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Case of the Month

Informed Consent Is No Shield to Negligent Surgical Advice

by Gordon Ownby

A new case from the Court of Appeal delves deeply into California law governing informed consent and negligent medical advice, starting with the threshold issue of whether a surgeon's full discussion on a particular procedure will shield the physician from liability if he or she was negligent in recommending the surgery in the first place.

The short answer is that it won't. But in getting there, the court offered a refresher on how courts properly rule on informed consent and on negligence when a physician proposes medical treatment.

A 33-year-old morbidly obese patient consulted with Dr. Carson Liu, a bariatric surgeon, about surgical weight-loss options. Dr. Liu performed a full medical workup of the patient's condition and referred her to a psychologist and a nutritionist. Based on the information he gathered, Dr. Liu diagnosed the plaintiff's morbid obesity as being caused by overeating rather than by any psychological, physiological, or hormonal cause.

The two discussed three options: gastric lap band surgery, gastric sleeve surgery, and gastric bypass surgery. The patient flatly rejected the bypass surgery and chose the lap band option. Dr. Liu explained the risks of the surgery, including leakage, bleeding, and infection. He also explained that the surgery would only "help" her to lose weight and so even after surgery, she must exercise and restrict her dietary intake.

Dr. Liu performed the lap band surgery without complications. In the 16 months following the surgery, the plaintiff was able to regulate her diet and she lost 73 pounds. When she lost her job, however, her stress increased, her healthier eating habits faltered, and she started to regain her weight.

Some eight months later, the patient contacted Dr. Liu about having him perform a gastric sleeve surgery. As the surgeon and his staff had been meeting with the patient regularly for the past two years and those visits included dietary consults, Dr. Liu did not refer her a second time to a nutritionist or psychologist. Dr. Liu explained the nature of the surgery and that possible risks included staple line leakage, bleeding, infection, and a small possibility of death. He quoted a risk of such complications at approximately five percent and the plaintiff agreed to the surgery and signed a consent form.

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Dr. Liu performed the surgery and the patient lost some weight over the following several months. By approximately one year post-op, however, she was "non-compliant" with her diet and regained her weight.

At that time, Dr. Liu and the patient discussed further options, including a gastric "resleeve" surgery. After conducing a "swallow test," Dr. Liu concluded that there had been an anatomic failure of the sleeve, which allowed the patient's stomach to expand. Dr. Liu recommended a resleeve surgery to remove more of the patient's stomach and, because he had been treating the patient during the years, he did not do further referrals to a psychologist or nutritionist.

The surgeon explained the risks of the resleeve procedure as "the same" as the original sleeve procedure and quoted the same five percent risk of complications. The patient consented to the surgery, which went forward without event. One day following the procedure, however, one of the staple lines leaked material from the plaintiff's gastroesophageal junction into her abdominal cavity, causing sepsis, respiratory failure, and acute renal failure. The plaintiff sued Dr. Liu.

In the litigation, plaintiff's counsel proposed that Dr. Liu was negligent on two theories: (1) He was negligent because the patient had "zero chance" of achieving weight loss success with the second surgery given her prior diet failures and thus no reasonable bariatric surgery would have recommended the resleeve surgery; and (2) he was negligent for not obtaining her informed consent to the gastric resleeve surgery.

The plaintiff's expert trial witness, a bariatric surgeon, testified that the resleeve surgery had little chance of success because of the plaintiff's prior failures to adhere to a dietary and exercise regimen. He also opined that the resleeve's risk of complications is "five to 10 times higher" than for the sleeve surgery and that Dr. Liu was negligent in not sending his patient back for a psychological and nutritional workup.

On informed consent, the expert opined Dr. Liu did not properly inform the patient because he did not tell her that the surgery was "more risky than the first-time operation." During his testimony, the expert revealed that he had performed resleeve surgeries himself and that the procedure had some — but not "a lot" — of data behind it.

Dr. Liu's bariatric surgery expert, like the plaintiff's expert, testified that gastric resleeve surgery is sometimes warranted and that he had also performed the surgery in his practice. He further testified that the surgery was appropriate because (1) no further workup by a nutritionist or psychologist was required in the plaintiff's case; and (2) reasonable bariatric surgeons could conclude that the probable benefits of the surgery outweighed the probable risks.

