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**[EXEMPT FROM FILING FEES -
Pursuant to Government Code
Section 6103]**

9
10 SUPERIOR COURT OF THE STATE OF CALIFORNIA
11 FOR THE COUNTY OF SAN DIEGO

12
13 THE PEOPLE OF THE STATE OF
CALIFORNIA,

Plaintiff,

v.

16 JOHNSON & JOHNSON, a New Jersey
17 Corporation; ETHICON, INC., a New Jersey
18 Corporation, and DOES 1 through 100,
inclusive

19 Defendants.
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Case No. **37-2016-00017229-CU-MC-CTL**

**COMPLAINT FOR PERMANENT
INJUNCTION, CIVIL PENALTIES, AND
OTHER EQUITABLE RELIEF**

(BUS. & PROF. CODE, §§ 17200 and 17500
et seq.)

[VERIFIED ANSWER REQUIRED
PURSUANT TO CODE OF CIVIL
PROCEDURE SECTION 446]

1 Plaintiff, the People of the State of California, by and through Kamala D. Harris, Attorney
2 General of the State of California, alleges the following on information and belief:

3 **INTRODUCTION**

4 1. Plaintiff brings this action against Johnson & Johnson and Ethicon, Inc. (together,
5 J&J or Defendants) for deceptive marketing of surgical mesh medical devices for women.
6 Surgical mesh is a synthetic woven fabric implanted through the vagina to treat common pelvic
7 floor conditions that a third to half of all women will face in their lifetime. J&J deceptively
8 marketed its surgical mesh devices as safe with minimal risk when in fact these devices exposed
9 women to a host of dangerous complications. By concealing this information, J&J took away
10 doctors' ability to accurately counsel patients and women's ability to make informed choices
11 about whether or not to have this risky device permanently implanted in their bodies.

12 2. Despite knowing all risk information prior to launching its surgical mesh products,
13 J&J concealed and misrepresented to doctors and patients many of the serious risks associated
14 with these devices, such as chronic pelvic pain, permanent urinary and/or defecatory
15 dysfunction, pain with sexual intercourse and/or loss of sexual function, and the potentially
16 irreversible nature of these complications. J&J further misrepresented serious risks unique to
17 surgical mesh that are not present with non-mesh surgical alternatives.

18 3. J&J marketed surgical mesh to doctors and patients as minimally invasive with
19 minimal risk, without disclosing the potential for permanent, debilitating complications. J&J did
20 this despite being urged by its own medical advisors and employees to warn doctors and patients
21 of pain with intercourse, sexual dysfunction, and impact on quality of life. J&J even persisted in
22 misrepresenting the safety of these devices after receiving complaints from doctors and patients
23 about severe complications, such as the following complaint from a pelvic surgeon: "She will
24 likely lose any coital function as her vaginal length is now 3 cm ... This patient will have a
25 permanently destroyed vagina."

26 4. Due to the severity and type of complications associated with surgical mesh
27 devices, the impact on a woman's quality of life can be devastating. Some women become
28 permanently disabled, unable to work or requiring accommodations from their employers.

1 Marriages have been destroyed due to the loss of physical intimacy. Women have undergone
2 multiple removal surgeries only to continue suffering from complications because the mesh
3 cannot be completely removed and/or the complications are irreversible. One mesh patient's
4 complaint, from August 2008, is illustrative of the toll that surgical mesh has taken on people's
5 lives:

6 **I then had all kinds of problems with chronic pain, bleeding, dyspareunia (even**
7 **my husband complained of scraping and poking) ... The pelvic pain was keeping**
8 **me awake at night, and the only relief was to sit on a tennis ball. The thought of**
9 **living like that, sitting on a ball, wearing a diaper, splinting my perineum to have**
10 **a bowel movement, having infrequent miserable sex, and marital problems was**
11 **almost more than I could bear.**

12 In August 2011, another woman complained:

13 **I experienced excruciating pain from day one. I felt as though my urethra was**
14 **being strangled, I couldn't pee, walking was out of the question, sitting was**
15 **agony, & I couldn't lie on my left side due to severe pain ... Over the course of**
16 **the next 14 weeks I visited/was admitted to the [hospital] 10 times ... I had no**
17 **quality of life. My consultant likened the mesh removal as to 'trying to remove**
18 **chewing gum from hair.'**

19 These are merely a few examples of countless women affected by complications of surgical mesh.

20 5. By misrepresenting (1) the full range of possible surgical mesh complications; (2)
21 the risks that surgical mesh poses, which are unique to mesh and not present in non-mesh repair;
22 and (3) the frequency and severity of the risks that were disclosed, J&J denied women the ability
23 to make informed choices regarding their health and caused them to unknowingly take risks with
24 their well-being. J&J's concealment of the severity of the risks associated with its surgical mesh
25 devices is all the more egregious because women suffering from POP and SUI could have
26 chosen (1) a non-mesh alternative that did not carry these dangers or (2) no surgical treatment
27 because POP and SUI are not life-threatening conditions.

