

THIRTY

CONSPIRACY

Negligent Training — Worker/Workplace Negligence

Plaintiff: Doctor got kickbacks for implanting pacemakers

VERDICT \$67,383,673
ACTUAL \$27,383,673

CASE Tommy Sowards and Barbara Sowards v. Las Cruces Medical Center LLC, d/b/a Mountain View Regional Medical Center; Demosthenis Klonis, D.O.; New Mexico Cardiology and Arrhythmia Consultants P.C.; White Sands Institute for Clinical Research LLC; Biotronik Inc.; and Edward Tague, No. D-307-CV-2009-2563

COURT Dona Ana County District Court, 3rd, NM
JUDGE Douglas R. Driggers
DATE 9/8/2014

PLAINTIFF
ATTORNEY(S) Kathy Love, McGinn, Carpenter, Montoya and Love, P.A., Albuquerque, NM
 Randi McGinn, McGinn, Carpenter, Montoya and Love, P.A., Albuquerque, NM

DEFENSE
ATTORNEY(S) William F. Gould (lead), Holland & Knight LLP, Washington, DC (Biotronik Inc.)
 Benjamin Silva Jr. (lead), Silva & Associates, P.C., Albuquerque, NM (Edward Tague)
 Joseph Cervantes, Cervantes Law Firm, P.C., Las Cruces, NM (Biotronik Inc.)
 Amy Craft, Serpe Jones Andrews Callender & Bell, PLLC, Albuquerque, NM (Las Cruces Medical Center LLC, Mountain View Regional Medical Center)
 R. Michael Hughes, Silva & Associates, P.C., Albuquerque, NM (Edward Tague)
 John S. Serpe, Serpe Jones Andrews Callender & Bell, PLLC, Albuquerque, NM (Las Cruces Medical Center LLC, Mountain View Regional Medical Center)
 Lawrence R. White, Miller Stratvert & Torgerson, Las Cruces, NM (Demosthenis Klonis, M.D., New Mexico Cardiology and Arrhythmia Consultants P.C., White Sands Institute for Clinical Research LLC)

FACTS & ALLEGATIONS On Jan. 7, 2007, plaintiff Tommy Sowards, a heavy equipment operator in his early 50s, presented to Mountain View Regional Medical Center, in Las Cruces, N.M. with complaints of exertional chest pain.

Beginning three days prior, Sowards reportedly began experiencing chest pains and soreness while lifting heavy objects.

Sowards was examined by cardiologist Demosthenis Klonis, who ordered a battery of tests on him, and determined that the patient would require a heart catheterization, for diagnostic purposes. Sowards was admitted and underwent the procedure, and Klonis decided to perform an intra-aortic balloon pump insertion to treat some narrowing of an artery, and then later referred him for a coronary artery bypass surgery.

On Jan. 19, Sowards, while still hospitalized, was taking a shower when he lost consciousness and collapsed. Upon learning of the incident, Klonis reportedly told Sowards that he would require an emergency pacemaker and that he would die without it. Klonis implanted a Biotronik pacemaker into Sowards' chest, with a Biotronik sales representative present in the cath lab during the procedure.

Sowards alleged that independent sales-representative Edward Tague worked in tandem with Klonis to unnecessarily implant Biotronik-manufactured pacemakers into him, when he medically did not need the cardiac device.

Sowards sued Klonis, Tague, Biotronik, and Mountain View Regional Medical Center on claims of civil conspiracy, negligence, and negligent training, supervision and retention. Sowards also sued Klonis' practice, New Mexico Cardiology and Arrhythmia Consultants P.C., and White Sands Institute for Clinical Research LLC, which was a corporation, plaintiff claimed, that was set up so that Klonis, as the sole shareholder and sole officer, could be paid to conduct studies for Biotronik.

Las Cruces Medical Center LLC, another named defendant, is the name of the hospital corporation that does business as Mountain View Regional Medical Center. Sowards settled with Klonis and Mountain View for confidential amounts, prior to trial. The case proceeded to trial on plaintiffs' claims against Biotronik and Tague.

According to plaintiffs' counsel, Biotronik wanted to break into the U.S. pacemaker and defibrillator market, and did so through a three-pronged approach: contract with a successful sales representative from a competitor, in this instance Tague; target high-implanting pacemaker and defibrillator physicians like Klonis; and place them with sales representatives in large hospital networks where they would have access to emergency room patients, catheterization labs, and bulk discounting of devices like pacemakers. The goal was to induce doctors' loyalty to Biotronik devices so that they would implant exclusively Biotronik devices, and as many as possible.

