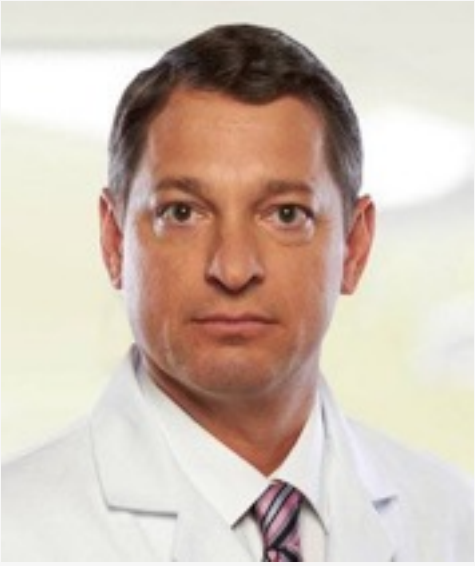
Hindsight Analysis: Defense Experts in Transvaginal Mesh Litigation to Comment on Warnings

Experts hired by the defendant manufacturers in the transvaginal mesh litigation were asked to comment on the 'adequacy of warning' of the device.



SANTA BARBARA, CALIFORNIA, UNITED STATES, September 25, 2019 /EINPresswire.com/ -- Experts hired by the defendant manufacturers in the transvaginal mesh litigation, such as Ethicon and Boston Scientific, are paid upward of $15,000 for a report where they are often asked to comment on the 'adequacy of warning' provided by the manufacturer's Instructions for Use (IFU) at the time the device was implanted. There are many jurisdictions that apply the 'Hindsight' analysis of which the sufficiency of warning listed in IFU at the time of implantation of an injured person compared to what is listed in the current IFU or what a reasonable company would include in an IFU based on current science, current peer reviewed literature, and current complaint data from post-marketing surveillance data.

On June 6, 2019, Dr. Geoffrey W. Cundiff, the President of the American Urogynecologic Society (AUGS) issued a policy statement for AUGS Code of Conduct for Expert Witnesses:

"AUGS may be asked to play in presenting the science and state of the art of our subspecialty to the public. This not only pertains to the media, but also in the court of law before juries of our peers. AUGS members should not shy away from providing opinion. And testimony, in courts of law or of public opinion……testimony before a court of law is an invaluable way to protect patients, but this endeavor must meet the same level of ethical responsibility to our patients that we expect in clinical care."

> "It will be hard to imagine how a defense expert in a 'hindsight' jurisdiction will be able to credibly testify given what is known today about the egregious complications shared by the TVM POP devices"
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> *Dr. Greg Vigna*

AUGS Expert Witness Policy for its members who serve as highly paid witnesses are expected to abide by the following:

"AUGS members whose testimony is deliberately erroneous, deceptive, misleading or without scientific basis may be subject to disciplinary action by AUGS with the following guidelines:

1) Perform a complete and thorough review of all available medical information, before rendering any opinion regarding the case.
2) Provide factual and scientific statements in a truthful manner.
3) Is ethically and legally obligated to tell the truth and such testimony may be subject to peer review. Failure to provide truthful testimony may result in disciplinary action.

On April 16, 2019, the FDA position on the remaining POP devices on the market, understanding that other devices including the Prolift, Prosima, and Pinnacle were 'voluntarily' removed from the market, is as follows:

'the manufacturers Boston Scientific and Coloplast, have not demonstrated a reasonable assurance of safety and effectiveness for these devices, which is the premarket review standard that now applies to them since the agency reclassified them in class III (high risk) in 2016...the companies will have 10 days to submit their plans to withdraw these products from the market.'

Greg Vigna, MD, JD, national pharmaceutical injury attorney, practicing physician, and testifying expert in Life Care Planning comments, "The jurisdictions such as New Jersey, the home of Ethicon, that analyze the adequacy of a warning based on 'Hindsight' is a very favorable jurisdiction for filing new injury cases because the adequacy of the warning disclosed in the IFU at the time of implant for an injured person is compared to what the jury believes a reasonable manufacturer should include in the warning based on current science, current peer reviewed literature, and current post-marketing surveillance data."

Dr. Vigna concludes, "Given that the FDA has a mandate to protect public health, it will be hard to imagine how a defense expert in a 'hindsight' jurisdiction will be able to credibly testify that a warning contained in an IFU for a POP device at the time of implantation of an injured woman was adequate understanding what is known today about the egregious complications shared by the TVM POP devices given that every TVM POP device has either been 'voluntarily' removed from the market or 'ordered' off the market by the FDA."

Cites:

https://www.augs.org/augs-code-of-conduct-for-expert-witnesses/?print=y

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