CLIENT ALERT

Medical Device Lawsuit Watch - June 2006

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This summary of key lawsuits affecting medical devices is provided by the Health Care Law Group of Crowell & Moring LLP, in collaboration with the firm’s Torts, Antitrust and Intellectual Property Law Groups.

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Emergency Care Research Institute v. Guidant Corp.

No. 2:06-cv-01898 (E.D. Pa. 5/04/2006)

Emergency Care Research Institute (“ECRI”), a medical device industry research group, has sued Guidant Corporation for a declaratory judgment that ECRI has not tortiously interfered with Guidant’s contractual relations by compiling and publishing pricing data about Guidant’s products.

ECRI is a health services research agency that publishes information about medical devices. Its publications include PriceGuide, a searchable database of prices paid by device purchasers for a range of single-use medical products. According to the complaint, approximately 400 hospitals, health systems, group purchasing organizations, and other entities subscribe to PriceGuide. Subscription to the database allows purchasers to gain information about competing devices and helps them negotiate prices with manufacturers. PriceGuide contains information about various Guidant products.

In 2001, Guidant changed its business policies to require customers to maintain confidentiality for the actual prices paid for Guidant devices. In 2004, Guidant contacted ECRI to object to the inclusion of certain pricing information related to Guidant on
the public portion of ECRI’s website, claiming that the information was subject to confidentiality agreements and that it had to be “returned” immediately to Guidant. ECRI allegedly complied with the request, and asked customers from whom it obtained information for PriceGuide not to supply ECRI with information that the customers were required to keep confidential.

In 2005, Guidant again contacted ECRI, this time to demand that ECRI cease and desist from publishing confidential pricing information about Guidant devices in PriceGuide. The parties thereafter met to discuss which Guidant information was confidential and therefore not to be published in PriceGuide. The parties have yet to come to an agreement.

Noting that Guidant is involved in litigation concerning similar issues against a company called Aspen Healthcare Metrics, ECRI filed the suit for declaratory judgment, asking for a ruling on its rights to continue to publish pricing information about Guidant products. Specifically, ECRI has asked the court to declare that (1) it has not committing the tort of interference with Guidant’s contracts or contractual relations; (2) the publication of ECRI’s PriceGuide does not tortiously interfere with Guidant’s contracts or contractual relations; (3) application of Guidant’s theories to support injunctive relief against ECRI would violate the First Amendment and the Pennsylvania Constitution; and (4) application of Guidant’s contractual confidentiality provisions against ECRI would violate ECRI’s right to due process.

**DME Supplier Pays Largest-Ever Civil Monetary Penalty to Resolve Kickback Allegations**

On May 15, 2006, the Office of Inspector General (“OIG”) announced that it had entered into a settlement agreement and corporate integrity agreement with Lincare Holdings Inc. and subsidiary Lincare Inc. to resolve kickback and Stark allegations.

The government alleged that Lincare engaged in a nationwide scheme to pay physicians to refer patients to the company, including paying consulting fees and entering into Medical Director agreements, and giving physicians free items such as golf equipment, fishing trips, tickets to events, and medical and office equipment. The OIG contended such payments resulted in referrals to Lincare to furnish durable medical equipment and supplies that were payable by federal health care programs.

The settlement requires Lincare to enter into a five-year company-wide corporate integrity agreement. The corporate integrity agreement mandates that the company hire an independent review organization to monitor the company’s compliance both with the settlement and with federal law. Lincare did not admit to any wrongdoing.

According to a May 25, 2006 copyright story in BNA’s Health Care Fraud report, the company simultaneously resolved three other ongoing investigations by the OIG and the Department of Justice, related to improper reimbursement under Medicare and other health care programs. The combined settlements will require Lincare to pay a total of $12 million.
**United States of America v. Ross A. Caputo**

*No. 03-cr-126 (N.D. Ill. 4/13/06)*

As reported by Mealy’s Newsletter Service on May 19, 2006, Ross A. Caputo and Robert M. Riley, the president and vice president of AbTox Inc., were convicted on April 13, 2006, of federal crimes arising out of the sale of an unapproved sterilizer. The sterilizer, known as the Plazlyte Sterilization system, allegedly caused eye damage or loss of sight in 18 patients.

