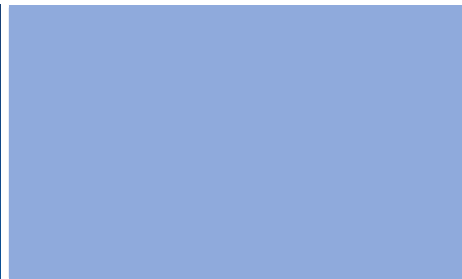




INVOKANA LITIGATION

DANIELLE WARD MASON

beasley
allen



LAW FIRM

The Overview:

Indicated to treat type II diabetes

Manufactured by
Janssen Pharmaceuticals,
a subsidiary of *Johnson & Johnson*



In a class of drugs known as
SGLT-2 inhibitors:
Invokana, Farxiga, Januvia

Hit the market in March 2013

Became a **BLOCKBUSTER** selling drug within two years

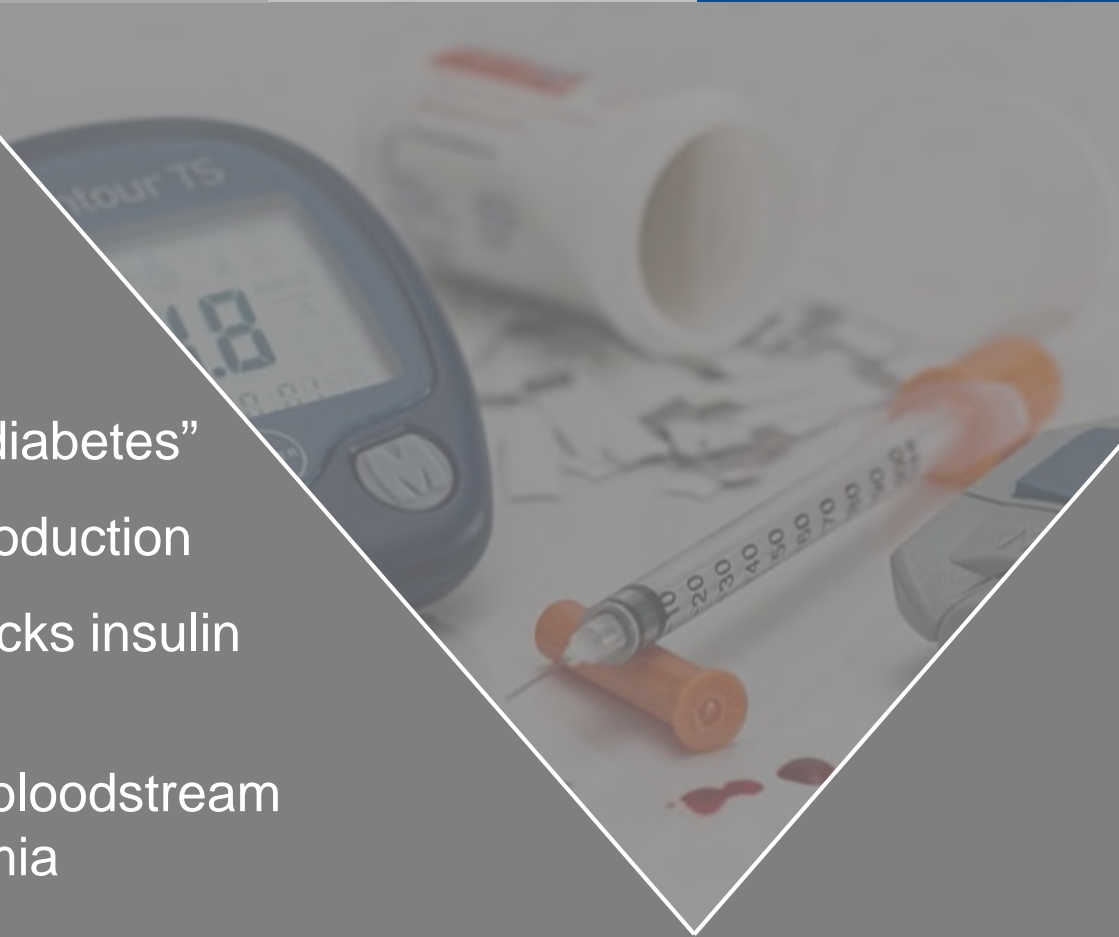
Diabetes: Type I vs. Type II

Type I

- Known as “juvenile diabetes”
- Little to no insulin production
- Immune system attacks insulin producing cells
- Glucose remains in bloodstream causing hyperglycemia
- Body turns to fat for energy (Lipolysis) which can lead to ketosis
- Primary treatment is insulin

