Drug Injury Watch: Stroke, DVT, Pulmonary Embolism, And Kidney Damage Linked To Invokana

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 31, 2016)

We will be monitoring the medical literature for developments and watching for any forthcoming FDA action concerning the association of acute kidney / renal injury, thromboembolic events (*e.g.*, DVTs, PEs), and/or strokes with Invokana, Farxiga, and Jardiance, as well as the other lesser-known SGLT2 inhibitor diabetes drugs.

What led us to this new drug safety vigilance is this part of a March 29, 2016 news report, "Possible Drug Risks Buried in Delayed FDA 'Watch Lists'", published online by *Medscape*:

The potential-signals list for the second quarter of 2015, the one that flagged SGLT-2 inhibitors for stroke and thromboembolic events, should have been posted on the FDA's website before September 30, 2015. Instead, it quietly appeared there on February 5, 2016, without any public notice. Concerning the issue with SGLT-2 inhibitors, the report said in its usual formulaic manner that "FDA is evaluating the need for regulatory action."

That same day, the agency posted the FAERS watch lists for the first and third quarters of 2015 as well. In total, the lists for the first 9 months of the year covered potential problems with 39 drugs or drug classes.

On March 22, the FDA finally caught up on its publication schedule when it posted the FAERS watch list for the last 3 months of 2015, which cited an additional six drugs or drug classes. SGLT-2 inhibitors popped up again, this time for acute renal injury. The refrain was the same: "FDA is evaluating the need for regulatory action."....

Here is some more detail about the FDA evaluating a possible need for additional drug safety regulatory action as regards the controversial class of relatively new diabetes drugs known as Sodium-Glucose Co-Transporter-2 (SGLT2) Inhibitors.

The following SGLT-2 inhibitors are currently approved by the FDA:

Farxiga (dapagliflozin) tablet -- AstraZeneca Pharmaceuticals
Glyxambi (empagliflozin/linagliptin) tablet -- Boehringer Ingelheim Pharmaceuticals
Jardiance (empagliflozin) tablet -- Boehringer Ingelheim Pharmaceuticals
Invokamet (canagliflozin/metformin HCI) tablet -- Janssen Pharmaceuticals

Invokana (canagliflozin) tablet -- Janssen Pharmaceuticals

Synjardy (empagliflozin/metformin HCI) tablets -- Boehringer Ingelheim Pharmaceuticals and Eli Lilly and Company

Xigduo XR (dapagliflozin/metformin HCI) extended release tablet -- AstraZeneca Pharmaceuticals

These seven diabetes medicines are currently being investigated by the FDA for the following possible "new" side effects:

- Strokes, also known as Cerebral Vascular Accident (CVA)
- Thromboembolic events such as Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE)
- Acute renal injury including kidney damage and kidney failure

We are interested in investigating possible drug injury lawsuits against the responsible pharmaceutical companies for diabetes patients who have developed any of the medical conditions listed above.

[Read this article in full at original source]

Earlier Invokana / Farxiga / Jardiance articles by attorney Tom Lamb on the <u>Side Effects</u> <u>Blog</u>:

- When Used By Type 1 Diabetes Patients, Invokana Can Cause Ketoacidosis
- Invokana Cases Involving Diabetic Ketoacidosis And Kidney Side Effects
- EMA Says Invokana / Farxiga /Jardiance Linked To Diabetic Ketoacidosis
- FDA Adds New Ketoacidosis Side Effect Warnings To Invokana Drug Label
- Invokana Label Gets New Warnings About Increased Bone Fracture Risks

Attorney <u>Tom Lamb</u> represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments. <u>http://www.DrugInjuryWatch.com</u>