McLane sought to recover damages for past and future medical costs and past and future pain and suffering.

Defense counsel argued that McLane's injury was a known complication of his surgery.

RESULT The jury found that there was no manufacturing defect in the cartridge used in the Contour Curved Cutter Stapler that was a cause of injury to McLane.

TRIAL DETAILS Trial Length: 4 days
Trial Deliberations: 3 hours

EDITOR'S NOTE This report is based on information that was provided by plaintiff's counsel. Defense counsel did not respond to the reporter's phone calls.

–Gary Raynaldo

DRUGS & SUPPLEMENTS

Failure to Warn — Marketing Defect — Breach of Warranty

Bisphosphonate meds not cause of man's ONJ: defense

VERDICT **Defense**

CASE Jimmy Earp and Patricia Earp v. Novartis Pharmaceuticals Corporation, No. 5:11-cv-00680-D
COURT U.S. District Court, Eastern District, NC
JUDGE James C. Dever, III
DATE 5/14/2014

PLAINTIFF ATTORNEY(S) **Lyn K. Broom**, Teague Rotenstreich Stanaland Fox & Holt, PLLC, Greensboro, NC
John J. Vecchione, Valad & Vecchione, PLLC, Fairfax, VA

DEFENSE ATTORNEY(S) **William J. Cople**, Hollingsworth LLP., Washington, DC
Susan P. McWilliams, Nexsen Pruet, LLC, Columbia, SC
Buffy M. Mims, Hollingsworth LLP, Washington, DC
Peter G. Pappas, Nexsen Pruet, PLLC, Greensboro, NC

FACTS & ALLEGATIONS In 1997, plaintiff Jimmy Earp was diagnosed with multiple myeloma. After Earp's multiple myeloma was treated with chemotherapy, steroids and a stem cell transplant, his oncologist prescribed Aredia in 1998 as the standard of care for multiple myeloma patients. Earp was switched to Zometa in 2001, and he received his last infusion of Zometa in February 2002 after just four infusions due to concern with his renal condition.

Aredia and Zometa are prescription bisphosphonate medications manufactured and sold by Novartis Pharmaceuticals Corp.

During the course of his treatment, Earp developed osteonecrosis of the jaw (ONJ), necessitating the extraction of several teeth, and resulting in other complications related to a necrosis of the jaw.

On Sept. 1, 2006, Earp and others filed a complaint alleging various claims against Novartis arising from osteonecrosis of the jaw that they alleged was caused by the use of Aredia and Zometa. The action was transferred to the United States District Court for the Middle District of Tennessee for Multi-District Litigation proceedings. After discovery proceedings and severance of the Earps case, the MDL court transferred the case back to the United States District Court for the Eastern District of North Carolina (Western Division) for further proceedings, including a trial.

Earp's lawsuit faulted Novartis for failure to warn that Aredia and Zometa could cause a new and dangerous disease: bisphosphonate-related osteonecrosis of the jaw (BRONJ). BRONJ is an area of uncovered bone in the maxillo-facial region that does not heal within eight weeks after identification by a health care provider, in a patient who was receiving or had been exposed to bisphosphonate therapy without previous radiation therapy to the craniofacial region.

Earp maintained that Novartis had a continuing, nondelegable duty to warn about the knowable dangers of Aredia and Zometa throughout the duration of his receipt of the drugs. Earp further alleged that Novartis knew or should have known of its drugs' dangerous propensities, but failed to properly test the drugs, review the medical literature to determine possible side effects, and determine a proper dose. Earp further contended that when third parties, including oral/maxillofacial surgeons, began to bring this new disease to Novartis' attention, Novartis ignored the information, downplayed the drugs' dangers, and designed its labeling, advertising, marketing and other efforts to divert attention away from and deny the fact that Aredia and Zometa, and bisphosphonates in general, are the cause of BRONJ.

Earps also alleged that Novartis mounted an aggressive marketing plan to switch patients from Aredia to Zometa when Aredia was going off patent and gave no notice that BRONJ occurs faster with Zometa. Earps alleged that this amounted to a failure to comply with Food and Drug Administration standards and those of the common law. He further alleged that Novartis failed to timely warn and instruct the medical community of the dangers of BRONJ, how to reduce the incidence rate of BRONJ, and how to treat BRONJ so as to avoid or reduce the severity of the disease.

Earps' lawsuit also alleged Novartis breached its implied warranty, in that Aredia and Zometa were not fit for their ordinary intended purpose, were not adequately packaged and labeled, and did not conform to the promises

and representations made in its packaging, labeling and advertising.

Novartis disputed that its products caused Earp's jaw problems or that it failed to adequately warn Earp's prescribing physicians of the products' dangers.

Alternatively, Novartis argued that Earp's oncologist would have prescribed the medicines to him regardless of the ONJ risk because of the value the medicines confer for the multiple myeloma for which he was being treated.

INJURIES/DAMAGES *jaw; osteonecrosis; tooth loss*

Earps developed ONJ and had several teeth extracted. He alleged that he suffered damages in the form of medical expenses, including the cost of the bisphosphonate infusion he would not have received had Novartis adequately warned him or his physicians about its products. He claimed prolonged pain and suffering, permanent injury, and the risk of further aggravation of his jaw problems that he would not have suffered had Novartis properly met its duties.

Earp sought punitive damages as well, contending that Novartis intended to defraud him or acted with willful or wanton conduct for his health and well-being, causing his injuries, and that Novartis executives participated in or condoned such acts.

Earp's wife, Patricia Earp, joined in the action, asserting a loss of consortium claim. The claim was abandoned prior to the start of trial.

RESULT After finding for Earps on medical causation and warning adequacy, i.e. the defendant's products caused the medical condition and there was a failure to warn, the jury answered "No" to the question "Did Mr. Earp prove by a preponderance of the evidence that Novartis's unreasonable failure to provide an adequate warning or instruction concerning the use of Aredia and Zometa was a proximate cause of Mr. Earp's osteonecrosis of the jaw?"

Earlier, in an oral order on May 9, 2014, Chief Judge James C. Dever III granted judgment as a matter of law for Novartis on Earp's punitive damages claim. He also granted judgment as a matter of law on the breach of implied warranty claim by oral order on May 12, 2014.

TRIAL DETAILS Trial Length: 7 days
Trial Deliberations: 6.5 hours
Jury Vote: 12-0

EDITOR'S NOTE This report is based on court documents and information that was provided by defense counsel. Plaintiffs' counsel did not respond to the reporter's phone calls.

–Jon Steiger