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Medicolegal Sidebar: Corporate Relationships and Increased Surgeon Liability Risk

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In our last column (January 2013; <http://dx.doi.org/10.1007/s11999-012-2686-8>) [1], we addressed the subject of corporate malfeasance and associated surgeon liability in relation to off-label marketing of Norian bone void filler by device manufacturer Synthes. The federal criminal complaint in that case was directed at the

company, and corporate executives at Synthes received jail sentences for their misconduct. The concern for consulting surgeons who helped market and promote Norian for a non-FDA-approved use—vertebroplasty—was that the corporate malfeasance could exaggerate surgeon liability, as injured patients sued individual surgeons for damages related to Norian used in vertebroplasty.

In this column, we examine the unusual outcome of a civil lawsuit filed against an orthopaedic surgeon and a device company, with the goal of understanding the mechanisms of surgeon-industry relations; while financially rewarding, they can expose surgeons to substantial liability risk. The case described below has educational value

for the orthopaedic community; all identities and factual information below are drawn from publicly available sources [3, 4]. We conclude by offering practical pointers to help avoid the scenario described below.

Case History and Background

On May 23, 2003, a 15-year-old patient named Whitney Engler underwent knee arthroscopy with a partial meniscectomy, loose body removal, plica resection, and chondroplasty for persistent symptoms related to such. Surgery was performed by head team physician of the San Diego Chargers, Dr. David Chao, at his San Diego clinic, Oasis MSO Inc. The operation was uneventful, and after surgery, a cold therapy device, Polar Care® 500 (Breg, Inc, Vista, CA, USA), was prescribed to help minimize swelling and reduce knee pain.

The Polar Care® 500 is a Class II prescriptive device, requiring a physician's prescription [4]. The device is designed to pump cold water through pads applied directly to the skin. Continuous cold flow therapy helps with knee swelling and pain after surgery, and the device is used commonly

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Note from the Editor-in-Chief: We are pleased to publish the next installment of Medicolegal Sidebar to the readers of Clinical Orthopaedics and Related Research®. The goal of this quarterly column is to encourage thoughtful debate about how the law and medicine interact, and how this interaction affects the practice of orthopaedic surgery. We welcome reader feedback on all of our columns and articles; please send your comments to eic@clinOrthop.org.

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by orthopaedic surgeons across the United States. Each ice change allows 8 to 11 hours of continuous-flow cold therapy to the affected limb.

Dr. Chao's clinic sold and rented the Polar Care[®] 500 to surgical patients and provided the device to Engler for use at home. Engler used the Polar Care[®] device as instructed and returned in a week, stating her left leg had symptoms of a nonfreezing cold injury. At that visit, she was reportedly told to continue using the device as much as possible. After another week of use, the plaintiff's mother noted on her calendar that the wound was red, angry, and blistered.

On June 12, Engler woke up to find a black eschar on the skin underneath the Polar Care[®] cold pad. Her parents brought her to the emergency room, on Dr. Chao's instructions. She claimed Dr. Chao stated he had never seen such an injury before, and she was referred to a plastic surgeon. Multiple soft tissue operations followed, leaving the patient with a scar and skin sensory changes.

Engler filed a lawsuit on August 16, 2006, against Dr. Chao, his clinic Oasis MSO Inc, and the device's manufacturer Breg, Inc. The complaint was filed in the San Diego Superior Court [2]. The legal cause of action against Dr. Chao was related to professional negligence, and all defendants were charged with fraud by misrepresentation

and concealment. Engler additionally alleged breach of fiduciary duty against Chao and Oasis MSO Inc and product liability against Oasis MSO Inc and Breg, Inc.

To help understand this lawsuit, the specific contentions [4] set forth by the plaintiff are listed below:

- Plaintiff alleged Dr. Chao recommended to her, and to her parents, that they use the Polar Care[®] 500 because it was better than a bag of ice or frozen peas, since it provided a continuous flow of cold water to the limb. Engler was told to use the cooling device as much as possible after the surgery to minimize swelling, including sleeping with the cooling pads in place around the knee, to maximize her chances of making a full recovery.
- Engler said she used the device continuously, as instructed, and within a week started exhibiting the hallmark symptoms of a nonfreezing cold injury. Engler said she returned to see Dr. Chao on May 30, 2003, with the symptoms of nonfreezing cold injury. She contended Dr. Chao misdiagnosed the skin injury and told her to keep using the Polar Care[®] 500, which they were renting from Dr. Chao's clinic. This continued until the emergency visit on June 12.
- Engler alleged, in response to her question about the cause of her

eschar injury, Dr. Chao said he had never seen anything like it before and referred her to a plastic surgeon for consideration of a full-thickness skin graft.