According to the indictment, the defendants obtained pre-market FDA approval for a sterilizer for use only on stainless steel instruments without hinges or lumens. The device actually marketed by Abtox, which was larger and had a different design, was never approved by the FDA. According to the government, when hospitals used the larger sterilizers for surgical instruments that contained brass joints, the brass reacted with the sterile solution to produce a copper acetate residue. This residue ultimately caused eye damage and blindness when used in eye surgeries.

Among the allegations in the indictment were that the company and its executives had concealed information from and made false statements to the FDA regarding the marketing and sale of the Plazlyte device, had misrepresented to customers that the sterilizer was a general purpose sterilizer, and misled hospitals, including the Veterans Affairs Administration, to believe that the Plazlyte device was approved by the FDA.

After a nine-week trial, the two executives were convicted for conspiracy to defraud the federal government, fraud, wire fraud, and selling adulterated devices. On May 8, the defendants moved for a new trial, arguing that evidence introduce at trial about eye injuries was irrelevant and highly prejudicial, as well as improperly admitted. They also contested their convictions on constitutional grounds, claiming that the FDA’s regulatory scheme was vague and unclear.

**Hall v. Johnson & Johnson**

*Case No. 1:03-cv-5153 (D.N.J. 4/25/06)*

The United States District Court for the District of New Jersey recently granted summary judgment for medical device manufacturer Johnson & Johnson, finding that the premature failure of a knee prosthesis was insufficient by itself to support a claim for product defect.

Plaintiff Bradley Hall filed suit against Johnson & Johnson on September 3, 2003 after his knee implant device, a P.F.C. Sigma® Knee System Curved Tibial Insert, failed only six years after implantation – well short of the device’s 15-20 year lifespan. Plaintiff alleged that the knee implant was defective due to a problem with Johnson & Johnson’s sterilization procedures, which caused the implant to degrade faster than expected.

Johnson & Johnson moved for summary judgment, arguing that this case was indistinguishable from the court’s previous decision in *McMillan v. Johnson & Johnson*, 04-cv-1180, in which the court granted summary judgment after the plaintiff failed
to present any evidence suggesting the device degraded faster than expected, or that the sterilization procedure was associated with plaintiff’s injuries.

Mr. Hall presented the court with various medical articles describing how problems with the sterilization procedure could affect the degradation rate of the knee implant, and deposition testimony attesting that his doctor told him the device would last 15 to 20 years. The court found this insufficient, finding that Mr. Hall in fact presented no credible evidence supporting his claim that the implant should have lasted longer than five years, or that its deterioration was due to a defect rather than normal wear-and-tear. While the court acknowledged that, in some instances, the “normal course of human experience” permits an inference that the product was defective due to the fact that it failed to perform as expected (e.g. when an automobile fails after only 4,000 miles of use), the knee implant at issue here was a “complex instrumentality” that could have failed for various reasons. Because of the complexity of the device, the court held that expert testimony was required to demonstrate a defect and to exclude other possible causes for the failure.

Finding that the plaintiff’s evidence merely showed that the sterilization method employed by Defendants was “imperfect”, but not defective, the court granted summary judgment for Johnson & Johnson.

**Burden v. Johnson & Johnson Medical**  
**No. 04-20777 (5th Cir. 4/19/2006)**

The Fifth Circuit recently asked the Texas Supreme Court to clarify the scope of a Texas indemnity law. The statute at issue in the case requires manufacturers to indemnify “innocent sellers” of the manufacturer’s products in the event of a products liability suit.

This lawsuit was originally filed in 2000 by Kathy Burden, a dental hygienist, as a product liability action. Ms. Burden’s injuries were allegedly caused by the latex gloves manufactured by Defendants Johnson & Johnson Medical, Ansell Healthcare Products, Inc. (“Ansell”), and Becton Dickinson & Co (“BD”), and sold by Defendant Owens & Minor, Inc (“Owens”). The case was eventually transferred to the latex glove multidistrict litigation. Eventually, Owens was dismissed from the suit because Plaintiffs were unable to show that Owens had sold any of the latex gloves that caused Ms. Burden’s injuries. After it was dismissed, Owens continued to pursue its cross-claims for indemnity against the glove manufacturers.

