THE 510(k) PROCESS – SAFETY FORGOTTEN

By Dan C. Bolton, Of Counsel, Keller, Fishback & Jackson LLP

The 510(k) process is relied upon by the medical device industry, including pelvic mesh manufacturers, such as Ethicon/Johnson & Johnson, Atrium Medical Corporation, and Davol/Bard, to quickly get devices marketed in the United States. (The term "510(k)" is derived from the statutory section that created the premarket notification process, section 510(k) of the Federal Food, Drug and Cosmetic Act.)

This procedure is substantially less rigorous than the premarket approval (PMA) process that evaluates the safety and effectiveness of other medical devices. A PMA submission, the most stringent premarketing application required by the FDA, requires clinical trials and other scientific evidence to prove a device is safe and effective. The 510(k) process does not.

This lack of regulatory review has enabled manufacturers to sell mesh for hernia repair, pelvic organ prolapse, urinary incontinence and other uses without any convincing evidence that mesh is safe and effective. As a result, too many mesh patients have suffered.

In a 510(k) submission, the focus is not on the safety and efficacy of the new device. Instead, the 510(k) process determines only whether the new device is "substantially equivalent" to a legally marketed "predicate" device. A device is substantially equivalent if it has the same intended use and same technological characteristics as the predicate device. It does not have to be identical.

The 510(k) process is flawed. Since the predicate device can be a device marketed before May 28, 1976 (before federal law required a 510(k) submission) or a device that was cleared through a previous 510(k) submission, the 510(k) process compares a new device with another one that was itself never reviewed for safety and effectiveness.

Since the predicate device was never reviewed for safety or effectiveness, a 510(k) clearance provides absolutely no assurance that a new device is not harmful. So, today pelvic mesh products are marketed based on claims of substantial equivalence to predicate mesh devices that were never reviewed for safety and effectiveness. And, those predicate devices were marketed based on earlier mesh products that were cleared for marketing without any assurance of safety.

The 510(k) submission provides minimal information to the FDA. The submission includes technological information about the new device, proposed labeling, a comparison to the predicate device, and the conclusory statement that the new device is substantially equivalent to the predicate device. Clinical or other scientific studies are provided in less than 10% of all 510(k) submissions.

Review by the FDA is quick. A decision, based solely on the information provided by the manufacturer, is usually made within 90 days. The FDA "clears" the device for sale. It does not "approve" the device. Denial of substantial equivalence is rare – only about 3% of 510(k) submissions are rejected by the FDA.

Moreover, if a manufacturer claims the new device is a "modification" of a device already marketed and is for the same indication, the modified device can be sold without a 510(k) submission. The FDA has stated that a 510(k) is not required for every modification and believes the manufacturer is best suited to determine whether one is necessary. Thus, a manufacturer can avoid even the minimal 510(k) process if it takes the position that a new device is a modification of a mesh product already on the market.

The pelvic mesh manufacturers have profited enormously from a regulatory scheme that permits the sale of a device, intended for long-term implantation in the body, solely on the manufacturer's substantial equivalence claim and without any scientific evidence proving that the new device is safe and effective.

It is no surprise that the independent Institute of Medicine (IOM), asked by the FDA to evaluate the 510(k) process, concluded in its 2011 report: "the 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions." The IOM emphasized that the 510(k) process is unworkable "as long as the standard for clearance is substantial equivalence to any previously cleared device." Consumers deserve better treatment from medical device manufacturers who profit from a broken regulatory process.

Dan Bolton – a plaintiff's lawyer for thirty years – has been fighting the pharmaceutical industry almost since the day he began his career. Mr. Bolton continues that fight today at Keller, Fishback & Jackson (kfjlegal.com) where he oversees the pharmaceutical and medical device practice. The firm, with offices in Los Angeles, Newport Beach, Oakland and New York, has a nationwide presence in mass tort actions, including hernia and transvaginal mesh litigation. Mr. Bolton's keen understanding of, and creative approach to, pharmaceutical litigation has led him to represent plaintiffs throughout the country. Mr. Bolton was even the subject of an editorial in The Wall Street Journal critical of his success on behalf of plaintiffs.