PELVIC MESH DANGERS
Prepared by Richard Zitrin, March 2017
With the assistance of the Arthur & Charlotte Zitrin Foundation Anti-Secrecy Database Project

The information below is divided into seven segments: *narrative summary; defect causing serious injury; estimates of number of incidents/cases and extent of harm; evidence that cases were settled secretly; companies' knowledge of the defect; status today of current lawsuits, public awareness of defect, etc.; and the science of the defect.* References are listed as necessary. Documentation is footnoted or noted by "Exhibit," or both. However, the exhibit number is only for indexing purposes and copies of the exhibits do not contain the number and are not necessarily attached. I have possession of all referenced documents.

Questions, comments, and additional information may be directed to Professor Richard Zitrin, zitrinr@uchastings.edu, 415-354-2701. Emphasis in quoted materials is mine except if noted.

1. Narrative summary:

"Pelvic organ prolapse" is a relatively common condition that occurs as women age, particularly if overweight or after bearing many children. It means that a pelvic organ "prolapses," or drops from its normal position, creating discomfort, pressure, extrusion from the vagina, and often considerable pain. Pelvic meshes were developed to help hold those organs in place, alleviating the pain and discomfort. Unfortunately, for tens of thousands of women, the "cure" has been worse than the problem. Meshes often cause a variety of medical issues more fully discussed in Sections 2 and 6.[1] Moreover, safer and equally effective procedures have been available.

In the early 2000s, drug and prosthetic companies, led by the Johnson & Johnson subsidiary Ethicon, recognizing a seemingly widespread need, began pushing the FDA for approval of pelvic meshes without the usual clinical trials, under an expedited FDA approval protocol called "501(k)."[2] Soon after approval the FDA began receiving many complaints. Over the years it sent bulletins warning first of general concerns about the procedure, and later of increased concerns. Despite these warnings and the extraordinarily high number of lawsuits, the mesh manufacturers did not warn customers or physicians; at their peak, at least 300,000 pelvic mesh procedures were done each year.[3]

[1] "POP" and stress urinary incontinence, or "SUI," are sometimes collectively called "pelvic floor disorders." Both conditions are commonly treated with similar but not identical and not equally harmful pelvic mesh surgery. The focus here is specifically on *POP meshes*.

[2] See footnote 5 for an explanation of that procedure, and other references in Sections 5 and 6 on the ultimate effects of that procedure, nullified by the FDA in 2016.

[3] Number of operations is from FDA website and Bloomberg.com. See note 23. It should be noted that these problems are best understood as being caused principally by the device, not by physicians performing the surgery.

As a result, pelvic mesh surgeries continue, and over 100,000 lawsuits have been filed. 100,000 have been consolidated in seven multi-district litigations in federal court for the Southern District of West Virginia alone. Many of these cases have now been settled, but under a tight veil of secrecy caused by protective orders in each case. Another 10,000 are consolidated in the state of New Jersey.

Deaths occur due to pelvic mesh surgery, but serious complications are more common. According to the Mayo Clinic, the complications include "mesh erosion, pain, infection, bleeding, pain during sex, organ perforation and urinary problems. Many of these complications require additional treatment, including surgery."[4]

2. <u>Defect causing serious injury:</u>

Because the approval of these meshes was expedited under the FDA's misapprehension that the products were similar to a previously-approved product, there were no clinical or human trials before approval.[5] Because of this, the ordinary "vetting" of these meshes never occurred, and complications were not fully understood. Pelvic meshes are simply often not accepted by a woman's body in a variety of ways. The "erosion" referenced on the Mayo Clinic site refers to "the process in which mesh wears through a woman's soft internal tissues."[6]

The resulting serious injuries include erosion itself, which can be extremely painful and cause external exposure of the mesh or organs themselves – called extrusion or protrusion. Vaginal erosion often leads to painful intercourse, may make sex impossible, and at the vaginal wall often requires multiple surgeries to attempt a repair. Urinary tract erosion causes repeated infections. Mesh eroding through formerly healthy internal tissues can puncture, or perforate, organs — usually the bladder, urethra, bowel or rectum. Severe organ perforation may result in infection and difficulty breathing. Mesh problems almost always require surgery, including for mesh removal, bowel resection, colostomy and blood transfusion. Perforated organs can leak urine or waste into the bloodstream, which can cause fatal complications like septic shock.[7]

---

[4] Mayo Clinic on-line medical summary, http://www.mayoclinic.org/diseases-conditions/pelvic-organ-prolapse/in-depth/transvaginal-mesh-complications/, accessed March 12, 2017.

