



For Immediate Release

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## **Paper Calls for Fair Assessment of Liability When Reprocessed Devices Cause Harm**

In recent years, medical device reprocessing – the cleaning, repair, and re-sterilization of used medical equipment – has grown into a profitable industry. The use of such devices has also become more common in hospitals, and increasingly judges, juries, and policy makers will have to confront the question “who is liable” if recycled devices cause harm. A new Washington Legal Foundation WORKING PAPER explores this important issue, and what impact its resolution will have on device’s original manufacturers, device reprocessors, and medical consumers.

The publication, **BEYOND THE “YUCK FACTOR”:** **PRODUCT LIABILITY IMPLICATIONS OF MEDICAL DEVICE REPROCESSING**, was authored for WLF by **Peter J. Goss**, a partner in the Minneapolis, Minnesota office of the law firm Faegre & Benson LLP.

According to a leading official in the reprocessors industry association, “the biggest single problem we have is the ‘yuck factor.’” Mr. Goss appropriately leads off the WORKING PAPER with this quotation, and in his introduction explains the basics of device reprocessing and the fact that many of the recycled devices were originally labeled “single use” by the device manufacturer. He also notes that federal regulatory scrutiny, in the form of tighter Food & Drug Administration regulations, and public examination through media reports, have brought to the forefront safety concerns beyond the “yuck factor.”

On the issue of liability, logic and fairness, Mr. Goss states, would impose liability for harm on the company which reprocessed an offending device. Mr. Goss states, however, that “the reprocessing industry continues to fly under the plaintiffs’ radar; to date, there are no reported verdicts or judicial opinions holding a reprocessor liable for injuries caused by a reused single-use device.” In the paper’s first section, the author identifies five factors which help explain why reprocessors have eluded product liability claims.

In the next two sections, Mr. Goss a troublesome conundrum that is developing in the medical device market, and how that is connected to safety and the pursuit of savings. The conundrum is that “at the same time that reprocessing is expanding, new devices are becoming increasingly ill-suited to reuse.” These new devices are smaller, contain more complex, microscopic features, and thus are difficult if not impossible to completely sterilize. The reprocessors argue that FDA regulation and improved cleaning techniques protect patients, and that any objections to reuse of devices should be overborne by the economic benefit to the health care system.

Those sections conclude with the question, “Accepting the reprocessing industry on its terms – that reprocessing is a matter of economics, not safety – are the risks and rewards of reprocessing allocated rationally and appropriately?” Mr. Goss feels that the answer is no,

and concludes the WORKING PAPER with a highly detailed and instructive narrative which works through a hypothetical product liability lawsuit. The hypothetical illustrates the wide range of troubles a reuse-oriented suit poses for a medical device's original manufacturer, including damage to reputation, reduction in stock value, loss of customers, and repercussions for insurance coverage.

As the author concludes, "not every product liability case involving a reprocessed SUD will follow the thread of the foregoing hypothetical. But no matter how well the OEM fares, the fundamental unfairness remains: the OEM is facing liability for a product it did not sell, and whose quality and characteristics after the first use are beyond its control."

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Copies of this educational paper, WLF WORKING PAPER, Number 141 (September 2006), can be obtained by forwarding a request to: Publications Department, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, D.C. 20036, or calling (202) 588-0302.