COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION II
CIVIL ACTION NO. 16-CI-867

COMMONWEALTH OF KENTUCKY, EX REL.
ANDY BESHEAR, ATTORNEY GENERAL

v.

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

And

ETHICON, INC
P.O. Box 151
US Route 22
Somerville, NJ 08876
A subsidiary of Johnson & Johnson

And

ETHICON U.S., LLC
US Route 22
Somerville, NJ 08876
A subsidiary of Johnson & Johnson

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Comes the Plaintiff, Commonwealth of Kentucky ex rel. Attorney General Andy Beshear, and states the following for its Complaint against Johnson & Johnson, Ethicon, Inc. and Ethicon US, LLC.

I. INTRODUCTION

1. The Commonwealth brings this action against Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC (together, J&J or Defendants) for deceptive marketing of surgical mesh

medical devices for women. Transvaginal mesh (or 'surgical mesh') is a synthetic woven fabric implanted through the vagina to treat common pelvic floor conditions that a 30 to 50 % of all women will face in their lifetime. J&J deceptively marketed its surgical mesh devices by failing to disclose a host of dangerous complications caused by these devices. By failing to disclose clinically relevant information material to decisions about treatment options, J&J impaired doctors' ability to accurately counsel patients and women's ability to make informed choices about whether or not to have such devices permanently implanted in their bodies.

2. J&J concealed and misrepresented to doctors and patients many of the risks of adverse events associated with these devices, such as chronic pelvic pain, urinary and/or defecatory dysfunction, pain with sexual intercourse and/or loss of sexual function, and the potentially irreversible nature of these complications. J&J further misrepresented clinically relevant risks unique to surgical mesh that are not present with non-mesh surgical alternatives.

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

4. Due to the severity and type of complications associated with surgical mesh devices, the impact on a woman's quality of life can be devastating. Some women become permanently disabled, unable to work or requiring accommodations from their employers. Marriages have suffered the loss of physical intimacy. Women have undergone multiple removal surgeries only to continue suffering from complications because the mesh cannot be completely removed and/or the complications are irreversible. One mesh patient's complaint, from August 2008, is illustrative of the toll that surgical mesh has taken on people's lives:

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

In August 2011, another woman complained:

I experienced excruciating pain from day one. I felt as though my urethra was being strangled, I couldn't pee, walking was out of the question, sitting was agony, & I couldn't lie on my left side due to severe pain ... Over the course of the next 14 weeks I visited/was admitted to the [hospital] 10 times ... I had no quality of life. My consultant likened the mesh removal as to 'trying to remove chewing gum from hair.' He had to shave the mesh from my urethra as it was so badly eroded...Since the resection I have started to feel relief, however, I still suffer left side and groin pain and numbness, buttock pain, sharp pains in my lower stomach and I am less continent now than I was pre op.

These are merely two examples of thousands of women affected by complications of surgical mesh.

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

II. PARTIES

6. Plaintiff is the Commonwealth of Kentucky. Plaintiff brings this action by and through Andy Beshear, Attorney General. The Attorney General is authorized by KRS 367.190 to bring this action to enforce KRS 367.170.

7. Defendant Johnson & Johnson is a multinational corporation engaged in the manufacture and sale of medical devices, pharmaceuticals, and consumer goods. Johnson &

Johnson is a New Jersey corporation headquartered in New Brunswick, New Jersey. At all relevant times, Johnson & Johnson has transacted and continues to transact business throughout the Commonwealth, including Franklin County.

8. Defendant Ethicon, Inc. (Ethicon) is a subsidiary of Johnson & Johnson. Ethicon is a New Jersey corporation headquartered in Summerville, New Jersey. At all relevant times, Ethicon has transacted and continues to transact business throughout the Commonwealth, including Franklin County.

9. Defendant Ethicon US, LLC, is a subsidiary of Johnson & Johnson incorporated in Texas. At all relevant times, Ethicon US has transacted and continues to transact business in the Commonwealth.

III. JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to KRS 367.190.

11. This Court has jurisdiction over Defendants under KRS 454.210 because each Defendant, by marketing and promoting its surgical mesh products and maintaining a sales force to sell such products to hospitals and doctors in the Commonwealth, intentionally availed itself of the Kentucky market so as to render the exercise of jurisdiction over Defendants by the Kentucky courts consistent with traditional notions of fair play and substantial justice.

12. The violations of law alleged in this Complaint occurred in Franklin County and elsewhere in the Commonwealth.

13. Venue is proper in this Court pursuant to KRS 367.190 because Defendants' marketing and sales activities included Franklin County and therefore Defendants' liability arises in Franklin County.

IV. BACKGROUND INFORMATION

14. Surgical mesh is a synthetic fabric woven or knitted from polypropylene threads (sometimes combined with other substances). Polypropylene is a synthetic substance derived from crude oil and is used to manufacture everything from rugs to lab equipment and auto parts.

15. 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.

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

17. J&J has marketed and sold 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 many of these devices today. This line of products includes among others the TVT Retropubic, TVT Exact, TVT Obturator, TVT Abbrevo 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 variations of the Prolift+M and the Prosima.

18. 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.

19. 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 J&J's synthetic mesh in transvaginal repair include the following: erosion, exposure, and extrusion (i.e., mesh implanted in the pelvic floor can erode of out of the vagina and/or into other pelvic organs); a chronic

foreign body response to the mesh and resulting chronic inflammation; bacterial colonization of mesh and mesh related infection (a risk heightened by implantation through the vagina); and mesh contracture or shrinkage inside the body (which can lead to vaginal stiffness, shortening distortion, and nerve entrapment). These mesh-related complications can lead to further problems for women, including severe, chronic pain; permanent dyspareunia; and sexual, urinary and defecatory dysfunction. The risk of these mesh-related complications is lifelong; mesh complications can arise years after insertion.

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

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

V. J&J MISREPRESENTED THE RISKS OF ITS PRODUCTS

22. J&J made the following misrepresentations to doctors and patients. These misrepresentations were clinically relevant to decisions about treatment options, and had a capacity to deceive doctors and their patients.

A. J&J Misrepresented its Surgical Mesh devices as "FDA Approved" When They Were Not

23. J&J misrepresented that its products are "FDA approved," even though J&J's surgical mesh devices were merely "cleared" by the FDA under the 510(k) equivalency process. The difference between "cleared" and "approved" is significant. FDA "approved" devices undergo a rigorous evaluation of their safety and efficacy—a process involving approximately

1200 hours of intense FDA review. In contrast, FDA "cleared" devices need only demonstrate that they are "substantially equivalent" to a device already on the market—a review that lasts approximately 20 hours. J&J made these misrepresentations understanding that the "FDA approved" designation leads doctors and patients to believe that a medical product has been well studied and scrutinized.

B. J&J Misrepresented the Full Range of Risks and Complications Associated With Its Surgical Mesh Devices

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

a. 1997-2008 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, *de novo* urgency incontinence, detrimental impact on quality of life, dyspareunia, permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal, difficulty and potential impossibility of removal, nerve damage, pain, chronic pain, pain to partner during sex, permanent urinary dysfunction, recurrence, sarcoma (cancer), urinary tract infection, vaginal scarring, and worsening incontinence;

b. 2008-2011 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, *de novo* urgency incontinence, detrimental impact on quality of life, permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal, difficulty and potential impossibility of removal, nerve damage, chronic pain, permanent urinary dysfunction, recurrence, sarcoma (cancer), urinary tract infection, and worsening incontinence;

c. 2011-2012 TVT patient brochures: chronic foreign body reaction, defecatory

dysfunction, *de novo* urgency incontinence, detrimental impact on quality of life, permanent dyspareunia, dysuria, difficulty and potential impossibility of removal, chronic pain, permanent urinary dysfunction, sarcoma (cancer), and worsening incontinence.

d. 2012- present TVT patient brochures: potential impossibility of removal. In addition, the present TVT brochure misleadingly points patients to the differences between SUI and POP implantation, rather than SUI and non-mesh procedures.