[5] The FDA used a "regulation 501k" procedure to expedite approval. This procedure *<u>avoids full clinical trials and any human testing</u>* when similar products are already on the market. However, *<u>the similar product in this case</u>* was Boston Scientific's ProteGen, which itself *<u>was soon removed from the market as defective</u>*. Thus, the meshes slipped through an approval "crack," that one commentator, Dr. Thomas Margolis, a California pelvic surgeon, described to Bloomberg.com as "The FDA [getting] caught with their pants down…. The ProteGen should have told them, 'Wait a minute, all of these mesh systems are bad.'" See, generally, on this approval, numerous Bloomberg.com articles, https://www.drugwatch.com/fda/fast-track/, http://publichealthwatchdog.com/phwd/?p=6216, and the FDA's own site.

[6] https://www.drugwatch.com/transvaginal-mesh/complications-and-problems/

[7] See sites referenced in notes 4, 5, and 6.

3. Number of incidents/cases and degree of harm:

1. Number of cases and information on injuries from cases: It is hard to estimate the number of cases filed on pelvic mesh injuries prior to the consolidation of cases in the seven "multi-district litigation" (MDL) cases in the Southern District of West Virginia federal court in 2011. At about that same time, two New Jersey state court MDLs were filed, one against Ethicon, the Johnson & Johnson subsidiary, and another against manufacturer CR Bard.[8] Pelvic meshes were approved to treat pelvic organ prolapse only in 2002, so cases before consolidation in West Virginia in early 2012 likely number "only" in the hundreds. The number of MDL cases is precise, however, as totals exist for each of the seven separate but related West Virginia MDLs against seven different manufacturers. ***There are a total 102,076 cases*** in these MDLs.[9] In the New Jersey MDL, there are 977 Bard cases and 9,011 Ethicon cases.

Because all seven MDLs in West Virginia and the two MDLs in New Jersey are bound by protective orders, the degree of harm and settlement amounts in individual cases is not possible to ascertain.[10] However, in the American Medical Systems MDL, we discovered a Master Settlement Agreement from 2013 in AMS's SEC filings.[11] This document, while redacted and marked "confidential" on each page, sets up a matrix with three categories for payment of a total of $54,500,000.00. Each category is a degree of bodily injury, although the specific injuries and numbers for each category are redacted. However, all payments are made only for "actual physical injury to the body of a person resulting in sickness, disease, disability, or death."[12]

2. Medical information and FDA notices. The medical information available on line is extensive and discusses common severe consequences of mesh rejection and erosion.[13] In

[8] See http://www.wvsd.uscourts.gov/nodeblock/multidistrict-litigation for West Virginia federal cases and http://www.judiciary.state.nj.us/mass-tort/pelvicmesh/case_list.html for New Jersey state cases.

[9] Information available on line at http://www.wvsd.uscourts.gov/nodeblock/multidistrict-litigation. Running totals for cases filed and closed are kept by the court for each of the seven manufacturers. As of March 26, 2017: American Medical Systems ("AMS") (20,979 filed, 16,481 closed); Boston Scientific (24,443 filed, 9,171 closed); Coloplast (2,588 filed, 2,097 closed); Cook Medical (614 filed, 116 closed); CR Bard (15,302 cases file, 7,557 closed); Ethicon (Johnson & Johnson – 38,013 filed, 5,539 closed); Neomedic (137 filed, 125 closed).