- Engler contended the Polar Care[®] 500 device was dangerous when used as directed; Breg, Inc, knew, the longer a patient used the device, the greater was the risk of developing nonfreezing cold injuries; and even after learning of injuries from the device, the company did not change the instructions or warnings on the device.
- Engler complained Dr. Chao and his clinic were involved in an unlawful prescription scheme to profit from selling and renting Polar Care[®] 500 devices; further, the manner in which the device was rented and sold violated state law and medical ethics.
- Engler said Dr. Chao knew the Polar Care[®] 500 device could cause injury because he had been sued previously by another patient who had been prescribed the same device and experienced a nonfreezing cold injury. That earlier lawsuit had been settled with Dr. Chao in 2002, only about a year before he prescribed the device to the plaintiff with the same usage instructions.

In their response to these complaints, the defendants answered Engler had misused the cold-therapy device and

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use of the Polar Care® 500 could not cause a nonfreezing cold injury if instructions were followed. Furthermore, Dr. Chao maintained the plaintiff had admitted to him that she had used the device at too cold a temperature; alternately, she had used the device with the wrong surgical dressings [4].

Nature of Damages Claimed

Engler claimed she had to undergo additional surgical procedures on her knee to minimize the scar and symptoms related to it. She anticipated additional scar revision operations in the future to maximize the function and appearance of her knee. She complained of a sensory neuropathy manifested by hyperesthesias and dysesthesias in the skin adjacent to the scar.

The defendants countered that, despite the need for surgical débridement of the wound and two scar revision operations, Engler suffered no permanent physical limitations and she returned to high school track and tennis and later participated in collegiate equestrian competitions.

Pretrial Negotiations and Outcome

The plaintiff's pretrial offer, made under the relevant section of California

Code of Civil Procedure, was to the USD 1,000,000 limit of Dr. Chao's insurance policy. The plaintiff's final demand just before trial was USD 4,000,000. Dr. Chao offered to waive costs and not file a malicious prosecution action if the plaintiff dismissed the case with prejudice. Breg, Inc, offered USD 150,001 on April 21, 2010; USD 275,001 on April 26, 2010; and USD 500,001, on September 16, 2010. Oasis MSO Inc offered USD 50,000 on June 3, 2010.

The parties could not agree to a settlement, and the case was heard by a San Diego jury. On July 31, 2012, the jury returned a verdict in favor of the plaintiff. Gross damages were awarded in the total sum of USD 12,696,220. The jury apportioned negligence as follows: Dr. Chao: 50%; Oasis MSO Inc: 10%; and Breg, Inc: 40%. Economic damages were USD 68,270, and noneconomic damages were calculated at USD 5,127,950. The excess verdict was for punitive damages, apportioned as follows: Dr. Chao: USD 500,000; Breg, Inc: USD 7,000,000; Oasis MSO Inc: USD 0.

Analysis of Verdict

Both plaintiff and defense counsels noted this was a highly contentious trial with each claiming improper conduct by the other side. Both parties

said they intended to file posttrial motions and, if necessary, an appeal. While the posttrial legal maneuvering continues, it is worth remembering our legal system generally regards the jury verdict as the final outcome of litigation. In one notable US Supreme Court decision, for example, the Court held a jury verdict would not be overturned even when evidence showed the jurors had been consuming copious amounts of liquor, cocaine, and marijuana during the trial and deliberations [5].

According to plaintiff's counsel, there are currently more than 250 additional cases, which have been consolidated in a mass tort action pending in the San Diego Superior Court against Breg, Inc.

