LEGAL THOUGHTS ON THE AMS TRANSVAGINAL MESH SETTLEMENT

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Recently, Endo Pharmaceuticals announced that it had reached a settlement in principle with four law firms representing plaintiffs in the transvaginal mesh litigation pending before Judge Goodwin in federal district court in West Virginia (MDL 2325). The Press Release issued by Endo states that it expects to pay over time "an aggregate pre-tax amount of $830 million in connection with the resolution of 20,000 claims relating to vaginal mesh products sold by Endo's subsidiary, AMS."

As an attorney who has represented women in pharmaceutical and medical device litigation for over thirty years, including DES, fen-phen and breast implants, and who currently represents women injured by transvaginal mesh, I was not surprised to learn that Endo and some of the plaintiff firms had arrived at a mass settlement. After all, in this type of litigation—known as mass torts—mass settlements are not unusual as they can resolve a large number of cases quickly and efficiently.

Of course, the goal of prompt resolution must not trump the plaintiff's right to be fairly compensated for her injuries. Considering the harm caused by these devices, including organ perforation, urinary and bowel problems, mesh erosion, vaginal scarring, severe pain, sexual problems, and revision surgeries, this proposed settlement, averaging $41,500 for each woman who had an AMS pelvic mesh device, made me pause.

I did not participate in the settlement discussions and none of my clients are included in this settlement. In other mass settlements I have participated in, plaintiffs were compensated based on the severity of their injuries. Here, it is likely that women who underwent revision surgeries would receive more than the average amount for their case, while others who only underwent implantation, may receive less than that amount. Still, it is reasonable to ask whether the terms of the settlement are adequate in light of the suffering caused by transvaginal mesh.

In assessing settlement value, it is important to recognize that the initial trials have gone exceedingly well for the plaintiffs:

- A $3.6 million verdict against Bard in California state court in 2012 (the implanting physician was held responsible for another $1.9 million in damages).

- A $11.1 million verdict against J&J/Ethicon, including $7.76 million in punitive damages, in New Jersey state court. The jury in that case found that defendants failed to warn of the risks of transvaginal mesh.

- A $2 million verdict in the first Bard case tried last year before Judge Goodwin in federal court, including $1.75 million in punitive damages, with a finding that the mesh was defective and contained inadequate warnings. Soon after, Bard settled a second case before trial.

- A $1.2 million verdict against J&J/Ethicon in Texas state court last month. The jury found that the mesh was defectively designed.

To my knowledge, the sole defense victory was a case where J&J/Ethicon obtained a directed verdict in their favor before the case got to a jury. In that case, though, the plaintiff was not allowed to present evidence on the inadequate warnings provided by the defendant.

Juries understand these cases and recognize the harm caused by defective mesh used for pelvic organ prolapse and stress urinary incontinence. The verdicts reflect that understanding–close to $18 million in compensatory and punitive damages in just four cases, with only one loss in a circumscribed case decided by a judge. While the jury system is inherently unpredictable and any trial is risky, these results underscore the strength of transvaginal mesh cases. Overall, this extraordinary track record in court enhances the settlement value of the cases.

It is important to remember that transvaginal mesh devices were never approved for safety and efficacy by the FDA. Rather, the mesh manufacturers relied upon the 510(k) process to quickly get devices marketed in the United States. The 510(k) process determines only whether a new device is "substantially equivalent" to a legally marketed "predicate" device.

As I discussed in another article, the 510(k) process is fundamentally flawed. Transvaginal mesh devices were marketed based on claims of substantial equivalence to predicate mesh devices that were never reviewed for safety and effectiveness. Any settlement negotiations must start with the recognition that the device manufacturers have never convincingly established safety and efficacy. The jury verdicts are consistent with this fact.

Hopefully, the settlement will be clarified for the thousands of women it affects as well as the plaintiffs whose cases will remain in the MDL. Transvaginal mesh devices have caused immense suffering for women and any settlement must fairly compensate each woman for her injuries. We owe it to our clients to vigorously defend their rights, and fight for fair and just compensation for their injuries.

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