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PRODUCTS LIABILITY UPDATE

By Rocky Little

***McKay v. Novartis Pharms. Corp.*, 2013 U.S. Dist. Lexis 47136, United States District Court for the Western District of Texas, El Paso Division, decided March 28, 2013.**

McKay was prescribed Aredia to treat osteoporosis, although the Food and Drug Administration (FDA) had not approved the drug for that purpose. After several years, McKay was also prescribed Zometa which, like Aredia, is manufactured by Novartis. McKay developed severe jaw and dental problems, including non-healing tooth extraction sites and exposed bones. He was diagnosed with osteonecrosis ("ONJ"), a condition marked by dead and dying bone in the jaw. McKay brought suit alleging products liability/strict liability based on an alleged failure to provide adequate warnings. The Court analyzed the application of Texas Civil Practice & Remedies Code §82.007, which pertains specifically to pharmaceutical products. Section 82.007 creates a rebuttable presumption that manufacturers are not liable with respect to an alleged failure to provide an adequate warning if the product and the accompanying warnings were approved by the FDA. However, §82.007 provides five means by which the non-liability presumption can be rebutted. One way to rebut the presumption of non-liability as provided in subsection (b)(1) is to show that the defendant withheld or misrepresented information from the FDA that was material and relevant to the performance of the product and was causally related to the alleged injury. This subsection is referred to as the "fraud on the FDA" rebuttal. However, the court held that the fraud on the FDA rebuttal is preempted by federal law and, therefore the FDA itself must find fraud. In this case, the FDA had not found that the Defendants withheld or misrepresented required information and therefore the alleged rebuttal is preempted by federal law, and not available to the plaintiff.

The Court also addressed another rebuttal provided by (b)(3)(A) of §82.007, which is sometimes referred to as improper or off-label marketing. This rebuttal to the non-liability presumption applies when a defendant recommends, promotes, or advertises a pharmaceutical product for an indication not approved by the FDA. In this case, McKay was prescribed Aredia for osteoporosis, although the FDA had not approved the drug for that purpose. However, plaintiff is required to provide evidence that recommendations, promotions, or advertisements by, or on behalf of, the manufacturer to use the pharmaceutical for off-label purposes reached and were relied on by the prescribing physician. Although the Plaintiff provided evidence that Dr. Berenson "marketed" Aredia to the prescribing physician, there was no evidence that there was any relationship between Novartis and Dr. Berenson. Therefore, there was a lack of evidence to support the allegation that the off-label promotion by Novartis reached the prescribing physician.