According to plaintiffs' counsel, in 2005, Biotronik identified Klonis as a high-implanting doctor and arranged for him to move to Las Cruces where he received a \$2 million recruitment contract with Mountain View Hospital. Biotronik moved Tague to Las Cruces to work exclusively with the cardiologist. Over the next five years, through 2010 (when Klonis left Mountain View), Klonis allegedly implanted 480 Biotronik pacemaker devices into patients.

Tague reportedly had never before sold devices in New Mexico, and he never sold them again after Klonis left New Mexico. During the five years, according to plaintiffs' counsel, Tague sold Biotronik products almost exclusively to Klonis, and the more financial incentives Klonis received from Biotronik through Tague, the more loyal he became to Biotronik, eventually implanting exclusively Biotronik devices, plaintiff's counsel asserted.

According to testimony from Mountain View personnel and people who worked for Klonis, the sales representative and physician were together all the time; Tague regularly worked in the doctor's clinic; he bought gifts for Klonis' children; the salesman accompanied Klonis to clinics around the region regardless whether they were to see pacemaker patients; and Tague allegedly ran personal errands and did personal favors for the doctor. Plaintiffs argued that these services were improper kickbacks that are illegal under Anti-Kickback laws and industry ethical rules.

Plaintiffs' counsel maintained that there were several ways in which Biotronik offered incentives and kickbacks to Klonis, in order for him to remain loyal to the company, mainly through having Tague as his own personal sales representative. A physician from Las Cruces testified that Klonis disclosed to him that, in an attempt to have Klonis remain loyal to Biotronik, the doctor received \$1,000 per implant.

Plaintiffs' counsel argued that Biotronik provided funding to Klonis to set up his own research clinic, where the physician hired someone else to conduct studies on potential pacemaker patients. Biotronik also allegedly paid consulting fees whenever Klonis allowed another physician or sales representative to observe him during surgery. According to plaintiffs' counsel, doctors would be paid for repeat observations by the same sales representatives and doctors.

Sowards' counsel presented a Biotronik document that sales representatives completed when attempting to identify new accounts. On the form, Biotronik sales representatives were to identify potential "target" physicians and determine if they were "pay-to-play" doctors. Plaintiffs' counsel also submitted e-mail correspondences between Klonis and Biotronik's director of sales for the southwest region and the director's e-mails to Biotronik's president discussing Klonis' request for a meeting to discuss business opportunities. According to testimony at trial, Klonis was flown within four weeks to Oregon to meet with the company's president.

Plaintiffs' expert in interventional cardiology opined that Sowards was not a candidate for a pacemaker, and that Klonis violated the standard of care by implanting one into plaintiff. The expert outlined the guidelines set forth by the American College of Cardiology regarding when it is necessary for a patient to receive a pacemaker, and Sowards reportedly did not meet any of the standards.

Klonis testified that he believed Sowards was a pacemaker candidate because he experienced lightheadedness. Plaintiffs' expert, however, opined that it was common for a patient

to be lightheaded post-surgery, and that the symptom did not validate surgery. The expert concluded that pacemaker implantation is nearly never an emergency procedure, and that there is always time to evaluate a patient before a surgery.

Sowards' cardiologist, who began treating him post-pacemaker, determined that Sowards did not need a pacemaker. The physician said he was unable to remove the device due to Sowards' clotting disorder and the risks involved.

Plaintiffs' counsel argued that Sowards was one of 34 patients whom Klonis unnecessarily implanted a pacemaker. Three former patients testified that Klonis told them they would die if they did not have a pacemaker installed, only to be later told by other medical providers the pacemaker was not needed. One of the witnesses was a 47-year-old woman who underwent the procedure soon after pregnancy and during a stressful job.

Biotronik and Tague maintained that they did not know how or when Klonis was using the company's devices. In response to the defense, plaintiffs' expert in FDA regulatory affairs testified that Biotronik and Tague were federally required to know how and when its devices were being used by Klonis, and to claim otherwise was false and misleading.

The defense denied that there was a conspiracy, and maintained that all money paid to Klonis was for valid services. According to the defense, Klonis was a reputable doctor.

The defense's experts in interventional cardiology testified that the pacemaker implanted in Sowards was medically necessary and did not breach the standard of care.

INJURIES/DAMAGES *emotional distress; pacemaker; scar and/or disfigurement*

On Jan. 21, Sowards was discharged. He was declared by a treating doctor to be disabled and unable to return to work. He began seeing a different cardiologist after he was discharged, and his cardiologist questioned his treatment by Klonis.

Sowards later questioned whether he needed the pacemaker. After regular visits and testing of the pacemaker, and a gradual decreasing of the pacemaker settings, his treating doctors determined that he did not need the pacemaker, and turned it off.