On informed consent, the defense expert agreed with the plaintiff's expert that the risk of the re-sleeve surgery is about 10 times higher than the initial sleeve procedure, but explained that such risk actually went from 0.5 percent (for the initial sleeve surgery) to five percent.

The Superior Court jury found in Dr. Liu's favor, but the plaintiff's appeal raised two questions: When can a physician be sued for negligently recommending a course of treatment; and (2) does the patient's informed consent negate any liability for a negligent recommendation?

The trial court judge had instructed the jury that a full informed consent can shield a physician who improperly recommends a surgery. In *Flores v. Liu*, the Los Angeles-based Second District Court of Appeal disagreed on that point but sustained the defense verdict anyway by noting that the plaintiff's case against Dr. Liu for negligently recommending surgery lacked sufficient facts to go to the jury in the first place.

In finding that an informed consent does not protect a physician for negligently recommending a course of treatment, the Court of Appeal noted the disparity in medical knowledge between the physician and patient and that patients are ill equipped to know whether a course of treatment is medically reasonable. Using one

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of the more unusual analogies you'll come across in California case law, the court explained:

"Just as a patron's fully knowledgeable selection of one entrée over another does not say anything about which entrees should be on the menu in the first place, a patient's fully knowledgeable selection of a particular course of treatment does not say anything about whether the physician was negligent in recommending that course of treatment in the first place."

In upholding the judgment in favor of Dr. Liu, the Court of Appeal rejected a series of the plaintiff's arguments.

On the informed consent contention, the appellate court found substantial evidence to support the jury's verdict that Dr. Liu disclosed to the plaintiff all the information that a reasonable person in the plaintiff's position should know when making a decision regarding gastric re-sleeving surgery.

Turning to the law on negligent recommendations in medicine, the appellate panel explained: "A physician can be found liable for negligently recommending a course of treatment if (1) his recommendation is based on a misdiagnosis of the plaintiff's medical condition, or (2) his recommendation, even if based on an accurate diagnosis, is one that no reasonable physician using such skill, prudence, and diligence as other members of the relevant medical community would recommend for the plaintiff."

As to the first of these prongs, the court found no evidence whatsoever that Dr. Liu misdiagnosed the plaintiff's condition of morbid obesity.

Then, in finding that plaintiff failed to meet her burden to show that "no reasonable physician" would have recommended plaintiff's resleeve surgery, the court noted that the expert witnesses on both sides testified that they've performed the surgery themselves. ("As a result, the evidence does not show that 'no reasonable physician' would ever perform this surgery.")

Second, the court found no substantial evidence that all reasonable physicians would have rejected resleeve surgery for *this plaintiff*. Further, there was no evidence that Dr. Liu incorrectly assessed the probable risks of the surgery beyond the five percent that he quoted the patient.

The appellate panel also disagreed with the argument that Dr. Liu's recommendation of the resleeve surgery was negligent because of the patient's past experience with diet.

"Where, as here, a plaintiff tells her physician that she — despite prior failures — desires to try again in losing weight, a physician does not act unreasonably in giving her that opportunity." The court explained that if "prior failure at complying with diets was sufficient by itself to render a surgical course of treatment unreasonable, then patients would be deprived of that choice and, what's more, nearly every recommendation to pursue an elective weight-loss surgery would be negligent because most patients only seek out those surgeries after lesser efforts of dieting have failed."

Finally, the court rejected the plaintiff's assertion that no reasonable physician would have recommended gastric resleeve surgery without doing another multi-disciplinary workup. (Her expert said that a "majority" of bariatric surgeons would have sent the patient back for psychologic and nutritional consults.) "Even if we ignored that there is no negligence for recommending a course of treatment as long as some reasonable physicians would support the recommendation (even if they do not constitute a majority), plaintiff presented absolutely no evidence that a further workup would have produced any information counseling against gastric resleeve surgery."

Gordon Ownby is CAP's General Counsel. Questions or comments related to "Case of the Month" should be directed to gownby@CAPphysicians.com.

March 2021

Risk Management and Patient Safety News

"Counts Are Correct": Retained Foreign Objects

by Lee McMullin, CPHRM

You've heard of cases where scissors, retractors, forceps, sponges, and other items get left behind in patients during surgery. It is natural to wonder *"how does that happen?"* At times, surgical/OR math just doesn't add up. Considering the risk of "fuzzy math," we've picked up on a few things we thought would be good for all surgeons to know.

