KAPPS v. BIOSENSE WEBSTER:
WHO IS LIABLE WHEN A REPROCESSED MEDICAL DEVICE CAUSES INJURY?

by
Stephen A. Klein
Andrew L. Reissaus
Hollingsworth LLP

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ABOUT THE AUTHORS

Stephen A. Klein is a partner at Hollingsworth LLP, where he practices in the Firm's Pharmaceutical Products and Toxic Torts & Products Liability groups, as well as the Firm's policyholder-side insurance coverage, environmental liability, and government contracts groups. Mr. Klein represents pharmaceutical and other clients in major post-*Daubert* federal and state court cases, including mass tort and multi-district litigation. Mr. Klein is a graduate of the University of Pennsylvania (B.A., 1987, *magna cum laude*) and the University of Michigan School of Law (J.D., 1990, *cum laude*) and was a member of the *Michigan Law Review*.

Andrew L. Reissaus is an associate at Hollingsworth LLP, where he practices in the Firm's Pharmaceutical Products and Toxic Torts & Products Liability groups. He is a graduate of Georgetown University (B.A., 2006, *magna cum laude*) and The George Washington University School of Law (J.D., 2009, *high honors*, *Order of the Coif*).

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As hospitals and medical providers face mounting pressure from insurers, consumers, and governmental reformers to decrease their operating costs while maintaining quality of care, one increasingly important arrow in their quiver is the use of reprocessed medical devices. Hospitals have lost more than $1 billion of late on procedures involving expensive medical devices and are looking at cheaper alternatives, including using reprocessed devices.[1] A provider will purchase a new medical device from the original manufacturer (often referred to as the Original Equipment Manufacturer, or "OEM"), use the device in one patient, and then contract with a "reprocessor" to collect, sort, clean, and re-packaging the device for subsequent use in another patient. The cost of a reprocessed device often is a fraction of the original price.

[1]Anjali Athavaley and Jon Kamp, Medical Device Makers Face More Pricing Pressure, WALL STREET JOURNAL (Oct. 17, 2011).

While the use of reprocessed devices undoubtedly provides significant societal benefits, the practice creates difficult questions of proof and liability when the reprocessed device causes injury during its subsequent use or uses:

- Did the alleged product defect occur during the original manufacturing process or during the reprocessing?
- Did the use of the product in the original patient somehow compromise the device's integrity in a manner not corrected during reprocessing?
- Who is responsible for providing warnings and instructions for use – the OEM or the reprocessor?
- Who should be considered the manufacturer?
- Is the reprocessed device even the same product as the one manufactured by the OEM?

A decade ago, legal commentators grappled with some of these questions,[2] but there has been little case law addressing the allocation of liability in the context of reprocessed medical devices. A recent decision by the federal district court in Minnesota begins to answer some of these questions.

The court's opinion in *Kapps v. Biosense Webster, Inc.*[3] provides a detailed analysis of the claims and issues arising when a reprocessed medical device fails, resulting in a lawsuit against both the OEM and the reprocessor. The opinion addresses *Daubert* motions to exclude expert testimony and motions for summary judgment filed by the device's original manufacturer, Biosense Webster, Inc., a division of Johnson & Johnson ("Biosense"), and by

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[2]*See, e.g.*, Emil P. Wang, *Regulatory and Legal Implications of Reprocessing and Reuse of Single-Use Medical Devices*, 56 FOOD & DRUG L.J. 77, 90 (2001).

[3]09-CV-1039 PJS/JSM, ___ F. Supp. 2d ___, 2011 WL 4470701 (D. Minn. Sept. 27, 2011).

the reprocessor, Ascent Healthcare Solutions, Inc. ("Ascent"), and in so doing dives headlong into the reprocessed-device thicket. The court's conclusions generally reinforce the difficulty of trying to hold an OEM liable when a device has been subjected to reprocessing.

I. REPROCESSING MEDICAL DEVICES: REGULATORY AND INDUSTRY BACKGROUND

The practice of reprocessing medical devices for a second use is expressly sanctioned by the Food and Drug Administration (FDA) in its industry guidance if not directly in FDA regulations.[4] FDA leaves it to the OEM to decide whether the original device is reusable or for single use only, and single-use devices ("SUDs") may be approved for reprocessing where the device is capable of being adequately cleaned and sterilized. GAO studied the practice and concluded that reprocessing does not result in elevated health risks. In its report, GAO neatly summarized the regulatory framework governing reprocessed devices:

> The decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable. . . . [Other devices] are labeled and marketed by the original manufacturer as single-use devices (SUD), but with clearance from FDA are marketed after being reprocessed for

[4] *See* FDA, *Guidance on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* 1 (Aug. 14, 2000).

