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LIFE SCIENCES
CLAIMS CASE STUDY

Light Therapy Device

Medmarc Defense Team Prevails in a Case Against a Light Therapy Device Manufacturer

EXECUTIVE SUMMARY

The plaintiff, in this case, suffered permanent scarring from burns left by an intense pulse light (IPL) device manufactured by Medmarc's insured, IPL Therapy Manufacturer (fictitious name). The plaintiff asserted multiple negligence claims, as well as failure to provide informed consent. The plaintiff demanded a jury trial and $1.2 million in damages. Medmarc settled favorably to avoid a jury trial and IPL Therapy Manufacturer paid the amount of its deductible.

THE MANUFACTURER & THE PRODUCT

IPL Therapy Manufacturer manufactures devices for medical and cosmetic applications. The device at issue provides IPL therapy, a technology that treats wrinkles, sun damage, and acne. IPL Therapy Manufacturer also manufactures companion handpieces for face, hand, and body applications.

THE INCIDENT

The plaintiff was the subject in a training event hosted by IPL Therapy Manufacturer at a medical spa. The plaintiff agreed to receive IPL therapy during the training.

Two IPL Therapy Manufacturer sales representatives instructed the aesthetician at the medical spa, an RN, on how to perform the procedure. The aesthetician used a deeper setting than recommended for the plaintiff's treatment. The laser burned into the dermis layer of the plaintiff's skin, causing second-degree burns and alleged permanent disfigurement.

The plaintiff also alleged that IPL Therapy Manufacturer did not provide informed consent which is consent by the patient to the surgical or medical procedure, after being informed of the relevant medical facts and the risks involved.

THE ALLEGATION

The plaintiff filed a state law complaint asserting the following claims:

- Negligent supervision, for IPL Therapy's failure to properly supervise its employees, who failed to protect the plaintiff from harm.
- Negligent entrustment, for IPL Therapy's entrustment of the device to the medical spa.
- Negligent supervision, for the defendant's failure to warn the medical spa staff of risks associated with the device use, as well as failure to ensure device users received proper training.
- Lack of informed consent.

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DAMAGES

The plaintiff asserted exemplary damages totaling $1.2 million for pain and suffering and emotional distress.

LEGAL CHALLENGES

- As a Class II medical device, the claims against IPL Therapy Manufacturer were not subject to pre-emption (barred) under federal law. Class II devices do not present an "unreasonable risk of illness or injury" in the eyes of the FDA. Class III devices receive higher scrutiny; under *Riegel v. Medtronic Inc.,* private plaintiffs cannot assert claims against them.

- The plaintiff in this case demanded a jury trial—often an unpredictable, expensive, and time-consuming scenario. "Medmarc is committed to mitigating risk," said Medmarc vice president of claims Sonia Valdes. "To reduce the risk for our customer, we worked to avoid a jury trial and obtain an early settlement."

THE PROCESS

IPL Therapy Manufacturer immediately investigated its training protocols and procedures for sales representatives and other employees.

Medmarc hired an expert to inspect the IPL device for any possible defects in design, manufacturing, or marketing. The expert also reviewed the plaintiff's medical records for useful information, such as current medications that could have caused skin sensitivity.

During discovery, Medmarc experts uncovered an issue: IPL Therapy Manufacturer had not received FDA clearance for the hand piece-console combination used during the training event. Upon learning of the oversight, the defendant immediately filed the appropriate paperwork with the FDA for approval for the two components to be used together. Resolving that issue brought down the value of the case in the eyes of the court.

RESULT

Medmarc's legal team moved to dismiss most of the claims. The district court agreed. Among other reasoning, the court concluded that IPL Therapy Manufacturer did not know the medical spa would use the device in a way that would harm the plaintiff. It also concluded IPL Therapy Manufacturer sales representatives did not owe the plaintiff a legal duty to inform them of the risks associated with a cosmetic procedure.

Claims for negligent supervision, training, and entrustment to the salespeople survived; however, with most claims dismissed, the case was subject to a $465,000 cap on noneconomic damages under state law.

After an original demand of $1.2 million and defense cost rising, Medmarc was able to favorably settle with the only cost to the insured limited to their deductible amount.

SUMMARY

- Cases involving serious physical injuries lead to intense emotions and excessive monetary demands. "Medmarc balances sensitivity with determination to get a favorable result for our customers," said Valdes. "Ongoing communication with our insureds is a key component of our 40 years of success."

- Parent devices and accessories receive individual classifications, UDIs, and clearances/approvals, and must be approved for use individually and together.

- Contact Medmarc as soon as you are notified of a serious adverse event. The sooner Medmarc receives notice, the sooner we can get to work.

Medmarc has a long history of insuring defending medical device manufacturers and providing risk management services.

To learn more about how Medmarc's claims management, call us toll-free at 800.356.6886

CASE STUDY DISCLAIMER