<u>Drug Injury Watch: Multiple Myeloma Drug Pomalyst Associated With Side Effects Risks Of Cardiac Failure, Interstitial Lung Disease, And Hepatotoxicity</u>

In May 2015 The Medicines and Healthcare Products Regulatory Agency In UK Issued A Drug Safety Update; Will There Be Similar FDA Action?

(Posted by Tom Lamb at www.DruglnjuryWatch.com on June 3, 2015)

**SUMMARY**: Pomalidomide (brand name: Pomalyst in the US; Imnovid in Europe) is a multiple myeloma drug.

On May 20, 2015 Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom issued this Drug Safety Update, "Pomalidomide: risks of cardiac failure, interstitial lung disease and hepatotoxicity", which stated:

A review by the MHRA and other EU medicines regulators concluded that [Pomalyst (pomalidomide)] can cause interstitial lung disease (ILD), cardiac failure and hepatotoxicity. This conclusion was based on data from clinical trials, reports from clinical practice and published case reports.

This May 2015 MHRA Drug Safety Update included this additional information about each of these Pomalyst side effects:

### Cardiac failure

... In most cases, this side effect occurred in patients with cardiac disease or cardiac risk factors and within 6 months of starting [Pomalyst (pomalidomide)]....

# Interstitial lung disease

... Onset of respiratory symptoms is usually within 6 months of starting treatment.

However, there have been cases where ILD occurred approximately 18 months after starting [Pomalyst (pomalidomide)]....

#### Hepatotoxicity

... The risk of serious hepatic events appears to be highest in the first 6 months of treatment, therefore regular liver function monitoring is recommended during this period....

We will continue to monitor the safety profile of Pomalyst (pomalidomide) including watching for any similar side effects warnings by the FDA.

### [Read this article in full at original source]

# Earlier articles by attorney Tom Lamb on the Side Effects Blog:

- Beyaz / Safyral / YAZ / Yasmin: These Drospirenone Containing Birth Control
   Pills Have A Higher Risk Of Blood Clot Side Effects Than Older Options
- May 2015 Diabetes Drugs Ketoacidosis Link Warning By FDA Covers Invokana, Farxiga, And Jardiance, With Label Changes Possible
- Testosterone Injections Or Shots Such As Depo-Testosterone Might Have Higher
   Risks Of Heart Attacks, Strokes, And Deaths
- Long-Term Combined Plavix Effient Use May Be Associated With An Increased
   Overall Risk Of Non-Cardiovascular Death Compared To Shorter Therapy Period
- With Zofran Birth Defects Lawsuits Filed, How Will GlaxoSmithKline Update Its
   Drug Label To Comply With New FDA Rule Effective June 2015

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.

http://www.DrugInjuryWatch.com