

# WILENTZ

—ATTORNEYS AT LAW—

WILENTZ, GOLDMAN & SPITZER, P.A.

## Invokana

Results achieved in prior matters are not meant to be a guarantee of success as the facts and legal circumstances vary from matter to matter.

The use of Invokana has been linked to serious side effects, including acute kidney injury, ketoacidosis, amputations and heart attacks.

### What is Invokana?

Invokana and other sodium-glucose co-transporter-2 (SGLT2) inhibitors are meant to lower blood sugar (glucose) levels in people with elevated glucose concentrations by reducing the kidneys' ability to recirculate glucose into the bloodstream and "forcing" kidneys to pass the sugar out of the body through the urine instead.

Manufactured by Janssen Pharmaceuticals, Inc., the medication was first approved by the U.S. Food and Drug Administration (FDA) in March 2013. In 2015, just two years after Invokana received FDA approval, government agencies in the U.S., Canada, and the European Union began issuing a series of warnings and advisories about risks associated with Invokana and other drugs in its class that could lead to hospitalization or even death.

The FDA warns patients who are taking Invokana and other SGLT2 inhibitor medications for type 2 diabetes to seek immediate medical attention if they experience the following symptoms:

- Difficult Breathing
- Nausea or vomiting
- Abdominal Pain
- Unusual Fatigue or Sleepiness
- Confusion

### What is Type 2 Diabetes?

Normally, the pancreas releases insulin, a hormone that helps your body store and use the sugar and fat from the foods you eat and ensures that glucose in your blood enters the body's cells, creating energy. Diabetes is a disease in which your blood glucose levels are too high.

Type 2 diabetes mellitus, also known as "insulin resistance," is the most common type of diabetes, also known as "insulin resistance." This chronic condition is characterized either by your body's inability to use insulin well or to produce enough insulin to keep your blood sugar levels in a healthy range. Over time, having too much glucose in your blood can lead to serious problems and damage your eyes, kidneys, and nerves. When untreated, type 2 diabetes can also cause heart disease, stroke, high blood pressure, and even the need to remove a limb. While some people are genetically predisposed to this condition, it is largely caused by lifestyle issues, such as obesity, excess consumption of sugar and lack of physical activity.

### Side Effects and Complications

#### Acute Kidney Injury (AKI)

Our kidneys are responsible for filtering waste products from the bloodstream, which are then excreted into the urine. They are also important in blood pressure control, as well as fluid and electrolyte balance. Kidney failure

occurs when the kidneys stop functioning properly without the use of dialysis or a kidney transplant and can cause weakness, shortness of breath, lethargy, confusion, abnormal heart rhythms, and sudden death.

Recently, the Canadian regulatory counterpart to the U.S.'s FDA, Health Canada, found after a review of data that the SGLT2 inhibitors available in Canada prior to August 2015, Invokana and Forxiga (known as Farxiga in the U.S.), may carry an increased risk of acute kidney injury.

### **Diabetic ketoacidosis (DKA)**

Diabetic ketoacidosis (DKA) is a serious medical condition that causes the body to produce excessive levels of blood acids and can lead to coma, organ injury, or even death. Multiple studies have demonstrated that patients taking Invokana or other SGLT2 inhibitors may develop DKA.

When your body doesn't have enough insulin to allow cells to process glucose the way a healthy body generates energy, your body starts to produce waste chemicals called ketones, a type of acid. As ketones accumulate in the bloodstream, they make it more acidic. High ketone levels are toxic and can poison your body.

### **Amputations**

Amputation may be required when tissues of the extremities have died. Cell death is due to the lack of the vascular system's ability to supply oxygen and nutrients through the bloodstream. When cellular death has occurred, an infection known as "gangrene" may develop. Gangrenous tissue will require surgical removal and may include amputation. Amputation of the toes is most common but more advanced cases may involve the feet and legs.

### **Heart Attacks**

A heart attack occurs when cells of the heart muscle are suddenly deprived of oxygen. Oxygen is transported in the blood to supply muscle cells and other tissues but when blood supply is restricted by blockage, the heart tissue is suddenly starved. This may result in cardiac weakness and irregular heart rhythm and if oxygen is not restored, will cause cell death. Excess potassium levels, known as hyperkalemia, can increase the risk of irregular heart rhythm and sudden death.

### **FDA Safety Warnings**

Although Invokana has not been recalled and does remain on the market, the FDA has issued three safety announcements warning patients about these potential injuries, and has mandated that a Black Box Warning be prominently displayed describing the link between Invokana and amputations.

- On May 18, 2015 the FDA issued a Drug Safety Communication about SGLT2 inhibitors, warning that they may put patients at risk of a serious health condition known as diabetic ketoacidosis, which may cause diabetic comas or death. The FDA's Canadian counterpart, Health Canada, issued a similar report in May 2016.
- On December 4, 2015, the FDA released an updated Drug Safety Communication announcing that after further review, the FDA has determined that additional warnings to the labels of SGLT2 inhibitors are necessary to warn about "the risks of too much acid in the blood and of serious urinary tract infections" associated with this class of drugs.
- On May 18, 2016, FDA issued a Drug Safety Communication warning the public about interim safety results from "an ongoing clinical trial that found an increase in leg and foot amputations, mostly affecting the toes," in patients who had taken Invokana.

### **Lawsuits**

Multiple Invokana lawsuits have been filed against Janssen and its parent company, Johnson and Johnson due to medical injuries that have occurred after the medication's use. These lawsuits, filed in both the U.S. and Canada, claim that Janssen knew about the risks of Invokana but continued to promote and sell the medication anyway, without additional warnings. If health care practitioners and patients had been warned about increased risks, many would not have used the medication.

### **How We Can Help**

If you have been diagnosed with type 2 diabetes and suffered serious health problems after taking Invokana, you may be entitled to reimbursement for medical expenses, lost wages, and other costs. Attorneys at Wilentz, Goldman & Spitzer P.A. may be able to help you recover compensation if you suffered serious injuries from taking Invokana. As one of New Jersey's largest personal injury law firms, Wilentz is committed to helping clients with their cases.

For a free consultation or more information about your legal options, please call the number below. Or, if you prefer to complete our free case evaluation form, our client relations representative will contact you shortly.

**To speak with an attorney about your legal options, please call: 732-855-0375.**