25. J&J's marketing and promotional materials for its other SUI mesh devices, and its POP mesh devices, similarly concealed known risks and complications.

26. J&J also misrepresented and failed to disclose known material risks in its informational, educational, and training materials directed to doctors.

27. In the Commonwealth of Kentucky, over 15,000 women had these devices implanted without J&J providing sufficient information to allow them to adequately weigh the risks and benefits of the full range of treatment options. J&J's deceptive representations and promotion prevented these women from having complete clinical information to make a potentially life-changing decision about their health.

C. J&J's Employees Urged the Company to Warn of Significant Dangers

28. J&J persisted in misrepresenting the risks and benefits of its surgical mesh products despite the urging of its own high level employees to more fully disclose known dangers. For example, J&J's medical director, Dr. Axel Arnaud, believed POP devices to pose such risks to sexual function that he suggested including a warning specifically aimed towards sexually active women. In a June 2005 email, he proposed adding the following disclosure:

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

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

29. With regard to SUI devices, Dr. Meng Chen, a medical director in the complaint review department, was concerned about the adequacy of the company's disclosures. She noted on more than one occasion the difference between the pre-operative consent expectations and post-operative complaint experience. She noted, "one of the paths for a better pre-operative consent is to provide an updated IFU [Instructions for Use] to the operating physicians that reflecting [*sic*] the current knowledge of the manufacturer's on the potential adverse reaction." Below is a meeting agenda drafted by Dr. Chen's describing her observations from patient complaints:

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

(**emphasis** added)

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

D. J&J Misrepresented the Risks Associated With Surgical Mesh That Are Not Present in Non-Mesh Surgical Options

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

31. For example, J&J misrepresented the following properties of mesh material, which, if disclosed to doctors, would have provided material information regarding the

additional risks and dangers associated with the use of synthetic mesh as opposed to native tissue repair surgery:

a. J&J knew that the presence of surgical mesh inside the body triggers a lifelong chronic foreign body reaction and accompanying chronic inflammation. J&J, however, misrepresented the foreign body response triggered by mesh as "transitory" despite knowing the "reaction never goes away." The body's chronic and permanent reaction to mesh plays a material role in the (i) lifelong risk of erosion/exposure of mesh; and (ii) contraction (i.e., shrinking and folding) and hardening of mesh inside the body, which can lead to chronic pain and dyspareunia.

b. J&J knew that the implantation of surgical mesh transvaginally can create a heightened risk of infection because of the (i) bacterial contamination that occurs due to implantation of mesh through the vagina, which is a clean-contaminated environment that cannot be sterilized; and (ii) the bacterial colonization that occurs in the woven mesh. J&J not only failed to disclose this heightened risk of chronic infection, but represented that mesh "does not potentiate infection" in some marketing materials. Moreover, when J&J did disclose its products' ability to "potentiate" infection, it misleadingly equated that risk with that of any other implanted material. The infection associated with mesh plays a significant role in mesh erosion and exposure, which can lead to severe pain and dyspareunia.

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

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

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

d. Despite knowledge to the contrary, J&J falsely represented that its "mesh is inert." This misrepresentation conveyed to doctors and patients that mesh would not trigger the chronic foreign body response, contracture, and hardening that leads to major complications of mesh, including erosion, dyspareunia, pain, and urinary dysfunction.

32. J&J misleadingly failed to disclose that certain complications were inherent risks of the mesh itself. J&J concealed its knowledge that surgical mesh itself causes complications, and instead misrepresented to doctors that complications such as erosion are the result of poor surgical technique. In materials addressed to doctors, J&J further failed to disclose the degree to which the inherent properties of mesh (chronic foreign body reaction, shrinkage, contraction) caused complications such as pain, dyspareunia and sexual dysfunction.