28 **PLAINTIFF**

5. Plaintiff is the People of the State of California. Plaintiff brings this action by and
through Kamala D. Harris, Attorney General. The Attorney General is authorized by Business
and Professions Code sections 17204 and 17206 to bring actions to enforce the Unfair

1 Competition Law (UCL) and by Business and Professions Code sections 17535 and 17536 to
2 bring actions to enforce the False Advertising Law (FAL).

3 **DEFENDANTS**

4 7. Defendant Johnson & Johnson is a multinational corporation engaged in the
5 manufacture and sale of medical devices, pharmaceuticals, and consumer goods. Johnson &
6 Johnson is a New Jersey corporation headquartered in New Brunswick, New Jersey. At all
7 relevant times, Johnson & Johnson has transacted and continues to transact business throughout
8 California, including in San Diego County.

9 8. Defendant Ethicon, Inc. (Ethicon) is a subsidiary of Johnson & Johnson. Ethicon
10 is a New Jersey corporation headquartered in Summerville, New Jersey. At all relevant times,
11 Ethicon has transacted and continues to transact business throughout California, including in San
12 Diego County.

13 9. Plaintiff is not aware of the true names and capacities of defendants sued herein as
14 DOES 1 through 100, inclusive, and, therefore, sues these defendants by such fictitious names.
15 Each fictitiously named defendant is responsible in some manner for the violations of law
16 alleged. Plaintiff will amend this Complaint to add the true names of the fictitiously named
17 defendants once they are discovered. Whenever reference is made in this Complaint to
18 "Defendants," such reference shall include DOES 1 through 100 as well as the named
19 defendants.

20 10. At all relevant times, each Defendant acted individually and jointly with every
21 other named Defendant in committing all acts alleged in this Complaint.

22 11. At all relevant times, each Defendant acted: (a) as a principal; (b) under express or
23 implied agency; and/or (c) with actual or ostensible authority to perform the acts alleged in this
24 Complaint on behalf of every other named Defendant.

25 12. At all relevant times, some or all Defendants acted as the agent of the others, and
26 all Defendants acted within the scope of their agency if acting as an agent of another.

27 13. At all relevant times, each Defendant knew or realized, or should have known or
28 realized, that the other Defendants were engaging in or planned to engage in the violations of

1 law alleged in this Complaint. Knowing or realizing that the other Defendants were engaging in
2 such unlawful conduct, each Defendant nevertheless facilitated the commission of those
3 unlawful acts. Each Defendant intended to and did encourage, facilitate, or assist in the
4 commission of the unlawful acts, and thereby aided and abetted the other Defendants in the
5 unlawful conduct.

6 14. Defendants engaged in a conspiracy, common enterprise, and common course of
7 conduct, the purpose of which is and was to engage in the violations of law alleged in this
8 Complaint. The conspiracy, common enterprise, and common course of conduct continue to the
9 present.

10 **JURISDICTION AND VENUE**

11 15. This Court has original jurisdiction over this action pursuant to California
12 Constitution article 6, section 10.

13 16. This Court has jurisdiction over Defendants because each Defendant, by marketing
14 its surgical mesh products and maintaining a sales force in the state of California to sell such
15 products to hospitals and doctors in this state, intentionally availed itself of the California market
16 so as to render the exercise of jurisdiction over Defendants by the California courts consistent
17 with traditional notions of fair play and substantial justice.

18 17. The violations of law alleged in this Complaint occurred in the County of San
19 Diego and elsewhere throughout California.

20 18. Venue is proper in this Court pursuant to Code of Civil Procedure section 395.5
21 because Defendants' marketing and sales activities included the San Diego region and therefore
22 Defendants' liability arises in the County of San Diego.

