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LITIGATIONS AGAINST SYNTHETIC MESH/SLING MANUFACTURERS: FOLLOWING THE THREAD!

Hypothesis / aims of study
To review published data on legal cases against the major synthetic mesh/sling (SMS) manufacturers and analyze relevant outcomes to date.

Study design, materials and methods
Using accessible official sources on the Internet, including PACER (Public Access to Court Electronic Records) and the multidistrict litigation (MDL) websites created by the federal court, cases against Bard, AMS, Coloplast, Boston Scientific, and Ethicon from 2009 to present were reviewed. Data extracted included number of legal cases in federal courts, number of settlements, and range of awards, as well as on-going and upcoming trials with their schedules.

Results
At nearly 100,000 cases, the SMS litigation is the biggest pharmaceutical/device MDL to date. Table 1 summarizes the most recent information for the 5 main manufacturers. In June 2012, Johnson and Johnson/Ethicon withdrew Gynecare Prolift, Prolift + M, TVT secur, and Prosima from the US market. Soon after, in July 2012, Bard stopped selling the Avaulta mesh (1). Seven MDLs are in front of Judge Goodwin in West Virginia. The judicial panel on MDL (JPML) website and each manufacturer MDL docket information were useful to review but terribly long documents (2). Docket control orders (DCO) provided updated number of cases being worked up in waves of 200 to 300 cases whereas Inactive DCO (from PACER and court websites) implied on-going settlement. Lawsuits dropped before trial, lawsuits with a settled amount not disclosed, and Defense verdicts were more difficult to track (3). The range of awards varied tremendously from 1 to 100+ millions. Bellwether cases (exemplar cases chosen by the lawyers and Judge) and State court litigations (TX, FL, OK, NJ (4), DE, MN, PA, MA, CA…) are ongoing and will extend into 2016 for product liability litigations and punitive damages.

Interpretation of results
It is important, although somewhat difficult without considerable efforts, to fully grasp where the field of litigation related to synthetic mesh for prolapse/sling for incontinence is currently evolving towards. Therefore, this review of accessible sources was undertaken to provide a current update and overview of this major pharmacological/device MDL process, the largest ever in the field of FPMRS.

Concluding message
Despite the lack of a national registry to track SMS implanted so far, the sheer number of litigations against SMS manufacturers in the US is staggering. It is not clear when this trend will end. Until then, practicing pelvic floor specialists should be aware of the rapidly evolving litigation scene in this matter.

Table 1. Summary of current MDL, website, and volume of cases ongoing/closed for each involved SMS manufacturer (n=83,821).

Ethicon MDL No. 2327 - In Re Ethicon, Inc., Pelvic Repair System Products Liability Litigation http://www.wvsd.uscourts.gov/MDL/ethicon/ 29,440 cases. 1039 are closed
Bard MDL No. 2187 - In Re C. R. Bard, Inc., Pelvic Repair System Products Liability Litigation http://www.wvsd.uscourts.gov/MDL/2187/ 12,735 cases. 433 are closed.
AMS MDL No. 2325 - In Re American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation http://www.wvsd.uscourts.gov/MDL/amsinc/ 19,972 cases. 9429 are closed.
Boston Scientific MDL No. 2326 - In Re Boston Scientific Corp. Pelvic Repair System Products Liability Litigation http://www.wvsd.uscourts.gov/MDL/boston/ 19,351 cases. 938 are closed.
Coloplast MDL No. 2387 - In Re Coloplast Corp. Pelvic Support Systems Products Liability Litigation http://www.wvsd.uscourts.gov/MDL/2387/ 2,323 cases. 266 are closed

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