[10] See Section 5 below for detail about protective orders and cases settled secretly. The West Virginia omnibus protective orders are extremely broad, and the New Jersey *Bard* order is as well. In the New Jersey *Ethicon* MDL, there are several protective orders addressing portions of the litigation. A leading New Jersey plaintiffs' firm has been able to post deposition excerpts of Ethicon upper management personnel: http://meshcomplications.com/, a website created by the law firm of Mazie Slater Katz & Freeman. While these depositions reference exhibits, the exhibits are not shown.

[11] Master Settlement Agreement of June 14, 2013, obtained through AMS's SEC filings. Exhibit 2. Found at https://www.sec.gov/Archives/edgar/data/1100962/000110096213000038/ex10144meshsettlementagree.htm.

[12] Master Settlement Agreement, note 11, pages 12-13.

[13] See notes 4, 5, and 6; see also website of the American College of Obstetricians and Gynecologists, especially pages under http://www.acog.org/Search?Keyword=pelvic+mesh, for consequences of pelvic mesh surgery.

addition, the Food & Drug Administration, which originally approved of the meshes through an expedited program, has raised a series of increasingly serious concerns about the health dangers of the meshes.[14]

3. Deaths and the MAUDE database. While the number of deaths can only be surmised by ancillary data, the FDA has a database called MAUDE, for Manufacturer and User Facility Device Experience. That site is a self-reporting repository for drug and prosthetics companies to provide information about adverse incidents, including deaths, in which a device was involved. *AMS reported 215 such deaths in which pelvic meshes were relevant, while Ethicon reported 21 such deaths.*[15] Note that the reports of deaths do not necessarily mean that they were caused by pelvic meshes. They must be read individually. For example, one AMS report may refer to cardiac infarction and other non-mesh-related issues, while another may refer to a list of causes of death that almost all relate to mesh issues. Thus, while it is difficult to estimate the number of deaths *due to* pelvic mesh complications or the resulting surgeries, it is reasonable to conclude they number at least in the several dozens.

4. Cases settled secretly:

At the very minimum, *41,086 cases have been secretly settled under the protective orders in the seven West Virginia MDLs.*[16] I am aware of *no* case without a protective order, though some of the litigation that the Mazie Slater firm has litigated and tried may have more limited protective orders.

While little is known about *settlement documents* in other MDLs, the American Medical Services MDL settlement document contains the following language:

> Claimants Counsel and Claimants who receive payments pursuant to this Master Settlement Agreement, *shall not offer in evidence* ***or in any way refer to*** in any civil, criminal, administrative, or other related action or proceeding, the MOU, this Master Settlement Agreement and any Addendums hereto, other than as may be necessary to consummate or enforce this Master Settlement Agreement. *If the subject of this Master Settlement Agreement shall rise* in any such legal proceedings, Claimants and Claimants *Counsel shall give AMS notice and opportunity to intervene and oppose disclosure*….
>
> To the extent not otherwise governed by an existing Protective Order and/or Confidentiality Order, *Claimant and Claimants Counsel will return all originals*

[14] For detail on this, see Section 5 below.

[15] The database may be searched at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. Note that most of the AMS reporting has been recent, far after the fact of death. This may be due to the threat of the FDA's movement towards more stringent regulation, as set forth in Section 5 and notes 27, 28, and 29.

[16] Totals are adding all closed cases from on-line detailed information, see note 9.

and all copies of documents that contain information provided by AMS in any Civil Action involving pelvic mesh products that were in their respective possession, custody or control….[17]

Thus, not only are there requirements of secrecy about terms, secrecy of documents and required return of all documents, but there is even secrecy *as to the very existence of the settlement* itself.