23 19. Venue is also proper in this Court pursuant to Code of Civil Procedure section
24 393(a) because violations of law that occurred in the County of San Diego are a part of the cause
25 upon which the Plaintiff seeks the recovery of penalties imposed by statute.

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BACKGROUND INFORMATION

20. Surgical mesh is a synthetic fabric woven or knitted from polypropylene threads. Polypropylene is a synthetic substance derived from crude oil and is used to manufacture everything from rugs to lab equipment and automobile parts.

21. Stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are common conditions caused by weakened or damaged tissues and muscles in the pelvic floor area. SUI occurs when muscles that control urine flow do not work properly, resulting in involuntary urine leakage during everyday activities such as laughing, coughing, or exercise. POP occurs when the muscles of the pelvic floor can no longer support the pelvic organs, causing the organs to drop downwards, and in some cases, bulge out of the vagina. An estimated 30 to 50% of women are affected by incontinence, and nearly 50% of women between 50 and 79 have some form of POP. SUI and POP therefore affect a large percentage of the female population.

22. There are a variety of surgical and non-surgical treatment options to address SUI and POP. Surgical options include: (1) pelvic floor repair using a synthetic material like surgical mesh, where the mesh is implanted through the vagina; and (2) non-mesh repair using the patient's native tissue. Non-mesh surgical alternatives are effective and do not pose the same risks that surgical mesh does.

23. J&J markets and sells a number of surgical mesh devices to treat SUI and POP transvaginally. J&J began selling the TVT sling line of products in 1997 to treat SUI and continues to sell these devices today. This line of products includes the TVT Retropubic, TVT Exact, TVT Obturator, TVT Abbrevio and TVT Secur (collectively, TVT). J&J began marketing and selling its POP pelvic floor repair kits with the Prolift product in 2005. Its POP line of products eventually included the Prolift+M and the Prosima.

24. J&J marketed and sold its SUI and POP surgical mesh devices as involving minimal risk, even though there are many complications associated with these devices.

25. In addition to the general risks associated with pelvic floor surgery, J&J's surgical mesh devices present unique risks and/or heightened risks, due in part to the nature of mesh and its reaction within the body. Complications associated with the use of synthetic mesh in

1 transvaginal repair include the following: erosion, exposure, and extrusion (i.e., mesh implanted
2 in the pelvic floor can erode of out of the vagina and/or into other pelvic organs); a chronic
3 foreign body response to the mesh and resulting chronic inflammation; bacterial colonization of
4 mesh and mesh infection (a risk heightened by implantation through the vagina); and mesh
5 contracture or shrinkage inside the body (which can lead to vaginal stiffness, shortening
6 distortion, and nerve entrapment). These mesh-related complications can lead to further
7 problems for women, including severe, chronic pain; permanent dyspareunia; and sexual, urinary
8 and defecatory dysfunction. The risk of these mesh-related complications is lifelong; mesh
9 complications can arise years – or even decades – after insertion.

10 26. In many cases, mesh removal surgery is required to treat complications. Complete
11 mesh removal, however, is extremely difficult and often impossible -- akin to trying to remove
12 rebar from concrete without damaging the overall structure. Because it is so difficult to remove
13 surgical mesh, removal can require multiple surgeries and may or may not resolve
14 complications. The additional surgeries further damage and scar the pelvic floor tissues, often
15 causing even more complications.

16 27. Complications resulting from transvaginal mesh surgery can have a crippling
17 effect on a woman's ability to work, sex life, daily activities, and overall quality of life. J&J
18 knew about the risk of the grave complications associated with its surgical mesh devices, but
19 misrepresented them to doctors and patients alike.

20 **J&J MISREPRESENTED THE SAFETY OF ITS PRODUCTS**

21 28. J&J made the following misrepresentations to doctors and patients. These
22 misrepresentations were material, and likely to deceive the reasonable doctor and patient
23 audience for these products.

24 **I. J&J MISREPRESENTED ITS SURGICAL MESH DEVICES AS "FDA APPROVED" WHEN** 25 **THEY WERE NOT**

26 29. J&J has misleadingly touted that its products are "FDA approved," even though
27 J&J's surgical mesh devices were merely "cleared" by the FDA under the 510(k) equivalency
28 process. The difference between "cleared" and "approved" is significant. FDA "approved"

1 devices undergo a rigorous evaluation of their safety and efficacy—a process involving
2 approximately 1200 hours of intense FDA review. In contrast, FDA “cleared” devices need only
3 demonstrate that they are “substantially equivalent” to a device already on the market—a review
4 that lasts approximately 20 hours. J&J made these misrepresentations understanding that the
5 “FDA approved” designation leads doctors and patients to believe that a medical product has
6 been well studied and scrutinized.