Type II

- Characterized by an insulin insufficiency or imbalance
- Linked to obesity
- Variety of treatments available
 - 1ST Line = Metformin
 - 2nd Line includes SGLT-2 inhibitors



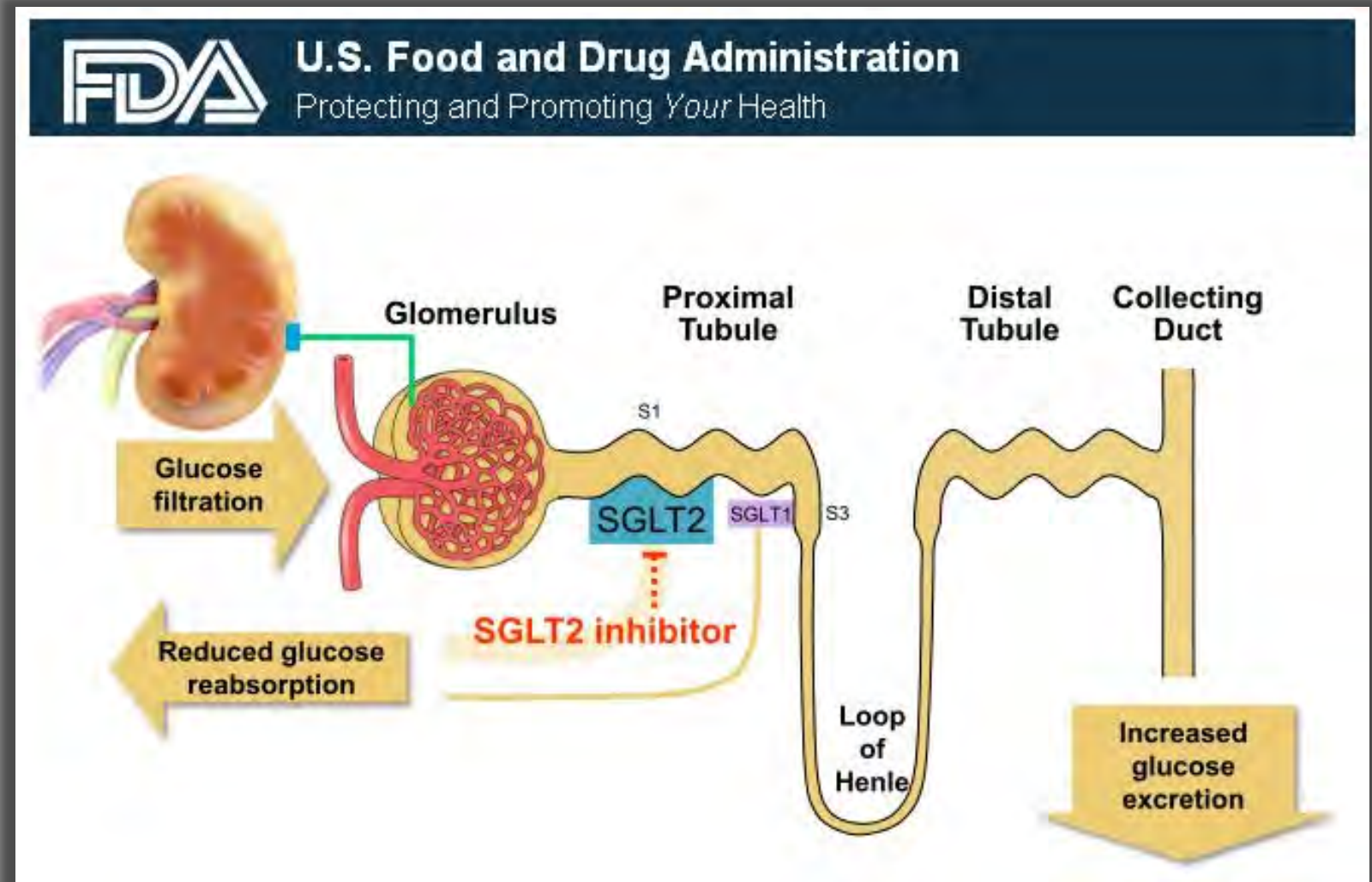
How SGLT-2 Inhibitors Work:

1

SGLT-2 proteins aid the body in reabsorbing glucose into the bloodstream

2

SGLT-2 inhibitors block absorption of glucose in the kidneys so excess glucose is passed through the urine

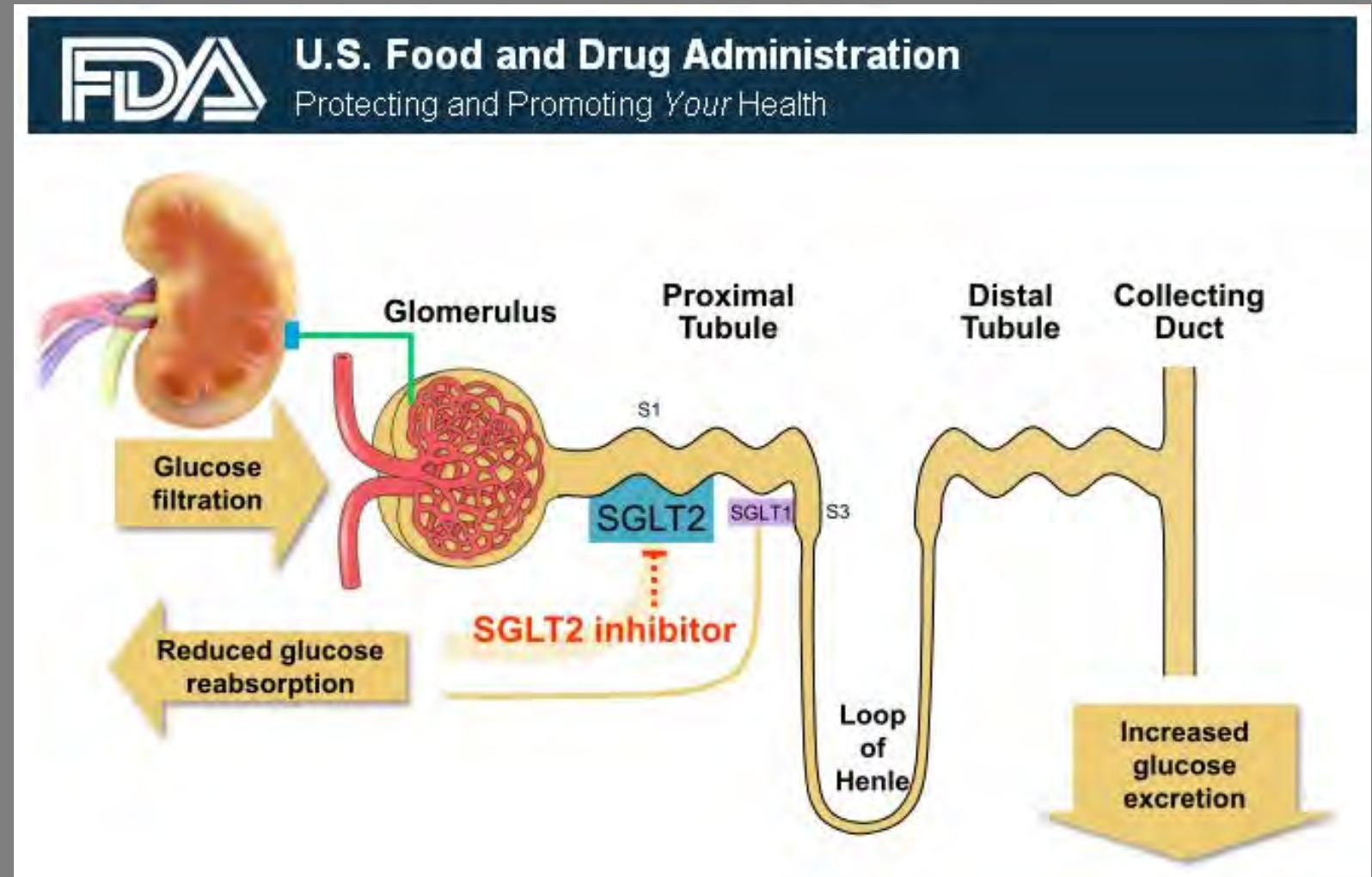


How SGLT-2 Inhibitors Work:

The Result

This process deprives the patient of water and necessary electrolytes resulting in

DEHYDRATION AND KETOSIS





Safety Announcement

[12-4-2015] A U.S. Food and Drug Administration (FDA) safety review has resulted in adding warnings to the labels of a specific class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors about the risks of too much acid in the blood and of serious urinary tract infections. Both conditions can result in hospitalization.