5. Companies' knowledge of the defect

Systemic secrecy has successfully prevented the disclosure of documentation of virtually everything that the mesh manufacturers knew, with the small and partial exception of Ethicon in New Jersey.[18] However, all seven manufacturers were well aware that *their products had never been through a clinical trial and had gained approval through an expedited process that was based on similarity to a Boston Scientific product that the FDA had recalled.* This alone should have put them on notice of possible dangers. The extraordinarily large number of lawsuits should have served as confirmation to the point where internal company knowledge may be conclusively presumed at the least for the four companies facing over 10,000 lawsuits.[19]

In the West Virginia Ethicon MDL, a magistrate judge issued an extensive ruling that *Ethicon had destroyed documents that should have been preserved* after April 30, 2007, the date Ethicon was on notice that ongoing lawsuits required it to preserve documents.[20] Thus, by this date at the latest, on which Ethicon's counsel had issued a notice advising company personnel to preserve all documents related to a principal mesh product, Ethicon was aware of the existence of significant product safety issues. While the court ultimately decided that there was insufficient proof the document destruction was intentional, it reserved for the plaintiffs the possibility that they would be able to comment on Ethicon's document destruction at trial, and required Ethicon to pay monetary "sanctions" to the plaintiffs.[21]

Perhaps more telling are the actions of the FDA after granting expedited approval of the meshes in 2002. By 2008, based on over 1,000 customer complaints, the FDA had realized that the pelvic meshes could be dangerous, and issued a "Public Health Notification" that stated: "Dear Healthcare Practitioner: *This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences*."[22] This bulletin, of course, put all mesh manufacturers on notice of the issue.

---

[17] See AMS Master Settlement Agreement, note 11, page 19.

[18] See note 10 reference to partial deposition transcripts.

[19] In order of number of lawsuits, Ethicon, Boston Scientific, American Medical Systems, and CR Bard.

[20] February 4, 2014 Order in *In Re Ethicon, Inc. Pelvic Repair Systems*, (SDWV MDL 2327).

[21] Order, note 7, pages 42-43.

[22] October 20, 2008 FDA bulletin. Available on line at FDA site and numerous other sources.

After 2,874 additional complaints over three years, the FDA changed its warning to "serious consequences associated with transvaginal mesh," and stated that it was "issuing this update to inform you that *serious complications associated with surgical mesh for transvaginal repair of POP are* ***not rare***," (Bolding in original) a change from the 2008 bulletin. Furthermore, the FDA stated that "*it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk.*"[23]

The FDA reported these most frequent complaints: erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. Many of these and other complications "require additional intervention, including medical or surgical treatment and hospitalization." The FDA then recommended that health care providers "recognize that *in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications*," and also that they "choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives."[24]

The West Virginia federal MDLs and New Jersey state MDLs were established at about the same time as this second FDA bulletin. The extent of the FDA's expressed concerns, details over the types of common injuries, and the huge number of lawsuits, coupled with the fact that *no human clinical trials had ever been done before FDA approval*, made the mesh dangers abundantly clear to all manufacturers.

With respect to Johnson & Johnson's subsidiary Ethicon, the evidence is more direct. There are: the destruction of documents resulting in sanctions; the videotaped depositions of eleven upper management officials referencing numerous documents; and a recent highly damning and probative report from Radar TV in the Netherlands.[25] Perhaps not coincidentally, Johnson & Johnson, alone among the seven mesh manufacturers, has refused to settle most of its lawsuits. Of the 102,076 cases in the West Virginia MDL, the Ethicon cases represent 37% of the cases, but only 14.6% have been settled. The other six defendants have settled well over half their cases.

6. Status today of lawsuits, public awareness, etc.

While as noted above, mesh manufacturers were clearly aware of severe pelvic mesh problems, the public remained largely in the dark. Moreover, the public was understandably oblivious to the process by which the meshes had been approved in the first place. Although

[23] July 13, 2011 FDA bulletin. Complaints were totals from the three years 2008, 2009, and 2010. The FDA estimated that 300,000 mesh procedures had been performed in 2010. See Bloomberg.com.

[24] July 13, 2011 FDA bulletin, note 23.