Both BD and Ansell maintained that they had properly offered to defend and indemnify Owens in accordance with Texas Civil Practice and Remedies §82.002. Owens claimed that BD and Ansell had made only offers of “partial and limited defense, with conditions”, instead of the full defense and indemnity Owens alleged was required by §82.002, because they offered to indemnify and defend Owens only for claims related to their own products. Owens argued that §82.002 required the BD and Ansell to provide a full defense and indemnity against all claims, and then seek contribution from the other manufacturers. While the district court disagreed with many of Ansell’s and BD’s arguments, it granted summary judgment in favor of the two manufacturers. Owens appealed, bringing the case to the Fifth Circuit.
The Fifth Circuit noted that “neither the plain language of §82.002 nor the legislative intent indicate the scope of the indemnification and defense required by §82.002 in a situation in which it is undisputed that the seller sold products made by the several manufacturers sued, yet the seller has sought indemnification from less than all of those manufacturers.” The Court acknowledged that the Texas Court of Appeals had answered the issue in a well-written and sound opinion in *Ansell Healthcare Products, Inc. v. Owens & Minor, Inc.*, -- S.W.3d --, 2006 WL 824236 (Tex.App.-Texarkana March 31, 2006), but that the Court could not rely on it because it was an unpublished, non-precedential ruling. In *Ansell*, the court held that limited offers to defend do not fulfill the duty to defend.

Stating that the Court could not resolve the remaining issues in the case without deciding the “central question”, the Fifth Circuit certified the following question for the Texas Supreme Court:

“When a distributor sued in a products liability action seeks indemnification from less than all of the manufacturers implicated in the case, does the manufacturer fulfill its obligation under Texas Civil Practice and Remedies §82.002 by offering indemnification and defense for only the portion of the distributor’s defense concerning the sale or alleged sale of that manufacturer’s product, or must the manufacturer indemnify and defend the distributor against all claims and then seek contribution from the remaining manufacturers.”

*In Re: Guidant Corp. Implantable Defibrillators Products Liability Litigation No. 05-1708 (MDL Docket No. 1708 4/27/06)*

In the latest development in the multi-district defibrillator litigation against Guidant Corp., the MDL court recently rejected arguments that Guidant Corp. was under federal control for the purposes of federal jurisdiction, and remanded two cases to Minnesota state court.

Plaintiffs filed their claims in state court in 2005, alleging various products liability and tort claims for injuries caused by defects in cardiac defibrillators manufactured by Guidant. Guidant had removed the suits to the federal multidistrict litigation under 28 U.S.C. §1442(a), which permits removal by defendants who act under the direction of a federal officer, show a nexus between the alleged conduct and the official authority, and have a colorable federal defense. Plaintiffs moved for remand, arguing that there was no federal subject matter jurisdiction to support removal.

Guidant argued that the design, manufacture, marketing, and distribution of its cardiac defibrillators were subject to “rigorous federal regulations” and were under the “continuous supervision and direction of the Federal Food and Drug Administration.” Guidant also pointed to the “comprehensive” approval authority the FDA wields over Guidant’s devices, and the pre-market approval process that the company must comply with before bringing devices to market. Because it was subject to such a comprehensive regulatory scheme, Guidant argued that it acted under the direction of the “United States or an [agency thereof]” in manufacturing the devices at issue.

The MDL court disagreed, finding that the level of FDA oversight in bringing medical devices is much less extensive than what is required by 28 U.S.C. §1442(a). The court found that the FDA did not exercise control over Guidant’s creation or sale of the...
defibrillators, and certainly not in a way that was related to the defects and deception alleged by the Plaintiffs. The court also stated that Guidant’s position would allow almost any participant in a federally regulated industry to claim federal jurisdiction.

Finding no basis for federal jurisdiction, the MDL court remanded the case to state court.

Wheelchair Supplier to Pay $2.7 Million to End Fraud Investigation

Settlement Agreement

According to a May 25, 2006 press release by the Office of the United States Attorney for the Middle District of Florida, Mobility Products Unlimited LLC (“Mobility”) and its chief executive, John Ward, have entered into a settlement agreement and corporate integrity agreement to resolve civil fraud allegations against the company.

Mobility is the country’s second-largest supplier of motorized wheelchairs and motorized scooters. The government began investigating the company after allegations surfaced that the company was billing Medicare for used wheelchairs and scooters as if they were new; that the company had separately billed for accessories, such as seatbelts and adjustable armrests, that came standard from the manufacturer; that the company was offering Medicare beneficiaries manual wheelchairs for free in order to induce the sale of a motorized chair; and that the company charged Medicare beneficiaries at higher rates than other customers.