> reuse – that is, they are cleaned, sterilized, and performance-tested by [the reprocessor].[5]

Devices that are commonly reprocessed include catheters, laparascopic instruments (scissors, clamps, graspers, and dissectors), compression sleeves, and non-ported trocars for endoscopic procedures. Reprocessors generally collect and reprocess a given hospital's devices and return the same units after reprocessing to the hospital that originally purchased them. In such cases, the reprocessing contract typically provides that the hospital retains title to the devices at all times. As such, the reprocessor plays something of a hybrid role between manufacturer and service provider. More recently, reprocessors have begun to utilize a different model in which they collect and mix used devices from multiple hospitals and clinics and resell the reprocessed devices without regard to a particular unit's original owner, thereby acting more like a true manufacturer. The latter model has an important advantage – it allows a hospital to acquire reprocessed devices on a much shorter timeframe, and often at even lower cost. For example, Ascent advertises that its new Rapid-Return™ program decreases reprocessing turnaround time as compared to its traditional "Client-Owned Device Return" program from 30 days to fewer than seven days.[6]

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[5]U.S. Gov't Accountability Office, GAO-08-147, *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk* 1 (2008).

[6]*See* Stryker Sustainability Solutions, *Product Return* (last visited Nov. 28, 2011).

II. *KAPPS*: THE FACTS

The device at issue in *Kapps* was a single-use "mapping" catheter for measuring the conductivity of tissues in the heart. The catheter had a "lasso" design featuring a lasso-shaped wire loop extending out from the catheter body. The wire was adhered to the catheter body with polyurethane glue.[7]

Biosense marketed the catheter as a SUD, with the explicit instruction that the catheter was "[f]or single use only." Yet, contrary to Biosense's instruction, Ascent contracted with a number of hospitals, including the Mayo Clinic, where Kapps received treatment, to collect and reprocess their Biosense lasso catheters. Ascent's contract with the Mayo Clinic provided that title to the catheters remained with the Mayo Clinic, but Ascent expressly warranted "the functionality of the reprocessed [catheters]," and in marketing materials it stated that, "[L]egally and practically, we are the manufacturers of our reprocessed and remanufactured devices."[8] Ascent's reprocessed catheters were stamped with a new serial number and were repackaged with new instructions for use prepared by Ascent.

Kapps suffered from atrial fibrillation. During a procedure at the Mayo Clinic in June 2005, the reprocessed catheter was manipulated inside Kapps's heart, but the lasso portion inadvertently caught on the mitral valve leading into his left ventricle. In his doctors' attempt to free the catheter, the lasso

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[7] *See, generally*, *Kapps*, 2011 WL 4470701, at *1-4.

[8] *Id*.

portion snapped off and remained entangled in the mitral valve. The doctors ultimately managed to extricate the lasso, but Kapps's mitral valve was damaged in the process and he required open-heart surgery to replace the valve with a prosthesis.[9]

"At the time of injury, the reprocessed device could not be said to have been in the same condition as when it left Biosense's control. This created problems of proof for the plaintiff that ultimately proved insurmountable."

Upon inspection of the catheter after the incident, three observations were made, the significance of which was subject to dispute: First, the polyurethane dome at the tip of the catheter body was darkened rather than clear; second, the used catheter body had what appeared to be a smear of polyurethane glue on it; and third, the lasso portion appeared to have pulled cleanly out of the catheter body.[10]

III. TRADITIONAL CLAIMS AGAINST THE OEM, WITH A (REPROCESSED-DEVICE) TWIST

Kapps brought claims against both the OEM, Biosense, and the reprocessor, Ascent, and asserted the usual litany of product liability claims: manufacturing defect, warning defect, design defect, breach of warranty, and negligence. But the claims against Biosense posed an inherent difficulty unique to the context of reprocessed devices: At the time of injury, the reprocessed device could not be said to have been in the same condition as

[9] *Id.*

[10] *Id.* at *6.

when it left Biosense's control. This created problems of proof for the plaintiff that ultimately proved insurmountable.