7 **II. J&J MISREPRESENTED THE FULL RANGE OF RISKS AND COMPLICATIONS**
8 **ASSOCIATED WITH ITS SURGICAL MESH DEVICES**

9 30. J&J misrepresented the safety of its surgical mesh products by failing to disclose
10 known risks and complications to doctors and patients, which would have been material
11 information in considering treatment options. For many years, J&J’s marketing and promotional
12 materials purported to provide complete risk information but failed include significant and/or
13 common risks. For example, the following is a non-exhaustive list of risks and complications
14 missing from the TVT brochures at various points in time:

- 15 a. Pre-2008-2008 TVT patient brochures: chronic foreign body reaction, defecatory
16 dysfunction, *de novo* urgency incontinence, detrimental impact on quality of life,
17 dyspareunia, permanent dyspareunia, dysuria, hematoma, mesh contracture, need
18 for removal, nerve damage, pain, chronic pain, pain to partner during sex,
19 permanent urinary dysfunction, recurrence, sarcoma (cancer), urinary tract
20 infection, vaginal scarring, and worsening incontinence;
- 21 b. 2008-2011 TVT patient brochures: chronic foreign body reaction, defecatory
22 dysfunction, *de novo* urgency incontinence, detrimental impact on quality of life,
23 permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal of
24 the device, nerve damage, chronic pain, permanent urinary dysfunction,
25 recurrence, sarcoma (cancer), urinary tract infection, and worsening incontinence;
- 26 c. 2011-2012 TVT patient brochures: chronic foreign body reaction, defecatory
27 dysfunction, *de novo* urgency incontinence, detrimental impact on quality of life,
28 permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal,

1 pain, chronic pain, permanent urinary dysfunction, sarcoma (cancer), vaginal
2 scarring, and worsening incontinence.

3 31. J&J's marketing and promotional materials for its other SUI mesh devices, and its
4 POP mesh devices, similarly misrepresented product safety by concealing known risks and
5 complications.

6 32. J&J also misrepresented the safety of its products by failing to disclose known
7 material risks in its informational, educational, and training materials directed to doctors.

8 33. As a result by 2012, over two million women had undergone treatment worldwide
9 without being warned by J&J of the serious risks and complications associated with the device,
10 and the debilitating impact it could have on a woman's quality of life.

11 **III. J&J'S EMPLOYEES URGED THE COMPANY TO WARN OF SIGNIFICANT DANGERS**

12 34. J&J persisted in misrepresenting the safety of its surgical mesh products despite
13 the urging of its own high level employees to include warnings about known dangers. For
14 example, J&J's medical director, Dr. Axel Arnaud, believed POP devices to pose such risks to
15 sexual function that he suggested including a warning specifically aimed towards sexually active
16 women. In a June 2005 email, he proposed adding the following warning:

17 **WARNING: Early clinical experience has shown that the use of mesh**
18 **through a vaginal approach can occasionally/uncommonly lead to**
19 **complications such as vaginal erosion and retraction which can result**
20 **in an anatomical distortion of the vaginal cavity that can interfere**
21 **with sexual intercourse. Clinical data suggest the risk of such a**
22 **complication is increased in case of associated hysterectomy. This**
23 **must be taken in consideration when the procedure is planned in a**
24 **sexually active woman.**

25 However, J&J never incorporated this warning into any of its marketing or promotional
26 materials.

27 35. With regard to SUI devices, Dr. Meng Chen, a medical director in the complaint
28 review department, was so concerned with the patients complaints she was seeing related to
post-operative pain and dyspareunia, that she requested that the company share this risk

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1 information with doctors. Below is a meeting agenda drafted by Dr. Chen's describing her
2 observations from patient complaints:

- 3 1. Tape exposure/erosion/extrusion very frequently reported
- 4 2. Patients did not feel there were adequate pre-op consent or risk benefit
assessment[s]
- 5 3. Patient-specific concerns
 - 6 a. The three Es
 - 7 b. The incontinence recurrence
 - 8 c. **Post-operative dyspareunia and pain affect quality of
life and affect daily routine**
 - 9 d. Re-operations-tape excision, removal, re-do sling
procedure[s]
 - 0 e. **Type and intensity of the post-operative complications
disprortion[ate] to pre-operative consent-expectations.**

10 J&J, however, continued to conceal the material risks of dyspareunia and pain affecting quality
11 of life in its marketing and promotional materials.