33. J&J misleadingly failed to disclose that there was no safe and effective means for removal of its surgical mesh products. Mesh removal is often the only treatment option for continuing mesh complications. Removal can require multiple surgeries, which may or may not resolve complications, and may in fact result in new problems. In most cases, complete removal of mesh is impossible and for many women, complications remain irreversible even after multiple surgeries. Yet, J&J failed to disclose the lack of a safe and effective means for

removal, and therefore the potential irreversibility and permanent disability associated with its serious complications.

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

35. J&J failed to disclose the risk of new (*de novo)* sexual problems arising after implantation of its surgical mesh products. While surgical mesh surgeries are undertaken in part to address underlying sexual dysfunction, they also carry the risk of the mesh itself causing new sexual problems such as erosion, chronic dyspareunia, and sexual dysfunction. J&J falsely represented that use of surgical mesh would have no negative impact on patients' sex lives when J&J knew that erosion of the mesh out of the vaginal wall could lead to pain for the woman, and abrasion, pain, and injury to a male sexual partner. J&J misleadingly touted the return of sexual function for its POP patients while failing to adequately disclose the potential risk of permanent dyspareunia and other sexual problems that can arise as a result of transvaginal mesh surgery.

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

E. J&J Misrepresented the Severity and Frequency of the Complications That It Did Disclose

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

a. J&J made false and misleading statements in its marketing, promotional, informational, and educational materials about complication rates of mesh,

selectively citing outcomes that appeared positive, while not disclosing clinically relevant information about negative findings in those same studies.

b. J&J knowingly cited to studies for which results were scientifically questionable due to study design and/or conflicts of interest. For example, J&J used the result of the Ulmsten study to sell its SUI products when J&J had (1) purchased the rights to the SUI device from Dr. Ulmsten and (2) contractually agreed with Dr. Ulmsten that he would only get paid a specific sum if his study produced favorable results regarding the product.

38. More than 15,000 Kentucky women were implanted with surgical mesh without knowing the full risks of the decision because the company misrepresented (1) the full range of possible complications; (2) the risks that surgical mesh poses, which are not present in the alternative non-mesh repair; and (3) the frequency and severity of the risks that it did disclose.

39. Defendants have engaged in and continue to engage in unfair, false, misleading, and deceptive acts or practices in violation of KRS 367.170. These acts or practices include, but are not limited to, material misrepresentations and/or omissions by Defendants regarding the risks of surgical mesh products for pelvic floor repair, and the unlawful practices in connection with the marketing, promotion, and sale of Defendants surgical mesh devices.

40. Defendants committed unfair, false, misleading, and deceptive acts through their deceptive marketing of surgical mesh devices. J&J misrepresentations and omissions to doctors and patients about the hazards of surgical mesh devices had the capacity to deceive Kentucky patients and their doctors. J&J failed to accurately disclose information clinically relevant to choices of medical care and informed consent to surgical procedures. Defendants committed unlawful acts by disseminating false and misleading statements to the public in violation of KRS 367.170, including false and misleading claims purporting to be based on factual, objective, or clinical evidence and/or comparing the products' effectiveness to that of other products.

VI. PRAYER FOR RELIEF

WHEREFORE, the Commonwealth *ex rel.* Attorney General Andy Beshear respectfully requests the following relief:

A. Entry of a judgment against Defendants finding that they committed repeated violations of KRS 367.170;

B. An Order permanently enjoining Defendants from further and repeated violations of KRS 367.170, including requiring the disclosure of clinically significant risk information;

C. That the Court make such orders or judgments as may be necessary to prevent the use or employment by any Defendant of any practice that constitutes unfair, false, misleading or deceptive acts or practices prohibited by KRS 367.170;

D. An award of civil penalties in the amount of two thousand dollars per each violation of KRS 367.170, and ten thousand dollars for each violation targeted to consumers over the age of 60, pursuant to KRS 367.990;

E. For an award of reasonable costs and fees to Plaintiff;

F. For a trial by jury;

G. For any and all such other relief as this Honorable Court deems just and proper.

Respectfully submitted,

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