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The Causation Problem in Robotically Assisted Surgical Device Litigation, Reuters News, August 31, 2021

By Abbye Alexander, Christopher Tellner, and Henry Norwood

Robotically assisted surgical devices (RASD) are one type of computer-assisted surgical systems. RASD have become popularized in recent years and are now commonly used by health practitioners to perform a variety of different surgical procedures. The precision and minimal invasiveness offered by these devices make them attractive to health practitioners and patients, but like all products, RASDs are not flawless and generally not regulated by any singular government agency.

The U.S. Food and Drug Administration (FDA) cleared RASDs for use in laparoscopic surgical procedures in general surgery, cardiac, colorectal, gynecologic, head and neck, thoracic and urologic. The FDA does not supervise or credential physician training, however. That role is assumed by manufacturers, physicians, and health care facilities. Some professional societies and specialty board certification organizations have developed and support training for RASD specialty physicians. Specialty boards also maintain RASD specialty physician certification status.

RASDs have been the subject of increased litigation due to alleged defects in the manufacturing or design, as well as the failure by health care facilities and practitioners to properly maintain and operate the devices. A variety of causes of action are available to plaintiffs in these matters, including strict products liability, negligence, corporate negligence, medical malpractice, and breach of warranty.

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