Safety Announcement

[12-4-2015] A U.S. Food and Drug Administration (FDA) safety review has resulted in adding warnings to the labels of a specific class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors about the risks of too much acid in the blood and of serious urinary tract infections. Both conditions can result in hospitalization.

WARNING



[06-14-2016]

Safety Announcement

The U.S. Food and Drug Administration (FDA) has strengthened the existing warning about the risk of acute kidney injury for the type 2 diabetes medicines canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR). Based on recent reports, we have revised the warnings in the drug labels to include information about acute kidney injury and added recommendations to minimize this risk.

Patients should seek medical attention immediately if they experience signs and symptoms of acute kidney injury. This is a serious condition in which the kidneys suddenly stop working, causing dangerous levels of wastes to build up in the body. Signs and symptoms of acute kidney injury may include decreased urine or swelling in the legs or feet. Patients should not stop taking their medicine without first talking to their health care professionals. Doing so can lead to uncontrolled blood sugar levels that can be harmful.



[06-14-2016]

Safety Announcement

The U.S. Food and Drug Administration (FDA) has strengthened the existing warning about the risk of acute kidney injury for the type 2 diabetes medicines canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR). Based on recent reports, we have revised the warnings in the drug labels to include information about acute kidney injury and added recommendations to minimize this risk.

Patients should seek medical attention immediately if they experience signs and symptoms of acute kidney injury. This is a serious condition in which the kidneys suddenly stop working properly, causing dangerous levels of wastes to build up in the body. Signs and symptoms of acute kidney injury may include decreased urine or swelling in the legs or feet. Patients should not stop taking their medicine without first talking to their health care professionals. Doing so can lead to uncontrolled blood sugar levels that can be harmful.

WARNING



Safety Announcement

[5-16-2017] Based on new data from clinical trials, the U.S. Food and Drug Administration (FDA) is announcing that the type 2 diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) causes an increase in risk of leg and foot amputations. We are requiring new warnings, including a **black box warning**, to be added to the canagliflozin drug label to describe this risk.

