

W&L Hopes Faster FDA Publication of Potential Risk Signals for SGLT2 Inhibitors: Newest – Stroke, Thromboembolic Events, Acute Kidney Injury

NEW YORK, N.Y., April 1, 2016 (SEND2PRESS NEWSWIRE) – Weitz & Luxenberg, P.C., said today it hopes potentially fatal side effects associated with SGLT2 inhibitor drugs will be reported to consumers faster, since people taking these next-generation diabetes medications deserve to be notified of the health dangers shortly after they have been reported to the U.S. Food and Drug Administration (FDA).

Unfortunately, the most recent report of serious potential side effect risks were not announced by the FDA this year until after a significant delay, the nationally known law firm said.

In lists of these medications and their side effects published this year, the FDA stated it has now identified potential new signals of serious risk for people taking SGLT2 inhibitors, including strokes, thromboembolic events and acute kidney injury, Weitz & Luxenberg pointed out.

The potential risk of strokes and thromboembolic events was detected during the second quarter of 2015 and should have been published on the FDA's website by the end of the third quarter of last year. Weitz & Luxenberg has learned, however, that this potential safety signal was not posted on the FDA's website until February of this year, four months overdue.

The potential risk for acute kidney injury had been determined by the FDA based on data received from consumers and healthcare providers between October and December of last year, said Weitz & Luxenberg.

Concerns with SGLT2 Inhibitors Identified:

There are currently seven SGLT2 inhibitor drugs. All of them were listed under the potential signals of serious risk for stroke, thromboembolic events and acute kidney injury. The FDA became aware of these potential serious risks through its Adverse Event Reporting System (FAERS), according to Weitz & Luxenberg.

The law firm said the seven SGLT2 inhibitor drug brands listed in the two FDA lists of potential signals of serious risks are:

- * Invokana (canagliflozin)
- * Invokamet (canagliflozin/metformin HCl)
- * Farxiga (dapagliflozin)
- * Glyxambi (empagliflozin/linagliptin)

- * Jardiance (empagliflozin)
- * Synjardy (empagliflozin/metformin HCl)
- * Xigduo XR (dapagliflozin/metformin HCl).

SGLT2 (sodium-glucose cotransporter-2) inhibitors are prescription medicines approved by the FDA to treat adult type 2 diabetes mellitus when combined with diet and exercise, said Weitz & Luxenberg.

SGLT2 inhibitors are prescribed in an attempt to lower blood sugar levels.

A growing body of scientific literature and adverse event reports made to regulatory bodies around the world, including the FDA, have linked SGLT2 inhibitors to a spectrum of serious adverse health consequences, the law firm said.

Lawsuits Commenced:

In 2015, Weitz & Luxenberg launched an investigation of those adverse health consequences. The firm said its findings convinced it to begin accepting cases from consumers injured by SGLT2 inhibitors.

The firm has filed five cases on behalf of individuals who suffered from diabetic ketoacidosis, who then went on to suffer one of the following devastating events: coma, kidney injuries, and infection leading to necrotizing fasciitis. Those cases are pending in the Court of Common Pleas of Philadelphia County.

Individuals Who Suffered Harm from SGLT2 Inhibitors Deserve Help:

Weitz & Luxenberg said delays in government reporting of newly-identified potential SGLT2 inhibitor health risks have not slowed the effort to bring the drugs' manufacturers to justice.

Still, attorneys within the firm said it would be beneficial to the public were FAERS reports made available sooner.

"By the time consumers find out there is a new pattern of problems being reported to the FDA with SGLT2 inhibitors, it may be too late, as many of them will by then have already suffered a devastating medical event," said attorney Ellen Relkin, who is leading the Weitz & Luxenberg SGLT2 inhibitors investigation.

"The FDA should consider ways to improve the processes by which it acquires and analyzes adverse event data, and also the processes by which it produces and readies FAERS reports," Relkin added.

Relkin said her firm is interested in hearing from adult patients who took an SGLT2 inhibitor and then experienced diabetic ketoacidosis requiring hospitalization, renal failure or acute kidney injury requiring hospitalization, stroke or other thromboembolic events, such as blood clots in the legs (deep vein thrombosis or "DVT") or lungs (pulmonary embolism or "PE").

She said Weitz & Luxenberg also is interested in talking to individuals who took SGLT2 inhibitors and were hospitalized after suffering urinary tract infections resulting in blood infections (urosepsis) or kidney infections (pyelonephritis).

Relkin said individuals harmed in any of these ways may be entitled to reimbursement for the cost of hospitalization and any related medical care, in addition to other expenses, plus lost wages and more.

About Weitz & Luxenberg:

Weitz & Luxenberg P.C. is among the nation's leading and most readily recognized personal injury and consumer protection law firms. Weitz & Luxenberg's numerous litigation areas include: mesothelioma, defective medicine and devices, environmental pollutants, products liability, consumer protection, accidents, personal injury, and medical malpractice. Victims of consumer fraud are invited to rely on Weitz & Luxenberg's more than 25 years of experience handling such cases. You can contact the firm's Client Relations department at 800-476-6070 or at info@weitzlux.com.

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