A. Manufacturing Defect

Kapps retained a biomedical engineering expert, Dr. Bruce H. Barkalow of the Michigan Technological University, to support his manufacturing defect claim. Dr. Barkalow posited that the catheter's failure could have been caused by any or all of four possible manufacturing problems, two of which would have been the responsibility of Biosense: (1) The device could have had some latent defect from the original manufacturing process that was not exposed during the initial use only because the lasso happened not to become ensnared on the first patient's mitral valve; (2) the catheter as manufactured by Biosense could have been defective in that it "could not withstand the Ascent remanufacture process;"[11] (3) Ascent might have damaged the catheter upon reprocessing by exposing the polyurethane to inappropriate chemicals, *i.e.*, solvents, that weakened the adhesive bond; and (4) Ascent might have physically damaged the catheter during reprocessing.[12]

"In a ruling that will have significance in many reprocessing cases, the court also held that the plaintiff could not rely on the doctrine of *res ipsa loquitur* to establish product defect as to Biosense."

[11]The court noted that this theory requires one to make two assumptions to impose liability on Biosense: that a non-defective catheter should be able to withstand ordinary reprocessing procedures, and that Ascent subjected the catheter only to ordinary reprocessing procedures. *Id.* at *7.

[12]*Kapps*, 2011 WL 4470701, at *6-8.

With regard to the theories implicating Biosense, Dr. Barkalow's testimony was far from clear and somewhat contradictory, but the court gave Kapps the benefit of the doubt and assumed Dr. Barkalow to be opining that the smear of polyurethane on the catheter body most likely occurred during the original manufacturing process and indicated a product defect attributable to Biosense. Even so, the court found that Dr. Barkalow was unable to provide a clear or persuasive opinion regarding how that supposed defect contributed to the device's failure. The court thus excluded Dr. Barkalow's opinions as to Biosense, finding that Dr. Barkalow failed to "reliably connect" his opinion to the underlying data – in this case the "single datum" of the polyurethane smear present on the catheter body – as required by Rule 702. The court rejected Dr. Barkalow's *ipse dixit* that the smear indicated a material defect that contributed to the product failure.[13]

In a ruling that will have significance in many reprocessing cases, the court also held that the plaintiff could not rely on the doctrine of *res ipsa loquitur* to establish product defect as to Biosense. The court observed that there were at least two events that could have materially changed the condition of the catheter after it left Biosense's control: the reprocessing by Ascent, and the use of the catheter in the second patient (Kapps). Thus, Kapps could not establish one of the elements of *res ipsa loquitur*, *i.e.*, that the product was in

[13] *Id.* at *16.

the same material condition at the time of failure.[14] This concern was not present with regard to the reprocessor, however, and thus the court found that the manufacturing defect claims against Ascent were viable under a *res ipsa loquitur* theory.[15] Under this analysis, *res ipsa loquitur* in cases involving reprocessed devices is likely to be available as to the reprocessor, but not the OEM.

B. Warning Defect

Although Ascent had replaced Biosense's label and instructions for use with its own as part of the reprocessing procedure, and Kapps's doctors admitted they did not read even that label, Biosense nonetheless also faced claims of defective warning. Kapps alleged that Biosense fell short in two respects: by not warning about the risk of mitral valve entrapment and failing to provide instructions on how to extricate an entrapped catheter, and by not warning of the dangers associated with reprocessing.[16]

To overcome the fact that Biosense's label on the original device was not even a part of Ascent's packaging, Kapps contended that Biosense should have issued a "dear doctor" letter to the medical community, which presumably would have been seen by the doctors using the reprocessed device. In response, Biosense argued that it was not the "manufacturer" of the

[14] *Id.* at *22.

[15] *Id.* at *29.

[16] *Id.* at *22.

reprocessed device and thus had no duty to warn the users of Ascent's product. Biosense analogized itself to a brand-name drug manufacturer sued by a patient prescribed only the generic equivalent – most courts find that the brand manufacturer has no duty to warn the consumers of the generic drug. But the court rejected the analogy, reasoning that unlike a brand manufacturer, an OEM in the reprocessed device context arguably *is* the manufacturer (or at least *a* manufacturer) of the product to which the plaintiff actually was exposed. The court declined to rule *per se* that the OEM is not the operative manufacturer.[17]

"Thus, the warning advocated by the plaintiff amounts to a statement by Biosense that '[w]e really mean it." The court found no duty by Biosense simply to "emphasize that it was serious about its warning [not to use reprocessed catheters].'"

