Lawsuit Blames Invokana For Toe Amputation

Published on March 1, 2018 by Sandy Liebhard

A recently-filed Invokana lawsuit claims that the side effects allegedly associated with the Type 2 diabetes treatment forced a Florida man to undergo two surguries to amputate his toe.

Invokana Lawsuit Allegations

According to a February 14th filing in the U.S. District Court, District of New Jersey, Richard Greenhut was prescribed Invokana in 2016 and took it as directed. On January 12, 2017, he was hospitalized for a swollen, ulcerated and malodorous second right toe, osteomyelitis and renal failure, which he claims were the direct result of his Invokana use. At that time, Greenhut underwent surgical amputation of the affected toe.

The plaintiff was readmitted to the hospital on January 25th due to ongoing ulceration and osteomyelitis. That same day, Greenhut underwent a right second ray partial amputation, which involved the removal of the corresponding metacarpal bones in the foot.

He is now permanently disfigured and injured.

"Richard A. Greenhut's injuries were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life threatening and debilitating risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokana," the complaint states. "The conduct and the product defects were a substantial factor in bringing about Plaintiff s injuries."

Invokana Gets Black Box Warning for Amputations

Johnson & Johnson's Janssen Pharmaceuticals subsidiary obtained regulatory approval to sell Invokana (canagliflozin) in March 2013. The drug was the first of a new class of Type 2 diabetes medications called SGLT2 inhibitors to come to market.

Invokamet, a combination drug consisting of canagliflozin and metformin, received U.S. Food & Drug Administration (FDA) approval in November 2014.

In May 2017, the FDA announced that a new black box warning – the strongest safety alert possible –regarding a risk of lower limb amputations would be added to the labels of Invokana and Invokamet, after early results from an ongoing clinical trial called Canagliflozin Cardiovascular Assessment Study (CANVAS) suggested that such amputations occurred nearly twice as often in patients treated with canagliflozin versus those treated with a placebo.

"Amputations of the toe and middle of the foot were the most common; however, amputations involving the leg, below and above the knee, also occurred," the FDA warned. "Some patients had more than one amputation, some involving both limbs."

Other Invokana Side Effects

Lower limb amputations are not the only potential side effects associated with Invokana.

In May 2015, the FDA launched a review of all SGLT2 inhibitor medications, after the drugs were linked to reports of diabetic ketoacidosis, a dangerous condition that can lead to diabetic coma and death. The following December, the agency ordered the drugs' manufacturers to add new warnings to their product labels regarding this possible complication, as well as a potential association with serious urinary tract infections that could lead to kidney complications.

In September 2015, the labels for Invokana and Invokamet were updated to note a possible association with an increased risk for bone fractures and decreased bone density.

The labels for ertain SGLT2 inhibitors, including Invokana and Invokamet, were again updted in 2016, after the medications were linked to more than 100 reports of acute kidney injury.