12 **IV. J&J MISREPRESENTED THE RISKS ASSOCIATED WITH SURGICAL MESH THAT ARE
13 NOT PRESENT IN NON-MESH SURGICAL OPTIONS**

14 36. J&J misled doctors and patients audiences regarding serious risks unique to
15 surgical mesh that are not present in native tissue repair and/or risks that are increased by the
16 use of mesh as compared with non-mesh surgical repair.

17 37. For example, J&J misrepresented the following properties of mesh material,
18 which, if disclosed to doctors, would have provided material information regarding the
19 additional risks and dangers associated with the use of synthetic mesh as opposed to native
20 surgery:

- 21 a. J&J knew that the presence of surgical mesh inside the body triggers a lifelong
22 chronic foreign body reaction and accompanying chronic inflammation. J&J,
23 however, misrepresented the foreign body response triggered by mesh as
24 "transitory" despite knowing the "reaction never goes away." The body's chronic
25 and permanent reaction to mesh plays a material role in the (i) lifelong risk of
26 erosion/exposure of mesh; and (ii) contraction (i.e., shrinking, crumpling, and

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1 folding) and hardening of mesh inside the body, which can lead to chronic pain
2 and dyspareunia.

3 b. J&J knew that the implantation of surgical mesh transvaginally causes a
4 heightened risk of infection because of the (i) bacterial contamination that occurs
5 due to implantation of mesh through the vagina, which is a clean-contaminated
6 environment that cannot be sterilized; and (ii) the bacterial colonization that occurs
7 in the woven mesh. J&J not only failed to disclose this heightened risk of chronic
8 infection, but falsely represented that mesh “does not potentiate infection” in some
9 marketing materials. The infection associated with mesh plays a significant role in
10 mesh erosion and exposure, which can lead to severe pain and dyspareunia.

11 c. J&J knew that mesh can shrink, harden, and become rigid. An internal document
12 entitled “LIGHTning Critical Strategy,” dated September 26, 2006, demonstrates
13 J&J’s knowledge regarding shrinkage and impact on sexual function:

14 **Mesh retraction (“shrinkage”) . . . can cause vaginal anatomic**
15 **distortion, which may eventually have a negative impact on sexual**
16 **function. Its treatment is difficult. Additionally, the scar plate that**
17 **forms with in-growth of tissue into the mesh can cause stiffness of the**
vagina that further impacts sexual function in a negative manner.

18 J&J also knew that claims of softness were “illusory.” Nevertheless, J&J
19 misrepresented that its mesh is “supple,” “remains soft and pliable” and has a “bi-
20 directional elastic property [that] allows adaptation to various stresses encountered
21 in the body.” The company knew the importance that doctors place on pliability
22 and elasticity in the pelvis, which needs to accommodate the flux and movement
23 associated with bladder, bowel and sexual function. Yet, J&J deliberately
24 misrepresented and concealed the risk that mesh can harden and become rigid
25 within the body, which in turn can cause pain and sexual and urinary dysfunction.

26 d. Despite knowledge to the contrary, J&J falsely represented that its “mesh is inert.”
27 This misrepresentation conveyed to doctors and patients that mesh would not
28 trigger the chronic foreign body response, contracture, and hardening that leads to

1 major complications of mesh, including erosion, dyspareunia, pain, and urinary
2 dysfunction.

3 38. J&J misrepresented the safety of its surgical mesh products by failing to disclose
4 that certain complication were inherent risks of the mesh itself. J&J concealed its knowledge
5 that surgical mesh itself causes complications, and instead misrepresented to doctors that
6 complications such as erosion are the result of poor surgical technique. In materials addressed to
7 doctors, J&J further misrepresented that the cause of other complications such pain, dyspareunia
8 and sexual dysfunction, were “unknown” when the company knew that the inherent properties of
9 mesh (chronic foreign body reaction, shrinkage, contraction) caused such complications.