But even assuming that Biosense had a duty to warn Kapps, the court still found the warnings claims to be deficient. Kapps's warnings expert, Dr. David G. Benditt of the University of Minnesota Medical School, a cardiologist, opined that Biosense should have issued a Dear Doctor letter instructing doctors to "be very careful" when using the lasso catheter because of reports of mitral valve entrapment. But, the court observed, such a warning is "virtually content-free," and thus Kapps could not show proximate

[17] *Id.* at *23-24. The analogy breaks down for another reason, but one that is favorable for OEMs. Whereas generic drugs are required by law to bear the same label warnings as the branded reference drug, *see* 21 C.F.R. § 314.150(b), reprocessors of medical devices are not similarly restricted, and indeed are obligated make changes to their warnings and instructions necessary to ensure that their label on the reprocessed product remains "truthful and not misleading." FDA, *Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA* 8 (July 30, 2001). Thus, unlike generics, a device reprocessor is not wholly dependent on the OEM's warnings.

causation, *i.e.*, that the Dear Doctor letter he proposed would have prevented his injury.[18]

As to Biosense's failure to warn of the dangers of reprocessing, the court noted that Biosense's instructions for use specifically designated the devices for single use only. Thus, the warning advocated by the plaintiff amounts to a statement by Biosense that "[w]e really mean it." The court found no duty by Biosense simply to "emphasize that it was serious about its warning [not to use reprocessed catheters]."[19] Under this holding, an OEM that markets its device as single use will be immunized against the claim that it nonetheless should have foreseen and warned that a reprocessor might ignore the single-use instruction.

C. Design Defect

In theory, design defect claims against the OEM do not entail the same proof issues as manufacturing defect claims. The OEM indisputably is responsible for the device's original design, and ordinary reprocessing procedures generally do not alter the product's basic design. Biosense still prevailed on Kapps's design defect claim, however, because the plaintiff failed to present reliable supporting expert testimony. The principal deficiency was Dr. Benditt's failure to offer an opinion concerning a proposed alternative design. As the court observed, "a plaintiff cannot prevail in a design-defect

[18] *Id.* at *12, 23-25.

[19] *Id.* at *25.

case simply by arguing, in the abstract, that a product is defectively designed."[20] Thus, while the design defect claims against Biosense were dismissed, OEMs may not always be able to escape such claims so easily, particularly if future courts share *Kapps*'s reluctance to find that the OEM is not an operative "manufacturer" of the reprocessed device.

D. Punitive damages

The court also dismissed Kapps's claims for punitive damages against both defendants, and its ruling with regard to Ascent was particularly noteworthy. The court found that FDA's express approval of the practice of reprocessing medical devices meant that Ascent's decision to reprocess the lasso catheter alone could not support an award of punitive damages, even in the face of Biosense's express single-use instruction.[21] This decision offers reprocessors some measure of protection and would require a plaintiff to go beyond the mere decision to market a reprocessed device.

IV. IS THE REPROCESSOR THE "MANUFACTURER?"

While the *Kapps* court, as noted, kept open the possibility that the OEM may be considered a manufacturer of the reprocessed device, it left no doubt with regard to the reprocessor. Ascent pointed to its contract with the Mayo Clinic specifying that the hospital retained title to the catheters at all times to

[20] *Kapps*, 2011 WL 4470701, at *28. With no evidence of product defect against Biosense, the court also dismissed Kapps' warranty and negligence claims. *Id.* at *28-29.

[21] *Kapps*, 2011 WL 4470701, at *32-33.

argue that it should not be deemed the manufacturer. But the court noted that Ascent replaced Biosense's instructions for use and product serial number with its own, warranted the functionality of the reprocessed catheter, and marketed the catheter as its own product equivalent to Biosense's, even expressly claiming to be the manufacturer "legally and practically." The court found that these indicia of a manufacturer overcame the contrary contract language, and it noted that Ascent appears to provide both a service (*i.e.*, reprocessing) *and* a product (a usable catheter). Thus, Ascent carried a manufacturer's duties to warn and to provide a defect-free product.[22]

V. ASCENT'S ALLEGED FDA VIOLATIONS: *BUCKMAN* PREEMPTION, LEARNED INTERMEDIARY, AND THE DUTY TO WARN

Kapps made a number of arguments based upon his allegation that Ascent failed to comply with FDA regulations governing reprocessed devices. The court made short work of his attempt to build a cause of action out of the regulatory firmament.

Most Class II medical devices such as catheters receive regulatory approval under the pre-market notification provision in Section 510(k) of the Food Drug and Cosmetic Act ("FDCA").[23] This section applies to original and reprocessed devices alike. Biosense received 510(k) approval for its lasso catheter in August 2000, and two years later Ascent filed a 510(k) application

[22] *Id*. at *29-30.