Sowards testified that the ordeal has caused him to no longer trust medical providers. He said that he is reminded constantly of the pacemaker since there is a "hunk of metal" bulging from his chest, which causes him pain when he tries to lie down to sleep and when he bends over or hits his chest on anything. Moreover, he is unable to undergo certain diagnostic testing (e.g. MRIs) because such tests would disrupt the device and potentially kill him.

Sowards sought to recover \$207,353.77 in past medical costs and \$29,440 to \$43,200 in future medical costs. Plaintiff further sought to recover \$637,877 in lost wages, \$255,348 in loss of household services, \$2.5 million to \$3 million in loss of value of life, \$750,000 in permanent impairment/scarring, and \$750,000 in pain and suffering.

Sowards' wife sought \$513,130.01 for her claim of loss of consortium, which was calculated at 10 percent of her husband's damages claim.

For Sowards' claim of punitive damages, an expert in economics testified about Biotronik's sales of \$1.5 billion, from 2005 to 2010.

RESULT The jury found that Sowards proved his three theories of liability against Biotronik and/or Tague: 1) negligence; 2) negligent training, supervision, and retention; 3) and civil conspiracy to implant a pacemaker into plaintiff that was not necessary or medically indicated.

According to the jury, the acts of omission of Biotronik and/or Tague were a cause of injuries to Sowards, and that the defense did not prove that the negligence of someone else caused Sowards' damages.

The jury further found that Biotronik and/or Tague engaged in willful, reckless, or wanton conduct with utter indifference or conscious disregard for a person's safety. Plaintiffs were determined to receive \$67,383,673.

POST-TRIAL: The defense filed several motions, including an appeal and to reduce the punitive damages award to \$25 million, which the court did. Plaintiffs' counsel filed a motion to reconsider the remittitur and a motion for sanctions.

BARBARA

SOWARDS \$60,000 loss of consortium

TOMMY

SOWARDS \$65,000,000 punitive damages
\$2,323,673 compensatory damages
\$67,323,673

TRIAL DETAILS

Trial Length: 3 weeks
Trial Deliberations: 6.5 hours

**PLAINTIFF
EXPERT(S)**

Stuart Fischer, M.D., interventional cardiology, Los Alamitos, CA
K. John Heilman III, M.D., cardiology, Rapid City, SD (treating)
M. Brian McDonald, Ph.D., economics, Albuquerque, NM
Morris Waxler, Ph.D., fda regulatory affairs, Madison, WI

**DEFENSE
EXPERT(S)**

Ronald D. Berger, M.D., interventional cardiology, Baltimore, MD
Sean P. Mazer, M.D., interventional cardiology, Albuquerque, NM

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EDITOR'S NOTE This report is based on information that was provided by counsel for plaintiffs and Klonis. Counsel for Biotronik, Tague, Mountain View Regional Medical Center, New Mexico Cardiology and Arrhythmia Consultants P.C., and White Sands Institute for Clinical Research LLC did not respond to the reporter's phone calls. Las Cruces Medical Center LLC was not asked to contribute.

—Aaron Jenkins

THIRTY-ONE**MEDICAL MALPRACTICE**

Failure to Communicate — Failure to Detect

Docs overlooked damage of patient's colon, suit alleged

VERDICT \$62,000,000
ACTUAL \$64,300,000

CASE

Stacey Galette v. Paul Byrne M.D. Michelle Quinones, M.D., Frederic Moon, D.O., Craig Zebuda, M.D., Cynthia A. Fretwell, M.D., David Halpern, M.D., Paul R. Byrne, M.D., P.C., Women's Contemporary Care Associates, P.C., Nassau Surgical Associates, P.C., and Winthrop University Hospital, No. 28327/10

**COURT
JUDGE
DATE**

Kings Supreme, NY
Ann T. Pfau
1/10/2014

PLAINTIFF**ATTORNEY(S)**

Ira M. Newman (co-lead), Sanocki, Newman & Turret, LLP, New York, NY
Edward J. Sanocki (co-lead), Sanocki, Newman & Turret, LLP, New York, NY
Sanford A. Rubenstein, Rubenstein & Rynecki, Brooklyn, NY

DEFENSE**ATTORNEY(S)**

Peter DeNoto, Heidell, Pittoni, Murphy & Bach, LLP, Garden City, NY (Winthrop-University Hospital)
Guido Gabriele, Gabriele & Marano LLP, Garden City, NY (Fredric Moon, Craig Zebuda, Cynthia Fretwell, Michelle Quinones, Paul Byrne, Paul R. Byrne M.D. P.C., Women's Contemporary Care Associates P.C.)
John D. Paterniti, Shaub, Ahmuty, Citrin & Spratt LLP, New York, NY (David Halpern, Nassau Surgical Associates, P.C.)