Drug Injury Watch: Diabetes Drugs Kombiglyze And Onglyza: Heart Failure Side Effect Seems To Be Valid, And FDA Notes There Is A Possible Increased Risk Of All-Cause Mortality

As Analysis Did Not Reveal Causes Of The Increase In Death Incidents, FDA Asks Its Advisory Committee To Discuss This Safety Issue At April 2015 Meeting

(Posted by Tom Lamb at <u>www.DrugInjuryWatch.com</u> on April 13, 2015)

SUMMARY: The AstraZeneca diabetes drugs Onglyza (saxagliptin) and Kombiglyze (saxagliptin plus metformin) will come under scrutiny at an April 14, 2015 FDA meeting according to early news reports about that upcoming event.

As regards what the FDA Briefing Material document for this Kombiglyze / Onglyza safety meeting contained and its significance, from an April 10, 2015 *Bloomberg* news report, "AstraZeneca's Diabetes Drug May Raise Death Risk, FDA Says":

AstraZeneca Plc's type 2 diabetes drug Onglyza showed an increased risk of death in an analysis by U.S. regulators of a clinical trial on the heart effects of the treatment. Food and Drug Administration staff said their analysis of deaths in the trial suggested patients using Onglyza experienced "significant or near-significant" increases in death from all causes, not just heart problems.

We will be watching for any significant developments coming out of this April 2015 FDA Advisory Committee Meeting concerning the safety of Onglyza and Kombiglyze such as a possible label change for these AstraZeneca diabetes drugs.

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Earlier articles by attorney Tom Lamb on the Side Effects Blog.

- <u>A 2004 Medical Journal Article Indicated A Possible Link Between The "Morning</u> <u>Sickness" Drug Use Of Zofran And Hypospadias</u>
- In Canada, ADHD Drugs Like Adderall, Concerta, And Ritalin Are Getting New Warnings About Suicide-Related Adverse Events
- Diabetes Drugs Bydureon And Victoza: Thyroid Cancer Label Change In March 2015 Comes Without Much Notice

- YAZ / Yasmin Litigation Update For March 2015: According To Bayer's 2014 Annual Report, "Additional lawsuits are anticipated."
- <u>Cardiovascular Safety Issues For Onglyza And Kombiglyze Will Be Discussed At</u> April 2015 FDA Advisory Committee Meeting

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>