THE
NATIONAL LAW REVIEW

Lawsuits Against Endoscope Manufacturers and Health Care Facilities to Increase Following UCLA's "Superbug" Outbreak

Sunday, March 8, 2015

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Biotech, Food, Drug
Consumer Protection
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On February 18, 2015, the *Ronald Reagan UCLA Medical Center* reported two patients had died after being infected with a "*superbug*," known as ***carbapenem-resistant Enterobacteriaceae (CRE),*** during endoscopic procedures performed at its hospital. UCLA also reported that five additional patients were infected and up to 179 were exposed to CRE from October 2014 to January 2015. UCLA professed that the source of the CRE outbreak stems from contaminated Endoscopic Retrograde Cholangiopancreatography (ERCP) duodenoscopes used during endoscopic procedures to diagnose and treat diseases of the liver, bile ducts and pancreas. Despite UCLA's decontamination and sterilization efforts, which it claims exceeds the manufacturer's (Olympus Medical Systems Group) standards and national guidelines, these reusable scopes reportedly had residual body fluids and organic debris from prior procedures within the device's crevices. The presence of such material exposed subsequent patients to serious CRE infections. In response to the contaminated scopes, UCLA averred that the manufacturer's cleaning standards did not completely eradicate CRE and that either additional cleaning techniques are required or a significant redesign of the product is necessary.

In addition to UCLA's announcements, the Food and Drug Administration (FDA) on February 19, 2015, released an alert to health care professionals, including those working in reprocessing units in health care facilities, explaining the particular challenge of effectively cleaning ERCP duodenoscopes. According to the FDA, the process of cleaning and disinfecting or sterilizing reusable duodenoscopes, known as "reprocessing," may be challenging due to its design and unique mechanisms. To prevent CRE transmissions, the FDA recommended device users to adhere to the manufacturer's cleaning instructions despite the devices inherent reprocessing difficulties.

On February 20, 2015, the Centers for Disease Control (CDC) also released a featured article reporting the rise of lethal CRE infections. According to the CDC, it has warned about CRE for more than a decade but the number of CRE infections has only substantially increased in recent years. In fact, the CDC reported a "seven-fold increase in the spread of the most common type of CRE during the past 10 years." The CDC also reported that CRE has been detected in at least one medical facility in 42 states. This considerable increase is alarming because of the antibiotic resistant nature of CRE and the fact that nearly half of those with a CRE infection die.

As a result of the UCLA outbreak, product liability lawsuits were quickly filed by infected UCLA patients or their family against Olympus Corporation. *See Young v. Olympus Am. Inc.*, No. BC573399 (Cal. Super. Ct., Los Angeles County, filed February 23, 2015); *The Estate of Antonia Torres Cerda v. Olympus Am. Inc.*, No. BC573665 (Cal. Super. Ct., Los Angeles County filed February 25, 2015). These recent cases, however, are not the first time the issue of contaminated endoscopes were the subject of a lawsuit. *See Alwine v. South Hills Endoscopy Ctr.*, No. GD-12-017815 (Pa. Ct. of Common Pleas, Allegheny County, filed September 24, 2012). In *Alwine*, plaintiff asserted a class action lawsuit against a medical center alleging its failure to properly clean, sterilize and disinfect endoscopes and thereby increasing the risk of contracting a viral or bacterial infection.

In light of the escalating number of CRE infections and heightened public awareness of the UCLA CRE outbreak,

additional lawsuits are likely to increase nationwide. With this in mind, it is imperative for manufacturers and device users to comply with federal and state regulations, particularly the mandatory reporting requirements for when an adverse event involving a medical device is discovered. *See* 21 C.F.R. § 803. Manufacturers should also review their product's warnings, labels, and instructions to reduce CRE transmissions and limit potential liability. In addition, health care personnel should continue to strictly comply with manufacturer instructions and thoroughly explain associated risks to patients when using reprocessed endoscopic devices.