10 39. J&J misrepresented the safety of its surgical mesh products by failing to disclose
11 that there was no safe and effective means for removal. Mesh removal is the only treatment
12 option for continuing mesh complications. Removal often requires multiple surgeries, which
13 may or may not resolve complications, and may in fact result in new problems. In most cases,
14 complete removal of mesh is impossible and for many women, complications remain irreversible
15 even after multiple surgeries. Yet, J&J failed to disclose the lack of a safe and effective means
16 for removal.

17 40. J&J misrepresented the safety of its surgical mesh products by failing to disclose
18 that erosions can arise at any time. Because mesh remains in the body forever, erosion into the
19 vaginal wall or one of the pelvic organs can occur many years after implantation. J&J failed to
20 disclose this lifelong risk of erosion despite knowing that “there is no safe time for erosion when
21 permanent materials are used.” This omission is significant because erosion is the most common
22 and consistently reported mesh-related complication and can be debilitating, leading to severe
23 pelvic pain, painful sexual intercourse or an inability to engage in intercourse.

24 41. J&J misrepresented the safety of its surgical mesh products by failing to disclose
25 the risk of de novo sexual problems. While surgical mesh surgeries are undertaken in part to
26 address underlying sexual dysfunction, they also carry the risk of the mesh itself causing new
27 sexual problems such as erosion, chronic dyspareunia, and sexual dysfunction. J&J falsely
28 represented that use of surgical mesh would have no negative impact on patients’ sex lives when

1 J&J knew that erosion of the mesh out of the vaginal wall could lead to pain for the woman, and
2 abrasion, pain, and injury to a male sexual partner. J&J misleadingly touted the return of sexual
3 function for its POP patients while failing to disclose the potential risk of permanent dyspareunia
4 and other sexual problems that can arise as a result of transvaginal mesh surgery.

5 42. At the same time J&J misrepresented the safety of its surgical mesh products by
6 concealing risks unique to and inherent in the use of mesh, J&J touted surgical mesh as superior
7 to native tissue repair by falsely inflating the failure rates of the non-mesh surgical options.

8 **V. J&J MISREPRESENTED THE SEVERITY AND FREQUENCY OF THE COMPLICATIONS**
9 **THAT IT DID DISCLOSE**

10 43. For the complications that it did disclose, J&J misrepresented the severity and
11 frequency of the complications associated with surgical mesh. For example:

- 12 a. J&J made false and misleading statements in its marketing, promotional,
13 informational, and educational materials about complication rates of mesh, citing
14 to studies that did not actually support the propositions they were cited for.
- 15 b. J&J knowingly cited to studies for which results were scientifically questionable
16 due to study design and/or conflicts of interest. For example, J&J used the result
17 of the Ulmsten study to sell its SUI products when J&J had (1) purchased the
18 rights to the SUI device from Dr. Ulmsten and (2) contractually agreed with Dr.
19 Ulmsten that he would only get paid a specific sum if his study produced favorable
20 results regarding the product.

21 44. Millions of women were implanted with surgical mesh without knowing the full
22 risks of the decision because the company misrepresented (1) the full range of possible
23 complications; (2) the risks that surgical mesh poses, which are not present in the alternative non-
24 mesh repair; and (3) the frequency and severity of the risks that it did disclose.

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1 **FIRST CAUSE OF ACTION AGAINST ALL DEFENDANTS**
2 **VIOLATIONS OF BUSINESS AND PROFESSIONS CODE SECTION 17200**
3 **(Unfair Competition Law)**

4 45. Plaintiff realleges and incorporates herein by this reference paragraphs 1 through
5 44, inclusive, as though set forth here in full.

6 46. Defendants have engaged in and continue to engage in, have aided and abetted and
7 continue to aid and abet, and have conspired to and continue to conspire to engage in unlawful,
8 unfair or fraudulent acts or practices that constitute unfair competition as defined in Business and
9 Professions Code section 17200. These acts or practices include, but are not limited to, material
10 misrepresentations and/or omissions by Defendants regarding the safety and efficacy of surgical
11 mesh products for pelvic floor repair, and the unlawful practices in connection with the
12 marketing, promotion, and sale of Defendants surgical mesh devices.

13 47. Defendants committed fraudulent acts through their deceptive marketing of
14 surgical mesh devices. J&J misrepresentations and omissions to doctors and patients about the
15 safety, efficacy and other characteristics of surgical mesh devices were material (i.e., likely to
16 affect doctors' and patients' choices about this product) and likely to deceive the reasonable
17 doctor and patient audience for these products.