[23] 21 U.S.C. § 360(k).

for reprocessing that listed 68 different models of Biosense mapping catheters, though not the specific lasso catheter at issue in *Kapps*. Instead, Ascent determined that that particular catheter was sufficiently similar to those listed in its application such that it could proceed by "line extension" of the approved devices rather than requiring a separate 510(k) approval.[24]

Kapps's expert, Dr. Barkalow, opined that Ascent's decision to rely upon a line extension was a violation of FDA regulations. The court assumed without deciding that Dr. Barkalow was qualified to offer this opinion, but nonetheless excluded this testimony as irrelevant to Kapps's claims: Ascent's reprocessing either caused a product defect or it did not, but the device's regulatory status had no impact.[25] Importantly, the court also found that federal law impliedly preempted any claims based on Ascent's alleged failure to comply with FDA regulations under *Buckman Co. v. Plaintiffs' Legal Committee*.[26] In *Buckman*, the Supreme Court held that there is no private cause of action to enforce FDA regulations. *Kapps* applied this rule to the plaintiff's negligence *per se* claim based on FDA regulations, because negligence *per se* requires conduct "'that would give rise to liability under state law *even if the FDCA had never been*

"Importantly, the court also found that federal law impliedly preempted any claims based on Ascent's alleged failure to comply with FDA regulations under *Buckman Co. v. Plaintiffs' Legal Committee*."

[24] *Kapps*, 2011 WL 4470701, at *5.

[25] *Id.* at *18-19.

[26] 531 U.S. 341 (2001).

enacted.'"[27] The court thus took a broad view of implied preemption under *Buckman*, which is important for Class II devices that are not the beneficiary of the express preemption applicable to Class III devices.[28]

Kapps also attempted to argue that Ascent's alleged violation of FDA regulations was relevant to its learned intermediary defense because his surgeon had testified that he would not have used the reprocessed device had he known it was not specifically approved by FDA.[29] The court found that Kapps's argument was properly understood as a failure to warn claim and held that it failed as such because a manufacturer does not have a duty to communicate "any and all information that might affect a customer's decision to use one of its products," for example, that a product was manufactured using child labor.[30] Rather, the duty to warn is limited to instructions for safe use and dangers inherent in improper use, and the regulatory status of Ascent's reprocessed catheter implicated neither. Thus, the court took an appropriately restrictive view of a device manufacturer's duty to warn; even if Kapps could show that Ascent's failure to warn about the absence of specific regulatory approval proximately caused his injury, he could not show that it was a breach of Ascent's duty.

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[27]*Kapps*, 2011 WL 4470701, at *5 (emphasis in original) (citation omitted).

[28]*See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

[29]*Kapps*, 2011 WL 4470701, at *20.

[30]*Id.*

CONCLUSION

Given the urgent focus on taming medical costs, the popularity and importance of reprocessed medical devices undoubtedly will continue to grow. The savings can be significant: Ascent has reported that a lasso catheter of the type used in Kapps costs $1,500-$1,650 new, but only $700 when reprocessed, a reduction of 53%-58%.[31] Ascent also claimed that its reprocessed devices saved its customers more than $170 million in 2009 alone, and it continues to expand the number and types of devices it reprocesses.[32]

As reprocessed devices increasingly find their way into the nation's operating rooms and health clinics, so too will they find their way into American court rooms. *Kapps* is one of the first cases to systematically consider the application of traditional tort concepts in the reprocessing context. If it is any guide, OEMs whose devices are reprocessed will not be immune from personal injury claims, but will be able to assert strong defenses to liability. *Kapps* begins to separate the wheat of such claims from the chaff, and plaintiffs who cannot link the reprocessed product's defect directly to the OEM may have difficulty trying to resort to evidentiary presumptions or an expansive reading of the duty to warn. While *Kapps* certainly will not be the last word, it offers a promising start.

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[31] *Ascent Receives 510(k) Clearance for Reprocessed Biosense Webster LASSO Circular Mapping Catheters*, DIAGNOSTIC AND INTERVENTIONAL CARDIOLOGY (Nov. 18, 2008).

[32] Julie E. Williamson, *Budget- and Eco-savvy Hospitals Boost Reprocessing Compliance*, HEALTHCARE PURCHASING NEWS 36, 39 (Mar. 2010).

