

## Will Invokana be the next J&J product to be treated as a mass tort?

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On the heels of the transfer of multiple federal cases alleging that Johnson's Baby Powder increases the risk of ovarian cancer, J&J now faces the same requests for cases related to another of its products, Invokana.

What is Invokana?

Invokana is a prescription drug sold by Janssen Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson, for the treatment of type 2 diabetes. Type 2 diabetes is a condition that limits the ability of the body to process glucose. For type 2 diabetics, their body does not efficiently process glucose or does not produce enough insulin to maintain appropriate blood levels. Invokana was approved by the FDA in March 2013 as part of a class of drugs called SGLT2 inhibitors.

What does Invokana do?

As compared to most other diabetic drug treatments that work by affecting the supply or use of insulin, Invokana works by causing blood sugar to be removed from the body through urine. Specifically, Invokana reduces the amount of sugar put back into the bloodstream after it had initially been removed by the kidneys. The benefits associated with Invokana include improved blood-sugar levels, weight loss, and reductions in blood pressure.

### **Invokana may cause diabetic ketoacidosis**

In March 2013, when Invokana was first approved by the FDA, literature warned of major side effects such as stroke and an increased risk of heart attacks within the first 30 days of taking the drug. By May 2015, the FDA issued a Drug Safety Communication related to the class of drugs, warning that the drugs may lead to a serious condition called diabetic ketoacidosis.

Diabetic ketoacidosis is an accumulation of ketones in the bloodstream. When insufficient insulin prevents a person from getting enough blood sugar to create energy, the body starts to burn fat. As the body burns fat, waste chemicals called ketones, are produced. Because ketones are a type of acid, a person's blood becomes more acidic as ketones build up. High ketone levels are toxic and can poison the body. On December 4, 2015, an updated Drug Safety Communication warned about "the risks of too much acid in the blood" that could lead to hospitalization.

Invokana has been linked to increased risk of kidney injury

By October 2015, the FDA had received 101 confirmable cases of acute kidney injury. The FDA has advised that if a person experiences acute kidney injury, they should promptly discontinue the drug and treat the kidney impairment. The FDA also advised that patients should seek medical attention immediately if they experience signs and symptoms of acute kidney injury. In May 2016, "Acute Kidney Injury" was added to the Invokana warning and, the FDA advised that Invokana is not recommended for patients with severe kidney disease.

In May 2016, the FDA also alerted the public about interim safety results from an ongoing clinical trial involving SGLT2 inhibitors indicating that there may be an increase in leg and foot amputations as compared to

placebos Although the FDA has not determined whether Invokana increases the risk of leg and foot amputations, the FDA is currently investigating this issue.

You may be eligible for compensation if you experienced ketoacidosis or kidney failure after taking Invokana

If you have been diagnosed with diabetic ketoacidosis or kidney failure after taking Invokana, you may be entitled to compensation. The lawyers at Wilentz, Goldman & Spitzer are available to consult on this potential claim. Please contact us today to speak with an attorney.

**Attorney**

- Lynne M. Kizis