18 48. Defendants committed unlawful acts by disseminating false and misleading
19 statements to the public in violation of Business and Professions Code section 17500.
20 Defendants also committed unlawful acts by making false and misleading claims purporting to
21 be based on factual, objective, or clinical evidence and/or comparing the products' effectiveness
22 to that of other products in violation of Business and Professions Code section 17508.

23 49. Defendants' conduct is in continuing violation of the Unfair Competition Law,
24 beginning at a time unknown to Plaintiff but no later than 1997 for the SUI products and 2005
25 for the POP products, and continuing to within four years of the filing of this Complaint.

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1 **SECOND CAUSE OF ACTION AGAINST ALL DEFENDANTS**
2 **VIOLATIONS OF BUSINESS AND PROFESSIONS CODE SECTION 17500**
3 **(False Advertising Law)**

4 50. Plaintiff realleges and incorporates herein by this reference paragraphs 1 through
5 49, inclusive, as though set forth here in full.

6 51. Defendants have engaged in and continue to engage in, have aided and abetted and
7 continue to aid and abet, and have conspired to and continue to conspire to engage in acts or
8 practices that constitute violations of Business and Professions Code section 17500.

9 52. Defendants, with the intent to induce members of the public to purchase and utilize
10 Defendants' surgical mesh devices, made and caused to be made and/or disseminated misleading
11 statements concerning the devices and matters of fact, which Defendants knew, or by the
12 exercise of reasonable care should have known, were untrue or misleading at the time they were
13 made. Such misrepresentations include, but are not limited to, (1) the full range of possible
14 complications; (2) the risks that surgical mesh poses, which are not present in the alternative
15 non-mesh repair; and (3) the frequency and severity of the risks that it did disclose.

16 53. These misleading statements were material and reasonable persons (doctors and
17 potential patients) were likely to be deceived by the misrepresentations and/or omissions
18 contained in J&J's misleading statements.

19 54. Defendants' conduct is in continuing violation of the False Advertising Law,
20 beginning at a time unknown to Plaintiff but no later than 1997 for the SUI products and 2005
21 for the POP products, and continuing to within four years of the filing of this Complaint.

22 **PRAYER FOR RELIEF**

23 WHEREFORE, the People pray for judgment as follows:

24 55. Pursuant to Business and Professions Code sections 17203 and 17535, that
25 Defendants, their successors, agents, representatives, employees, and all persons who act in
26 concert with them be permanently enjoined from committing any acts of unfair competition or
27 false advertising as defined in Business and Professions Code sections 17200 and 17500,
28 respectively, including, but not limited to, the acts and practices alleged in this Complaint;

1 56. That the Court make such orders or judgments as may be necessary to prevent the
2 use or employment by any Defendant of any practice that constitutes unfair competition or false
3 advertising, under the authority of Business and Professions Code sections 17203 and 17535,
4 respectively;

5 57. That the Court assess a civil penalty of \$2,500 against each Defendant for each
6 violation of Business and Professions Code section 17200 in an amount according to proof,
7 under the authority of Business and Professions Code section 17206;

8 58. That the Court assess a civil penalty of \$2,500 against each Defendant for each
9 violation of Business and Professions Code section 17500 in an amount according to proof,
10 under the authority of Business and Professions Code section 17536;

11 59. In addition to any penalties assessed under Business and Professions Code sections
12 17206 and 17536, that the Court assess a civil penalty of \$2,500 against each Defendant for each
13 violation of Business and Professions Code section 17200 perpetrated against a senior citizen or
14 disabled person, in an amount according to proof, under the authority of Business and
15 Professions Code section 17206.1;

16 60 That the People recover their costs of suit, including costs of investigation;

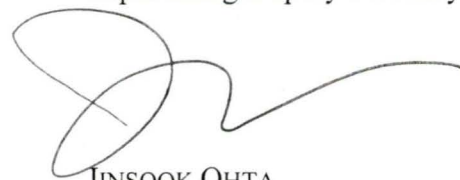
17 61. That the People receive all other relief to which they are legally entitled; and

18 62. For such other and further relief that the Court deems just and proper.

19
20 Dated: May 24, 2016

Respectfully Submitted,

21 KAMALA D. HARRIS
22 Attorney General of California
23 JUDITH A. FIORENTINI
24 Supervising Deputy Attorney General



25 JINSOOK OHTA
26 Deputy Attorney General
27 Attorneys for
28 The People of The State of California

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