Naturally, surgeons must be aware of whatever processes, procedures, and protocols exist in accounting for surgical tools, sponges, needles, etc. at their facilities, whether they are ambulatory or acute care. Most critically, these cases can have a lasting effect on the course of a surgeon's career since the liability claims, litigation process, and payments made under it are regulated by federal statutes that require reporting to state medical boards and the National Practitioner Data Bank (NPDB).

Secondly, there is the emotional impact when a surgeon learns his or her patient has a retained foreign object. That response may be influenced by the realization of the potential claims impact and likelihood the surgeon may be responsible for the acts or omissions of others in the surgical theater. This "Captain of the Ship" legal doctrine has been successfully challenged in some states, yet it continues to play a role in California "retained foreign object" cases.

Case Examples

Mr. X underwent a colostomy reversal and the surgical count at the time of closing the abdomen was reported by the OR staff to the general surgeon as "correct," both before and after closing. Several years later, Mr. X began to experience hip pain and went to see an orthopedist. A pelvic X-ray revealed that a pair of scissors was left behind during the abdominal surgery.

In another case, a post-renal cancer patient underwent "routine" screening by MRI that revealed a surgical sponge in the retroperitoneal space. The patient was asymptomatic throughout the post-surgical period at all office encounters. During the second surgery, the surgeon noted the sponge to be imbedded into the surrounding tissue and concluded that dissection would be more harmful to the patient than leaving it alone and left it in the patient. In the ensuing medical malpractice claim, the patient's lawyer asserted his client had significant discomfort over the post-surgical period and that since the sponge could not be extracted, he would be forever in pain. While neither patient had any complaints until discovery of the object, the patients and their attorneys would subsequently argue otherwise. Even cases in which there appears to be limited or benign effect, the retained object can have serious consequences.

Given the legal environment, it is crucial to reemphasize simple "habits" that protect both the patient and the OR team. These strategies envision clear communication of the counting processes and careful recording during the procedure as well. Moreover, documentation of the patient's postoperative behaviors will aid your defense team should you become involved in a retained foreign object case.

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In closing, CAP recommends the following risk mitigation and patient safety measures:

- Understand whose job it is to perform the surgical count and what he or she will be counting. Communication must be crystal clear.
- Ensure OR staff have adequate, uninterrupted time to focus on the surgical counts. Disturbing their concentration while performing this critical task increases the risk of error.
- Conduct a visual and manual sweep, as appropriate, of the surgical site during the procedure and before closing.
- Use wands and scanners for RFI tagged items like sponges and X-rays, as needed.
- Utilize a double-blind count process by two separate team members. Teaming a critical task with a second person of the same skill set significantly improves accuracy.
- The count should be conducted before closing – and then again afterwards. In a double-blind count, that is four times.
- Likewise, document in the Operative Report the reported count (i.e., "correct") before closing – and then secondly after closing.
- Instruct that the surgical count include an inspection to confirm the physical integrity of the tools and that they appear intact – no broken or missing parts left behind. If you encounter a latent retained foreign object case, note (or quote) in the medical record if the patient is truly asymptomatic.
- Consider participation on a quality improvement committee at the location where you perform surgery.
- Advocate for improved technologies that reduce the risk of retained foreign objects.
- Call the CAP Cares Team at 800-252-0555 if your patient experiences a retained foreign object.

Lee McMullin is a Senior Risk Management and Patient Safety Specialist for CAP. Questions or comments related to this article should be directed to lmcmullin@CAPphysicians.com.

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March 2021

All Eyes Now on the American Rescue Plan

by Gabriela Villanueva

A week before the Presidential Inauguration, then President-elect Biden's team released the incoming administration's $1.9 trillion emergency relief plan designed to continue to guide the country through the ongoing medical and economic challenges of the global pandemic. On February 27, 2021, the House of Representatives passed the American Rescue Plan (ARP) and while President Biden has expressed a strong desire for a collaborative effort to pass the bill on a bipartisan basis, the prospect of that happening appears doubtful at this time. There are yet to be any Republicans on record in support of the comprehensive package the Biden administration seeks.