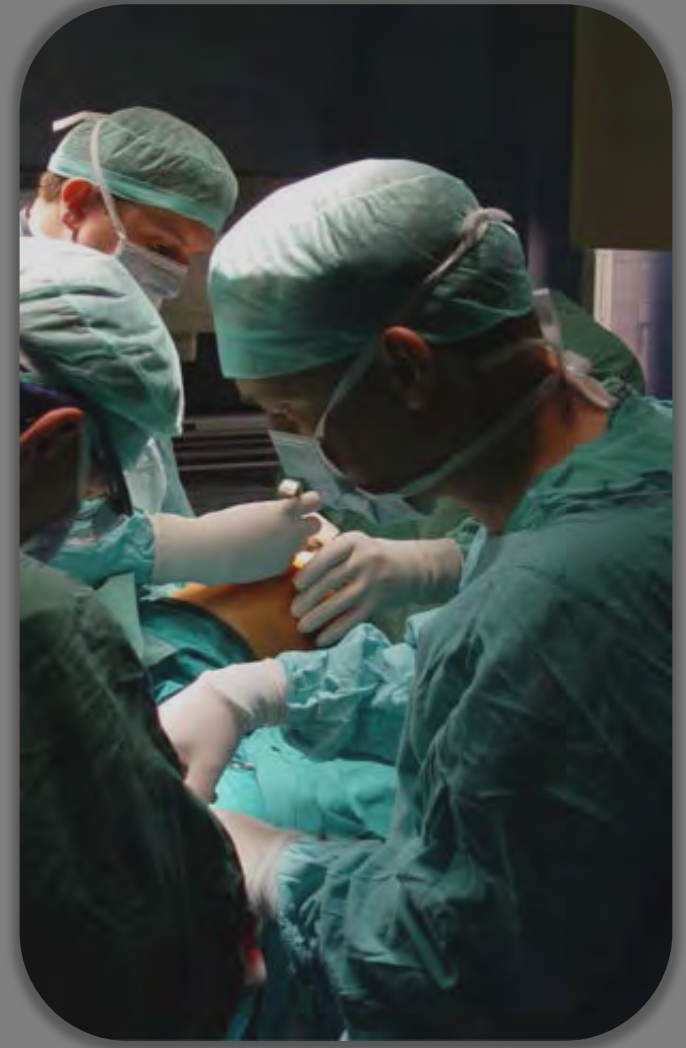
**BLACK BOX
WARNING**



Safety Announcement

[5-16-2017] Based on new data from two large clinical trials, the U.S. Food and Drug Administration (FDA) has concluded that the type 2 diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) causes an increased risk of leg and foot amputations. We are requiring new warnings, including our most prominent *Boxed Warning*, to be added to the canagliflozin drug labels to describe this risk.

What are the Injuries?



What are the Injuries?

Ketoacidosis (DKA)

- Potentially life-threatening.
- Characterized as a build-up of acids (ketones) in the blood.
- Common in Type I diabetics but extremely rare in Type II diabetics absent treatment with SGLT-2 inhibitors.
- Often misdiagnosed in Type II because of the rare occurrence.

Acute Kidney Injury (AKI)

- Kidneys cannot perform their waste-clearing function properly.
- Measured by patient's creatinine level.
- Creatinine > 50% constitutes AKI.

Amputation

- Loss of foot or leg.
- Extended hospital stay.
- Requires long term recovery and physical rehabilitation.
- Emotional support, including counseling, to help with grief over the loss of the limb.



DKA and AKI explained

DKA and AKI:

Ketoacidosis (DKA)

SGLT-2 inhibitors create an insulin deficiency similar to type 1 diabetics.



The increased loss of fluids and sodium from kidneys lead to increase in stress hormones.



SGLT-2 inhibitors create an insulin deficiency similar to type 1 diabetics.

Acute Kidney Injury (AKI)

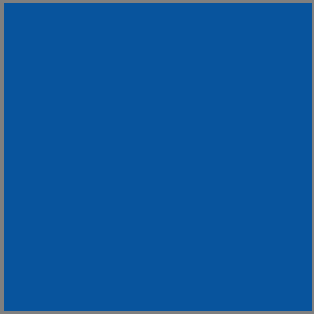
SGLT-2 inhibitors increase glucose excretion through urine.



Increased loss of fluid leads to dehydration and reduction of plasma volume.

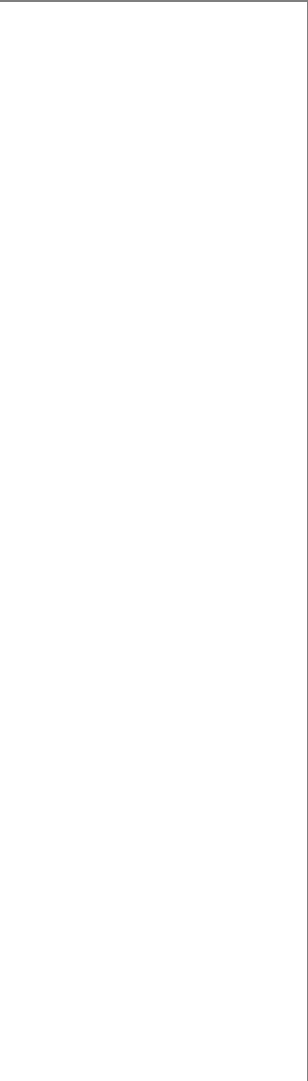


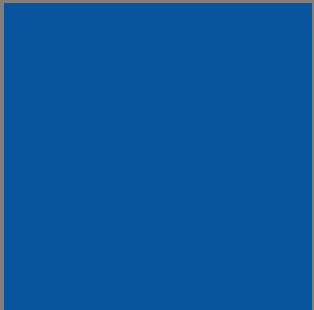
Low plasma volume leads to reduced blood flow to the kidney.



beasley
allen
LAW FIRM

Thank you





beasley
allen
LAW FIRM

Danielle Ward Mason

Danielle.Mason@beasleyallen.com