[25] The television program may be viewed at https://www.youtube.com/watch?v=lBxj4h8C36M&feature=youtu.be.

the FDA had issued two pronouncements, those were never disseminated to the public nor is it clear that all physicians performing mesh surgeries received these notices. Surgeries still proliferated and lawsuits continued to increase.[26]

After the July 2011 report, the FDA continued to evaluate whether it should take stronger measures regarding pelvic meshes. But this took place behind closed doors. Given the blanket secrecy attendant to the MDL proceedings, public information on pelvic mesh dangers centered on speculation and third-party science, but information about what manufacturers knew did not exist in a public forum. Finally, after almost three years, the FDA issued a proposed regulation that would reclassify pelvic meshes into a more stringent category.[27] In the next 20 months, the agency received only 26 comments about its proposed regulation.[28]

After a 20-month comment period the FDA issued a federal regulation on January 5, 2016 to require both the *re-categorization and pre-market approval (or "PMA") of all pelvic meshes* used for POP procedures. *The regulation effectively reversed the 15-year-old decision to allow the meshes' expedited approval, and requires full clinical testing, without which the products will be forced off the market.*[29] However, manufacturers were given 30 months to comply, or until July 5, 2018, and while the 2016 regulation noted that "patient labeling should be reflective of the risks and benefits of individual devices," the FDA recognized that its previous 2008 and 2011 bulletins did not adequately warn the public. Nor was there any specific obligation for manufacturers to warn the public under the 2016 regulation.

Despite the relatively wide-ranging FDA announcements in the health-care community, almost nothing was said about what the mesh manufacturers themselves knew of the problems with the devices from their own research. That information remains entirely closed to the public by virtue of protective orders in the MDL cases and previous protective orders in individual cases that pre-date the MDLs. As for the manufacturers' compliance, it is unlikely to happen because they are aware that *clinical trials will not demonstrate that the products are safe*; many have already been removed from the market.[30]

7. The science of the defect:

---

[26] Between our on-line checks on February 17 and March 26, 2017, *967 additional lawsuits* had been filed in the West Virginia MDLs.

[27] Federal Register of May 1, 2014 (79 FR 24634; 79 FR 24642). The change was to Category III, the category requiring the most pre-market vetting prior to approval.

[28] Federal Register of January 5, 2016 (2015-33163).

[29] See regulation, note 25. "Under the final order, a PMA for surgical mesh for transvaginal POP repair is required to be filed on or before July 5, 2018, for any preamendments class III devices [i.e., current meshes] … that has [sic] been found by FDA to be substantially equivalent to such a device on or before July 5, 2018.

[30] Phone calls of March 28, 2017 with Jane Akre, editor of http://www.meshmedicaldevicenewsdesk.com/.

The expedited, non-human-testing process by which pelvic meshes were approved is clearly documented. So are the injuries that have occurred. The technical reasons for the failure of pelvic meshes are not yet well understood, precisely because clinical trials with human subjects are necessary to vet such devices before they "go to market," and *because the scientific evidence gathered by the manufacturers is all secret.*

Nevertheless, some clues can be gleaned from the available evidence. From the depositions of Ethicon officials, it is clear that an issue of "bridging fibrosis," or fibrosis that spreads from one organ to another, was a serious concern, as was the heavier weight of Ethicon's meshes.[31] Meanwhile, medical organizations such as the American College of Obstetricians and Gynecologists, the Mayo Clinic, and others have suggested myriad ways other than pelvic mesh surgery to treat pelvic organ prolapse with success at least equal to mesh surgery and without the complications that mesh implantation creates.[32]

[31] See Mazie Slater video depositions, note 10.

[32] See numerous references to therapies at: www.acog.org, the site of the American College of Obstetricians and Gynecologists, and the site reference in note 13, website for the Mayo Clinic, note 4, and other patient-centric sites noted above. These methods range from preventive exercise to non-surgical silicon "pessaries" that cradle the organs, use of the woman's own strengthened tissues and ligaments, called "uterosacral ligament suspension" or "sacrospinous fixation," and three surgical procedures that reinforce the vaginal wall, uterus, and other organs without meshes, called "colporrhaphy," "sacrocolpopexy," and sacrohysteropexy."