Because of that, Democrat leadership in the Senate was prepared to use the budget reconciliation process to pass the American Rescue Plan and get it on President Biden's desk for his signature and enactment. Via budget reconciliation, Congress can use expedited parliamentary procedures (with limits on the scope of provisions) to consider spending, revenue, and debt-limit laws set by an annual resolution. More importantly, and in this current environment, this process allows the Senate to enact legislation with a simple majority vote of 50 plus 1.

With full passage likely at the time of this writing, committees are drafting the policies that will be likely advanced through the reconciliation process. The Senate amended the House-passed provisions, and President Biden and his administration have needed to reconsider its priorities and see which measures can be passed through reconciliation and which measures require regular order. Some of the most popular items of direct stimulus checks and extended unemployment aid qualified for the reconciliation process.

Amongst the provision in the ARP, specifically to the President's request for $160 billion in direct pandemic medical relief, more than half — $83 billion — would be used to increase development and access to vaccines, testing, and therapeutics, along with critical supplies.

The American Rescue Plan provides direct COVID relief funding in the following ways:

1. Vaccination Efforts

- $15.5 billion for Community Vaccination Clinics and Mobile Vaccination Units.
- $4.5 billion to accelerate manufacturing and supply chain, vaccine awareness campaign, and increase the federal portion of Medicaid's state assistance percentage to vaccinate Medicaid recipients.

2. Testing Expansion

- $46.5 billion to procure and administer regular screening tests.
- $3.5 billion to Invest in U.S. laboratory capacity for diagnostic and screening tests.

3. Domestic Manufacturing Capacity and Supply Chain

- $4 billion to build and equip two state-of-the art facilities.
- $1 billion to create a stockpile of essential raw materials and supplies for vaccines.
- $3 billion to expand domestic manufacturing capacity for additional supplies.
- $2 billion for onshore manufacturing of test kits and related supplies.

4. Therapeutics Development

- $2 billion for Biomedical Advanced Research and Development (BARDA), purchase and production.
- $1 billion for research on treatments for long-term health impacts of COVID-19 "long haulers."

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5. Other Provisions Include:

- $340 million for genomic sequencing.
- $8 billion to expand public health workforce.
- $30 billion funding for the Disaster Relief Fund (for FEMA use).
- $11 billion towards the global response by replenishing health and humanitarian assistance ($5.7 billion); the Support Global Fund ($1.5 billion); and to fulfill commitments to the WHO, G-7, and G-20 ($3.8 billion).

Even though Democrats control both houses, with such a wide-ranging proposal to address and confront the many fronts afflicted by this ongoing medical and economic emergency at home and abroad, the American Rescue Plan is the opening salvo in a COVID-19 relief debate that may well be President Biden's first major legislative test.

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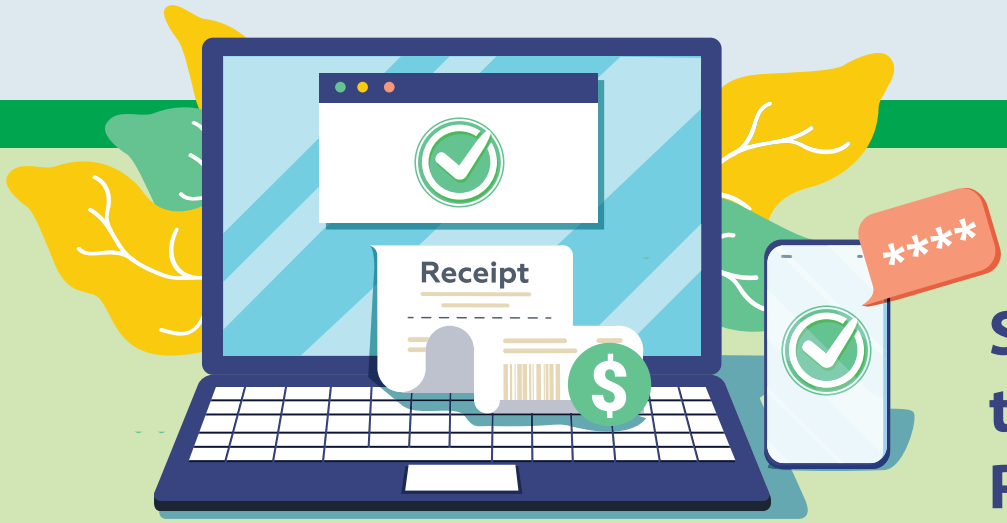

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