress;

f. Consequential damages;

g. Disgorgement of profits obtained through unjust enrichment;

h. Restitution;

i. The maximum penalty pursuant to California Health and Safety Code §24176;

j. Exemplary/Punitive damages according to proof;

k. Reasonable attorneys' fees where recoverable;

l. For prejudgment interest and the costs of suit; and

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

DEMAND FOR JURY TRIAL

129. Plaintiffs hereby request a jury trial on all issues raised in this Complaint.

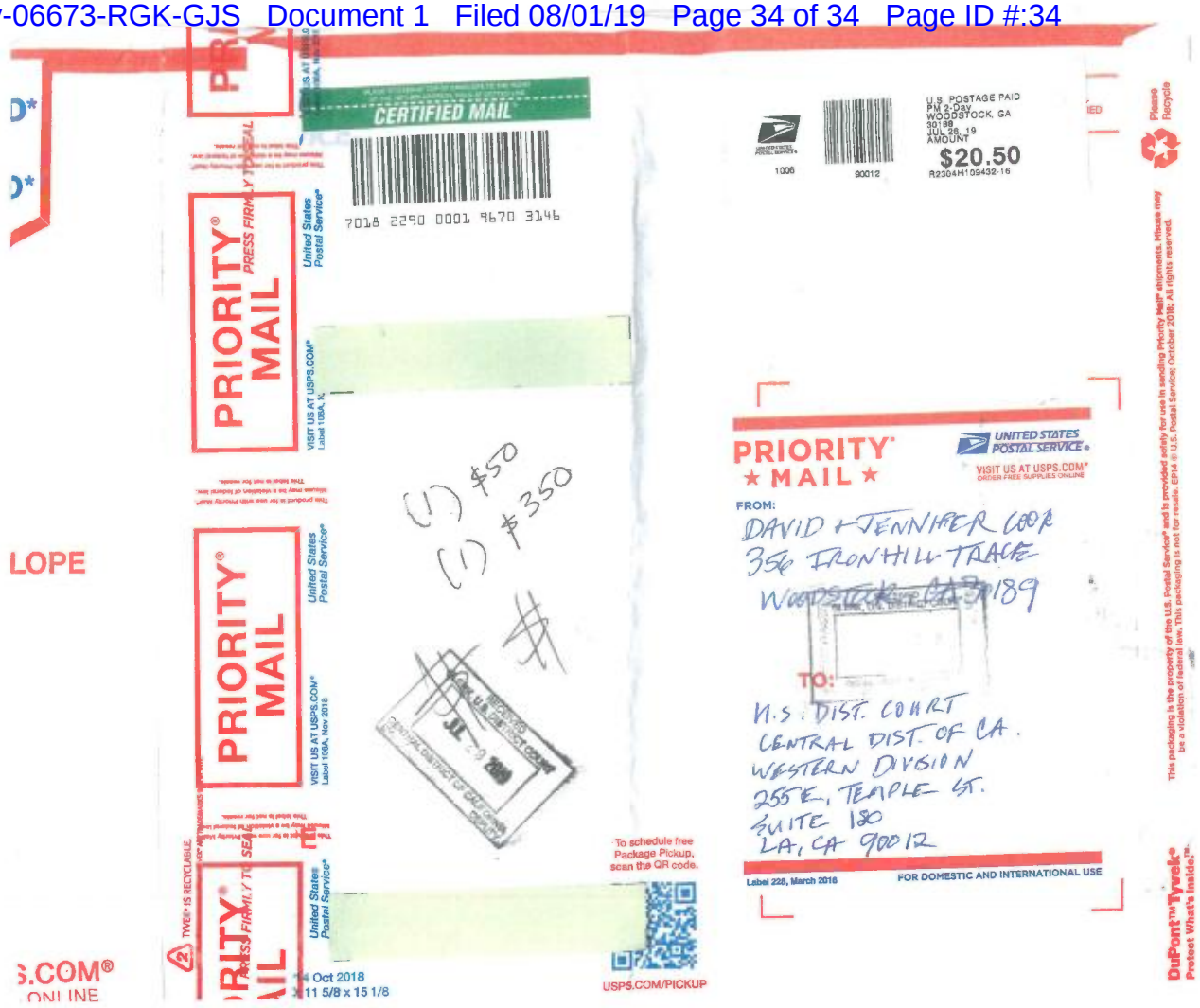
Respectfully submitted,

Dated: July 26, 2019

Jennifer Ann Cook
Plaintiff In Pro Per

Dated: July 26, 2019

David Christopher Cook
Plaintiff In Pro Per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