Denial of Summary Judgment in Transvaginal Mesh Case - A Departure from Products Liability Precedent

In the context of an allegedly defective medical product or device, a plaintiff's remedy typically takes the form of a product liability claim against the manufacturer and/or distributor of the product or device. A current trend among the plaintiff's bar is to add claims against the hospital where the medical device at issue was used or provided to the patient. While historically courts have rejected such claims and have readily disposed of them on summary judgment, at least one Connecticut superior court judge has denied summary judgment filed by a Connecticut hospital sued in products liability. In Farrell, et al v. Johnson & Johnson, Superior Court, Complex Litigation Docket at Waterbury, Docket No. UWY-CV-116014102S, *Order Regarding Motion for Summary Judgment* (*Agati, J*., July 1, 2014), the court rejected the hospital's argument that, as a matter of law, it is not a product seller under the Connecticut Products Liability Act (CPLA). This marks a departure from the current state of the law in Connecticut. This article will summarize this departure and provide some guidance as to how a hospital may prepare for and manage such claims.

A number of superior courts have explicitly rejected products liability claims against hospitals. See, e.g., Zelle v. Bayer Corp., 2012 Conn. Super. LEXIS 892 (Conn. Super. Ct. Feb. 2, 2012.) Plaintiff in Zelle claimed to have suffered an adverse reaction to a contrast agent used during an MRI. On behalf of defendant Danbury Hospital, this firm moved for summary judgment, successfully arguing that the hospital was not a "product seller" of the contrast agent and that, as a matter of law, a plaintiff cannot maintain a products liability claim against a party who is not a product seller. In granting the hospital's summary judgment motion, Judge Brazzel-Massaro relied upon Zichichi v. Middlesex Mem. Hosp., 204 Conn. 399 (1987) which held, "[o]nce a particular transaction is labeled a 'service' as opposed to a 'sale' of a 'product,' it is outside the purview of our product liability statute." The court in Zelle found that the contrast agent was only incidental to the main purpose of the service, obtaining the MRI, and so, as a matter of law, the hospital was not a product seller. In fact, as Judge Adams observed a year later in O'Dell v. Greenwich Healthcare Svs., Inc., 2013 Conn. Super LEXIS 972, *7 (Conn. Super. Ct. Apr. 25, 2013), "[f]ollowing Zichichi there have been what appears to be a unanimous chorus of appellate and trial

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court decisions, either barring product liability claims against hospitals or defining 'product' in a manner hospitable to hospitals."

Despite this "unanimous chorus" among Connecticut courts, at least one superior court judge has now denied summary judgment filed by a Connecticut hospital sued in products liability. In Farrell, which is ongoing, plaintiff had surgery at a Connecticut hospital where her urogynecologist implanted vaginal mesh, and plaintiff's insurance covered the surgery. There was no evidence that the hospital designed, patented, or manufactured vaginal mesh. Plaintiff did not pay for the vaginal mesh and the hospital asserted that the provision of mesh was only incidental to the service of the surgery performed by plaintiff's attending urogynecologist at the hospital.

Regardless of these facts and despite the "unanimous chorus" holding that a hospital is not a product seller, the court in Farrell rejected the hospital's arguments and denied summary judgment, noting that it simply disagreed with the precedent from the past decade and that it viewed the question as one for the trier of fact to determine. All of the transvaginal mesh cases transferred to the Complex Litigation Docket are handled by the same judge. This will not be a one-off decision. Since the mesh products manufactured by these companies were widely distributed across the country, Connecticut hospitals can expect to see an increase in litigation of this type in the future.

By way of background on the product at issue in the Farrell case, surgical mesh has been cleared by the FDA for use in treating stress urinary incontinence since 1996 and for use in the treatment of pelvic organ prolapse since 2002. In October 2008, the FDA issued a notice informing clinicians and patients of adverse events related to the implantation of mesh. According to the FDA, adverse events were "rare" but included vaginal mesh erosion, pain, infection, urinary problems, bleeding, organ perforation, recurrent prolapse, neuro-muscular problems, vaginal scarring, and related emotional effects. However, in July 2011, the FDA published an update, concluding that serious adverse events related to transvaginal mesh were not "rare," contrary to the statements published by the FDA in the 2008 notification, and that transvaginally-placed mesh did not improve clinical outcome over traditional non-mesh repair.

As a result, thousands of product liability lawsuits have now been filed, and continue to be filed, in state and federal courts across the country for injuries alleged to have been caused by transvaginal mesh

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products used for the treatment of pelvic organ prolapse and stress urinary incontinence. Most recently, a verdict of $5.7 million was awarded by a California jury after determining that Ethicon, Inc., a subsidiary of Johnson & Johnson, was liable for the defective design of a mesh product implanted in a plaintiff as well as for the failure to warn of risks of using the product. In addition to Johnson & Johnson and its subsidiaries, other companies including Bard, Endo Health Solutions Inc., Boston Scientific Corp., Coloplast, and Cook Medical Inc. are involved in similar lawsuits across the country. These companies supplied mesh to hospitals in Connecticut and nationwide.

In our practice, we are seeing an increasing number of cases involving transvaginal mesh in which plaintiffs are bringing product liability claims against the manufacturer of the device but also asserting products liability claims against the hospital where the surgery was performed based on allegations that the hospital supplied and sold the mesh to the plaintiff in the course of undergoing surgery. Based on precedent from the past decade, the expectation was that summary judgment would be granted on the grounds that the use of mesh was incidental to the main purpose of the surgery and, as a matter of law, the hospital is not a product seller. Unfortunately, based on the court's denial of summary judgment in Farrell, many hospitals will now find themselves defending against CPLA claims. Moreover, although that decision was rendered in the context of a mesh case, the decision has potentially wide-reaching consequences, as it will certainly be cited by plaintiffs in support of other products liability claims against hospitals.

What should hospitals do? It is advisable to file for summary judgment very early in the proceedings and to pursue argument prior to transfer to the current Complex Litigation Docket. In addition, hospitals should prepare for discovery. It will be necessary to determine the process that was in place for the review, approval, and purchase of vaginal mesh products from 2002 until 2011. This can be a time consuming undertaking as the process for reviewing, approving, and purchasing products has evolved in many institutions, and many of the individuals who had been involved in the process may no longer be accessible. However, having a grasp on the process as early on as possible will assist counsel in maintaining control over written discovery and depositions. The hospital and its counsel will also need to strategize about the ongoing defense of the case and whether to simply cede defense of the defective products portion of the case to the actual manufacturers of the products. The hospital's primary focus in defending the case will likely be amassing evidence to convince the jury that the hospital is not a "product seller" and had no involvement in marketing or promoting the use of the product in these surgeries.

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