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Utah Court Should Find Medical Devices Merit Exception to Strict Product Liability

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The Utah Supreme Court will soon have the opportunity to answer vitally important questions that may have wide-ranging implications for innovation and access in the medical device industry—within Utah and beyond. Recently, in *Burningham v. Wright Med. Grp., Inc.*, 2018 WL 922362, at *1 (D. Utah Feb. 15, 2018), a federal district court in Utah issued an order certifying questions to the Utah Supreme Court regarding, essentially (1) whether the "unavoidably unsafe" exception to strict liability in design-defect claims, in Comment k to Section 402A of the Restatement (Second) of Torts, applies to implanted medical devices, and if so (2) whether it applies equally to medical devices "approved" through the Food and Drug Administration's premarket approval process ("PMA") and those "cleared" through FDA's 510(k) process.

In *Burningham*, a married couple brought several strict liability design-defect claims against a medical device manufacturer, seeking damages for injuries the husband allegedly sustained from three implanted hip devices that FDA cleared through the 510(k) process. The defendants moved to dismiss these claims on the ground that the devices were "unavoidably unsafe," and therefore, categorically barred from strict liability design-defect claims under Comment k. Comment k provides that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965).

Significantly, the Utah Supreme Court applied the Comment k "unavoidably unsafe" exception to FDA-approved prescription drugs in *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991). Wright Medical Group has argued that the exception is not limited to prescription drugs. In its view, *Grundberg* adopted a categorical bar to strict liability claims for *any* class of products that are "unavoidably unsafe"—including medical devices.

The plaintiffs have argued that the "unavoidably unsafe" exception does not apply for two reasons. First, they contend that the Utah court specifically limited its holding in *Grundberg* to FDA-approved drugs. Second, they argue that even if the exception does apply to implanted medical devices, it should apply only to those products that have been "approved" by FDA through the PMA process, and not those that have been "cleared" through the 510(k) process, as the devices at issue in this case were.

With regard to whether Comment k should apply to implanted medical devices, the defendants have the better of the argument. In *Grundberg*, the court applied the "unavoidably unsafe" exception to prescription drugs because of (1) "their unique nature and value," (2) public policy considerations, including the chilling of innovation and driving up the cost of pharmaceutical companies' liability insurance, which would in turn increase drug prices, and (3) "the elaborate regulatory system overseen by the FDA." *Grundberg*, 813 P.2d at 95.

This same reasoning supports extending the exception to medical devices. Medical devices, like prescription drugs, are unique and provide a tremendous benefit to many individuals. Moreover, the public policy considerations that apply to prescription drugs also apply to medical devices in that increased and unpredictable

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liability will inevitably chill innovation and development, and, in turn, limit patient access to these products. Further, liability-insurance cost increases could lead to increases in the price of some medical devices.

Finally, like prescription drugs, medical devices are subject to "an elaborate regulatory system overseen by the FDA." *Grundberg*, 813 P.2d at 95. In *Grundberg*, the Utah Supreme Court observed that FDA weighs prescription drug risks and benefits pre-market and then monitors drugs for safety issues post-market (*e.g.*, through surveillance and adverse-event reporting). *Grundberg*, 813 P.2d at 97. According to the Utah Supreme Court, "[a]llowing individual courts and/or juries to continually reevaluate a drug's risks and benefits ignores the processes of this expert regulatory body . . .." *Id.* at 97.

The same rationale applies for medical devices. By way of background, FDA's regulatory framework subjects medical devices to different levels of oversight based on risk. Sponsors of the highest risk devices, generally, must submit PMAs to FDA, and the agency will "approve" those applications if the evidence shows that "there is a reasonable assurance of safety and effectiveness" for the product's intended use. Sponsors of low-and-moderate-risk devices often must submit premarket notifications, known as 510(k)s. FDA will "clear" a 510(k) when the device is shown to be "substantially equivalent" to a device that is already on the market. Devices are also subject to post-market surveillance, and adverse events reporting requirements.

On the question of whether Comment k should be applied to PMA and 510(k) medical devices alike, the defendants have the better argument as well. As an initial matter, anything less than an across-the-board application of Comment k to medical devices does not make sense. Notably, the Utah Supreme Court in *Grundberg* applied Comment k to *all* FDA-approved prescription drugs for the reasons explained above, and also because the court was "troubled by the lack of uniformity and uncertainty inherent in the case-by-case approach and fear[ed] the resulting disincentive for pharmaceutical manufacturers to develop new products." *Id.* at 94-95. A lack of uniformity in applying Comment k to medical devices would similarly chill innovation and development.

Moreover, for the purpose of liability, there is no reason to treat medical devices approved via the PMA process differently from those cleared through the 510(k) process. Although the 510(k) clearance process is less rigorous than the PMA process, both processes, like the approval process for drugs, implicate safety and efficacy. The agency has previously stated that "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review." U.S. Food & Drug Admin., *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications* (2014). Indeed, FDA's governing statute states that a medical device may only be cleared through the 510(k) process if "the device is as safe and effective as a legally marketed device, and [] does not raise different questions of safety and effectiveness." 21 U.S.C. § 360c(i)(1)(A)(ii)(I).

Even if the Utah Supreme Court were to evaluate the application of Comment k to medical devices on some sort of case-by-case basis, the court should not make binary decisions about the comment's application based on whether the medical device at issue was subject to the PMA or the 510(k) process. Not all 510(k)s are created equal. Some are more robust than others, and 510(k) submissions increasingly contain significant preclinical and clinical data. Although in 1996 the U.S. Supreme Court, in *Medtronic v. Lohr*, 518 U.S. 470 (1996), estimated that FDA's 510(k) review process took as little as 20 hours. Now, more than 20 years later, the process typically takes approximately 177 days. *See* Emergo, *How Long It Takes the US FDA to Clear Medical Devices via the 510(k) Process*, at 5 (Mar. 2017), https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf.

In sum, the differences between FDA-approved prescription drugs and medical devices—whether subject to FDA's PMA or 510(k) process—are not sufficient to justify disparate treatment under Comment k's "unavoidably unsafe" exception. Differential treatment would be arbitrary and would undoubtedly chill innovation and development in the medical device space, reduce patient access, and increase prices for products that are vital to patients' health. Accordingly, the Utah Supreme Court should adopt a categorical application of Comment k for all medical devices.

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