Hybrid Thinking and Medical Devices

"Hybrid" is one of those pop terms showing up in all walks of life. Witness the case of *Shuker v. Smith & Nephew, PLC*, No. 16-3785 (3rd Cir. March 1, 2018) Krause, C.J. With the Medical Device Amendments of 1976, Congress added comprehensive medical device approval processes to the Federal Food, Drug, and Cosmetic Act, prescribing tiers of federal requirements for certain devices corresponding to the device's inherent risk level. In exchange for compliance with the strictest federal mandates, Congress afforded manufacturers express preemption from state laws imposing different or additional "safety or effectiveness" requirements for those devices. 21 U.S.C. § 360k(a)(2).

This case presents an issue of first impression among the Courts of Appeals: how courts should apply that express preemption provision to state law tort claims challenging the design and manufacture of a medical device comprised of multiple components, some of which are from "Class III" medical devices subject to federal requirements, *Riegel v. Medtronic, Inc*., 552 U.S. 312, 322-23 (2008), and some of which are from medical devices that carry a different class designation and are not subject to those requirements, see *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-78, 494-95 (1996).

Since the plaintiffs' negligence, strict liability, and breach of implied warranty claims in their Second Amended Complaint are expressly preempted, the District Court's ruling was affirmed in those respects. However, the plaintiffs adequately pleaded other, non-preempted claims, and because jurisdictional discovery is warranted with respect to personal jurisdiction over one of the defendants, the Third Circuit reversed the District Court's dismissal of some of the plaintiffs' claims in their Third Amended Complaint. The appellate tribunal vacated the District Court's personal jurisdiction ruling, and remanded for proceedings consistent with the opinion.

After Walter Shuker underwent a hip replacement surgery that resulted in unexpected complications, he and his wife, Vivian Shuker, brought tort claims against Smith & Nephew, Inc. ("Smith & Nephew"), the manufacturer of his hip replacement system, and Smith & Nephew, PLC ("PLC"), the manufacturer's parent company.

The question of first impression confronted by the court was at the intersection of the different classes of devices with their each unique approval schemes: How does the court apply the Medical Device Amendments' express preemption provision to a "hybrid system," i.e., a system that is itself a "device" but that is comprised of Class II components in addition to one or more Class III components?

Mr. Shuker underwent total hip replacement surgery in 2009. The hip replacement system "implant[ed]" was regulated as a "device" under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h), but was comprised of multiple components, all

manufactured by Smith & Nephew. Some components replaced the top of Mr. Shuker's thighbone (or femur) with a metal head, metal sleeve, and a stem connecting the metal head to the thighbone, while another component rested on his hip socket (or acetabulum). These components were all Class II devices approved through the relatively lenient § 510(k) process. A final component, the "R3 metal liner," mediated the connection between his hip socket and his thighbone and was seated atop the hip socket component, App. 42; unlike the other components, the liner underwent the rigorous premarket approval process as a supplemental component for a separate Smith & Nephew Class III device, the Birmingham Hip Resurfacing System. *Shuker v. Smith & Nephew PLC*, No. 13-6158, 2015 WL 1475368, at *2-3 (E.D. Pa. Mar. 31, 2015). Together with the metal head and metal head sleeve replacing the top of Mr. Shuker's thighbone, the metal liner created a "metal-onmetal articulation" at Mr. Shuker's hip socket.

As the parties agreed, because the R3 metal liner's labeling reflected that the FDA had not approved the liner for use outside of the Birmingham Hip Resurfacing System or in a total hip replacement system, Smith & Nephew's promotional materials marketing the R3 metal liner as an "option for its R3 Acetabular System," a separate hip system constituted "off-label promotion" and the liner's use in Mr. Shuker's total hip replacement system constituted an "off-label" use.

About twenty-one months after his hip replacement surgery, Mr. Shuker "began developing increasing pain and discomfort in his buttocks, groin, and thigh, limiting his daily activities." His surgeon performed an aspiration procedure that revealed "metallic debris" within Mr. Shuker's body, indicating that "Mr. Shuker's pain was caused by metal sensitivity due to the degeneration of the metal-on-metal articulation," which needed to be replaced to relieve his pain. Mr. Shuker then underwent revision surgery to replace the R3 metal liner, followed by additional surgeries to remove and replace his entire hip replacement system when the first revision surgery did not relieve his pain.

Seeking to hold Smith & Nephew and its parent company PLC liable for Mr. Shuker's hip replacement complications and for Mrs. Shuker's loss of consortium, the Shukers filed suit, bringing various common law claims, and later adding claims based on violations of federal law. 6 PLC moved for dismissal from the case for lack of personal jurisdiction, and Smith & Nephew moved for summary judgment on some of the Shukers' claims, asserting that the Medical Device Amendments expressly preempted those claims.

Taken together, the statutory definition of "device," the treatment of off-label uses, and the guidance of the FDA all counsel in favor of scrutinizing hybrid systems at the component-level. In that circumstance, § 360k(a) preempts any state law "with respect to" a Class III component that is "different from, or in addition to" a federal requirement and that relates either "to the safety or effectiveness of the device" or "to any other matter included in a requirement applicable to the device under [the Act]." 21 U.S.C. § 360k(a).

In sum, the negligence, strict liability, and breach of implied warranty claims asserted in the Second Amended Complaint, would impose non-parallel state law requirements and are therefore expressly preempted. The appellate court affirmed the District Court's order in that regard. This is not to say that all failure-to-warn allegations as to hybrid systems would be preempted. On the contrary, as the FDA notes, a claim premised on a state requirement that the R3 System carry a warning against "use with metal liners," or that it only be used with polyethylene liners, for example, "would not implicate § 360k(a)" because "the FDA did not impose device-specific labeling requirements on the R3 system components."

Together these factual allegations lead to the reasonable inference that Smith & Nephew's marketing materials caused Mr. Shuker's surgeon to recommend the R3 metal liner and to install it within Mr. Shuker's hip replacement system, a course of action which in turn caused Mr. Shuker's subsequent injuries.

The court held that the Shukers were entitled to limited jurisdictional discovery to explore their alter ego theory of general personal jurisdiction, i.e., jurisdiction arising from a defendant's "'continuous and systematic' contacts with the forum, whether or not those contacts are related to the [plaintiffs'] cause of action."

Driving a hybrid vehicle will be a lot easier than understanding the scope and existence of a hybrid FDA medical device claim.

Clifford A. Rieders, Esquire
Rieders, Travis, Humphrey,
Waters & Dohrmann
161 West Third Street
Williamsport, PA 17701
(570) 323-8711 (telephone)
(570) 323-4192 (facsimile)

Cliff Rieders is a Board Certified Trial Advocate in Williamsport, is Past President of the Pennsylvania Trial Lawyers Association and a past member of the Pennsylvania Patient Safety Authority. None of the opinions expressed necessarily represent the views of these organizations.