In exchange for a release under the OIG’s permissive exclusion authority, Mobility agreed to pay $2.775 million, plus interest, and to comply with a five-year corporate integrity agreement (“CIA”). The CIA requires Mobility to hire an independent review organization to conduct comprehensive reviews of Mobility’s claims to Medicare. Mobility acknowledged no wrongdoing, and the government made no concession that its claims were unfounded.

Aetna Settles Suit with Sonar Imaging Device Manufacturer

Order Granting Motion to Dismiss

According to an April 27, 2006 copyright story reported by The Denver Business Journal, Aetna Inc., one of the country’s largest health insurance companies, has reached a settlement agreement with Cavitat Medical Technologies, a maker of sonar imaging systems.

Cavitat filed suit against Aetna in 2004, after Aetna allegedly refused to cover diagnostic procedures for neuralgia-inducing cavitational osteonecrosis (“NICO”) that involved the use of Cavitat’s device. The device is used to detect infected cavities in the jaw bone through the use of computer imaging technology. Aetna deemed the procedures experimental and stated there was a lack of scientific data proving the clinical value of the procedure. Cavitat alleged Aetna’s statements were defamatory and that they cost the company sales and profits.
After most of Cavitat’s claims were dismissed, Aetna filed a countersuit against Cavitat in June of 2005. Aetna claimed Cavitat orchestrated efforts defraud Aetna by making misrepresentations to providers regarding the manner and form in which providers could submit claims to Aetna for NICO services. Aetna also claimed the company made false statements to the FDA, the ADA, and others regarding the capabilities of the Cavitat device, that Cavitat executives had engaged in the unauthorized practice of medicine, and that the lawsuit was brought in order to intimidate insurance companies into paying for services associated with the use of the device. Based on these acts, Aetna claimed Cavitat violated the Colorado Consumer Protection Act, engaged in fraud, and civil conspiracy to defraud.

In January of 2006, the court dismissed all of Aetna’s counterclaims, finding that it lacked standing to assert its claims under the Colorado Consumer Protection Act, and that Aetna failed to plead its fraud claims with the requisite level of particularity. Because the underlying claims failed, the civil conspiracy claims were also dismissed.

The terms of the settlement are confidential, but include a release of all claims relating to the suit.

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**Applied Medical Resources Corp. v. United States Surgical Corp.**

On May 15, 2006, the Court of Appeals for the Federal Circuit vacated a district court’s grant of summary judgment of non-infringement by United States Surgical Corporation (“U.S. Surgical”) of an Applied Medical Resources patent for a laparoscopic surgery device.

In 2003, Applied Medical filed suit alleging that U.S. Surgical’s VERSAPORT™ PLUS trocar infringed Applied Medical’s own patent. (the “’553 patent”). A trocar is a medical instrument that provides a channel through the abdominal cavity through which instruments can be inserted during laparoscopic surgery. During laparoscopic surgery, the patient’s abdomen is inflated with a gas in order to maintain a distended state. To prevent the gas from leaking out, trocars have a valve which forms a seal around the inserted instrument. The seal disclosed in the ’553 patent is a floating seal to provide for movement to an off-axis position during use. The inner portions of the seal, which define the orifice, move substantially intact and without deforming.

The Federal Circuit found that the district court erred in its analysis of the structures disclosed in the ’553 patent and how they perform functions set forth in the asserted claim. In addition, the district court erred in finding the declaration of Applied Medical’s technical expert insufficient to raise a disputed issue of fact. The Circuit Court vacated the grant of summary judgment of non-infringement and remanded the case for further proceedings.
PHT Corporation Announces Settlement with CRF Corp.

According to a March 31, 2006 press release, PHR Corporation has settled its patent infringement suit against CRF Corp. PHR Corporation, a provider of electronic patient reported outcome (ePRO) solutions, filed suit against CRF on January 28, 2004, alleging infringement of PHR’s 6,095,985 patent. The patent relates to a portable health monitoring system.

The terms of the settlement agreement are confidential, but include dismissal of all of the claims and counterclaims in the lawsuit and grant CRF a world-wide license.

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