HUIE

MEDICAL DEVICE LITIGATION

Litigation by patients and their families related to healthcare often include claims implicating a medical device. These types of claims can create unique defense concerns and strategies when questions arise regarding alleged defects, maintenance, training and proper use. Knowledge of the law pertaining to design, manufacturing, and the use of medical devices is critical, but no more so than understanding how the maintenance and use of that device fits into the delivery of care to the patient. HUIE's thirty years of experience defending health care related claims includes numerous occasions where these potentially dangerous waters have been successfully navigated on behalf of health care providers, manufacturers, and distributors.

Exemplary medical device cases defended by HUIE attorneys include claims arising from the use of breast implants, dialysis devices and disposables, infant incubators, pediatric catheters, pacemakers, pacemaker leads, hospital beds, Latex gloves, ventilators, radiology contrast medium, hyper-hypothermia devices, defibrillators, magnetic resonance imaging devices, anesthesia breathing circuitry, and TMJ implants.

EXEMPLARY MEDICAL DEVICE CASES

TUMT Device: Summary Judgment was obtained in favor of the manufacturer of a Microwave Delivery device used during a transurethral microwave thermotherapy (TUMT) procedure. The device was a Class III non-surgical device restricted to prescription use that is intended to relieve symptoms and obstructions associated with benign prostatic hyperplasia (BPH). Plaintiff sued the manufacturer and the physician who performed the procedure claiming that he suffered abdominal and bladder pain, dysuria (painful urination) and urinary incontinence as a consequence of the procedure. Summary Judgment grounds included (1) data captured and stored by the device established there was no malfunction during the patient's procedure; (2) there was no warranty for use of the device on patients for whom the safety and effectiveness had not been determined or on patients not diagnosed with benign prostatic hyperplasia; (3) use contrary to the labeling and instructions constituted unforeseeable product misuse and an intervening and superseding cause that relieved the manufacturer/seller of liability pursuant to *Morguson v 3M Co.*, 857 So.2d 796 (Ala. 2003) and (4) as a Class III prescription medical device it could by definition "present a potential unreasonable risk of illness or injury" and, thus, was not defective or unreasonably dangerous when properly prepared and accompanied by proper directions and warnings under the Alabama Extended Liability Manufacturer's Doctrine.

This case was defended by HUIE partner, J. Allen Sydnor, Jr.

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External Cooling Device: Summary Judgment was obtained in favor of the manufacturer of a Class II "external cooling device." The device is prescribed for use by a patient's physician and is intended to be used only by sophisticated, trained users. Plaintiff alleged she was burned when the device was used on her knee postoperatively at a Montgomery hospital. The Complaint characterized the incident as a "chemical burn, probably from bleach." The hospital owned seven (7) of the cooling units but could not identify which one was involved in Plaintiff's treatment. The Court held that Plaintiff did not have a breach of warranty cause of action and that the learned intermediary doctrine barred Plaintiff's claims. It noted there was no allegation that Plaintiff sustained a thermal injury and that the subject unit was a cooling device that did not have the capacity to heat water to a temperature that would burn human skin. Because the manual established that only distilled water should be used, use of other liquids constituted a misuse or unintended use of the device barring any liability under the Alabama Extended Liability Manufacturer's Doctrine. It was undisputed that use of the device with "distilled water only" would not cause a "chemical burn" and distilled water does not have the odor of bleach.

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Extremity MRI: A favorable settlement was obtained for the North American distributor of an extremity MRI manufactured in Italy after opening statements at trial. The MRI was a Class II device that received 510k pre-market clearance in 1993. The device was sold to an orthopedic group and the distributor's personnel provided user training. The device was used to scan Plaintiff's left thigh to help evaluate a palpable nodule. Plaintiff alleged that the MRI failed to show the presence of the tumor and that the tumor went untreated such that it grew and ultimately caused the patient's death. A personal injury lawsuit was filed and pending at the time of the patient's death. Plaintiff alleged that the device was not designed, manufactured, sold, distributed, or intended to perform MRI's of the thigh and that the manufacturer and distributor failed-to-warn of dangers associated with the use of the MRI. There were additional claims of breach of express and implied warranties based on the theory that the MRI was not reasonably fit and suitable for the purposes for which it was intended to be used. Plaintiffs further alleged that the distributor negligently or wantonly trained or instructed the co-defendant orthopedist and his staff regarding the proper use of the device. Plaintiff's training claim was supported by testimony of the codefendant orthopedist as an attempt to shift blame. The distributor and the manufacturer retained experts to support the position that the MRI film did capture the tumor in its image sufficient to warrant follow-up if accurately interpreted and to support the adequacy of the design of the product and the appropriateness of the training manual and instructions.

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Hypo-Hyperthermia Device: A favorable settlement was obtained during mediation of a personal injury/wrongful death action involving burns sustained during the use of a 16-year-old hypo-hyperthermia device. The device had three high temperature safety devices and three low temperature safety devices as well as displays and alarms. The manuals and labeling made it clear that the device was intended to be used only by trained healthcare providers who had read the Operation Manual and had a thorough understanding of the device. Preventive Maintenance procedures were to be performed on a quarterly basis including testing of the high temperature safety devices. The manual cautioned "Use distilled/sterile water only. Failure to use distilled/sterile water may result in poor performance and damage." It was established that (1) treating nurses never read the manuals and had not been trained; (2) patient was left unmonitored for longer than the recommended times; (3) there was significant corrosion on the key components of the high temperature safety devices; and (4) the recommended Preventive Maintenance had not been performed. Defense experts included a metallurgist who examined the corrosion to establish poor maintenance and the existence of high levels of chlorine which meant tap water rather than saline/distilled water had been used, design engineers who established conformance with accepted designs and a hospital clinical engineering expert who established the practices that would be reasonable for a manufacturer to expect to be in place.

This case was defended by HUIE partner, J. Allen Sydnor, Jr.

Blood Tubing Sets: A favorable settlement was reached in a wrongful death case involving an allegedly defective blood tubing set (BTS) used in dialysis. HUIE had defended several suits in Alabama arising out of injuries and deaths allegedly caused by BTS manufactured by the same company that were the subject of a voluntary recall. Certain lots of BTS linked to one mold used in a facility in Mexico were associated with incidents of hemolysis (i.e., destruction of red blood cells). Plaintiff's theory was that the same defect existed in the BTS used in the subject treatment. After passing out, CPR was initiated and paramedics transported the patient to a local hospital where she expired. An autopsy revealed severe atherosclerotic vascular disease with 80% to 95% occlusion of three main vessels. A subsequent report referenced "Multiorgan vascular congestion consistent with history of acute hemolysis." Hemolysis has a number of potential chemical and mechanical causes and there was an absence of evidence that established the cause of the hemolysis. Production and sales documents were used to establish the history of the product and the absence of any connection to the earlier recall. The subject BTS underwent functional testing that included comparison of the results with those of identical testing on additional samples. After the functional test, the BTS underwent well-documented destructive testing including dissection of the cartridge that confirmed the absence of any obstructions like those involved in the recall that could cause hemolysis and to make measurements proving conformance with manufacturing specifications.

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