This legal case is of interest given the relatively recent verdict, the size of the jury award, the recovery of punitive damages, and the business nexus between Dr. Chao and Breg, Inc. Since actual damages in this personal injury case were neither limb- nor life-threatening, in that the patient was able to return to competitive sports, the most likely explanation for the large monetary award is that the jury's passions were inflamed during trial proceedings. Punitive damages against a physician accused of medical malpractice are very rare; such damages are reserved for particularly egregious conduct that society wants to punish and deter. In general, under California

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law, the plaintiff would have to prove the defendants acted with malice, oppression, or fraud, to recover punitive damages. Since trial case proceedings are published only rarely, we do not know how the plaintiff was able to overcome the relevant standard of proof to be awarded punitive damages in this case.

What available facts do show is that this was highly contentious litigation, where the accused doctor offered to waive costs and not file a countersuit if the patient dismissed her complaint. It is probable that the jury believed Dr. Chao was driven by financial motives related to renting out Polar Care[®] 500 units at a profit and encouraging their use accordingly. Financial agreements between Breg, Inc, and Dr. Chao would undoubtedly have been presented to the jury by plaintiff's counsel to frame arguments in their favor. Information from the trial proceedings also showed defense counsel tried to steer blame away from Dr. Chao to the corporate entity, Breg, Inc; this strategy did not prevail.

In medical malpractice trials, jurors generally favor physician defendants and want to believe physicians. The testimony of the physician defendant is often the most important part of a medical negligence trial, and jurors pay close attention to identify a caring and concerned doctor who placed the injured patient's first and foremost.

Motivation toward financial gain, allegiance to corporate interests, and trivializing the patient's injury and pain rarely gain a jury's sympathy.

Veteran counsel know the outcome of a jury trial is only partially related to the truth; many other subjective factors such as courtroom demeanor, behavior of parties, body language, verbal communication, attitude, and appearance play a decisive role in the final outcome. In fact, there is an industry devoted to preparing and coaching parties for jury trial and the courtroom environment. The unusually large verdict in the *Engler v Breg, Inc* litigation suggests an impassioned jury, an ill-prepared physician defendant, or both.

Conclusions

Many practicing orthopaedic surgeons have corporate relationships. From the industry side, these may arise from legitimate business needs for advice, product development, marketing and promotion, research, and a desire to drive sales. However, these relationships can result in a complex set of potential and actual conflicts, including those relating to surgeon ownership in implant distributorships, conflicts related to hiring relatives to serve as implant sales representatives, or as in the present case, using a clinic as a

retail outlet to sell or rent products to patients for a profit.

While none of the above relationships with corporations are illegal, when they are complex, surgeons might consider hiring expert counsel at the outset to understand and construct the necessary legal structures, firewalls, and insulations to protect the surgeons against risk. Specifically, counsel can help identify the need for sufficient insurance protections beyond traditional medical malpractice coverage and help the surgeons understand and appreciate the incremental risk to their career, professional reputation, and financial well-being. Any agreements executed with corporate entities should be reviewed by counsel to ensure compliance with the law, to structure agreements to ensure client protection, and as part of a strategy of overall risk management. To what extent Dr. Chao's interests were protected by these mechanisms before the *Engler v Breg, Inc* litigation is unknown, but this case is a reminder that financial arrangements with corporate entities, while legal, can complicate medical malpractice litigation and have profound consequences.

References

1. Bal BS, Brenner LH. Corporate malfeasance, off-label use, and surgeon liability. *Clin Orthop Relat Res*. 2013;471:4–8.

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2. *Engler v Breg, Inc.*, GIC870982 (CA Super Ct, San Diego 2012).
3. Haas C, Stickney R. Jury awards \$5 M to track star in medical lawsuit. NBC 7 San Diego. July 26, 2012. Available at: <http://www.nbcsandiego.com/news/local/Jury-Awards-5M-to-Track-Star-in-Medical-Lawsuit-163939596.html>. Accessed January 21, 2013.
4. Jury Verdict Alert. \$12 million for medical and medical device product liability, including punitives. San Diego County. Available at: <http://www.juryverdictalert.com/jury-verdicts/item/medical-malpractice-2/engler-v-breg-et-al>. Accessed January 21, 2013.
5. *Tanner v United States*, 483 US 107 (1987).