Epogen / Procrit / Aranesp: The July 2012 News Report Which Tells Story Of Big Pharma Profits Over Patient Safety And Drug Efficacy

Once The FDA Started Paying Attention The Writing On The Wall Became Apparent, Albeit Too Late For Some

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 20, 2012; see http://bit.ly/O3LRwb)

This lengthy and well-presented news report, "Anemia drugs made billions, but at what cost?", written by Peter Whoriskey and published July 19, 2012 by *The Washington Post* (free registration required), is a must-read for anyone with a concern or interest in how larger pharmaceutical companies might put corporate profits ahead of patient safety and drug efficacy.

Here is an excerpt from this *Washington Post* article which will give you a sense of what went on that, in hindsight, is so disturbing:

> For years, a trio of anemia drugs known as Epogen, Procrit and Aranesp ranked among the best-selling prescription drugs in the United States, generating more than $8 billion a year for two companies, Amgen and Johnson & Johnson. Even compared with other pharmaceutical successes, they were superstars. For several years, Epogen ranked as the single costliest medicine under Medicare: U.S. taxpayers put up as much as $3 billion a year for the drugs.
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> The trouble, as a growing body of research has shown, is that for about two decades, the benefits of the drug — including “life satisfaction and happiness” according to the FDA-approved label — were wildly overstated, and potentially lethal side effects, such as cancer and strokes, were overlooked.
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> Last year, Medicare researchers issued an 84-page study declaring that among most kidney patients, the original and largest market for the drugs, there was no solid evidence that they made people feel better, improved their survival or had any “clinical benefit” besides elevating a statistic for red blood cell count.

As for some of the key events which led up to this revelation of sorts, we start with a June 24, 2011 FDA press release, "FDA modifies dosing recommendations for Erythropoiesis-Stimulating Agents -- Cites increased risk of cardiovascular events when used to treat chronic kidney disease", which included the following:

> The U.S. Food and Drug Administration today recommended more conservative dosing guidelines for Erythropoiesis-Stimulating Agents (ESAs) when used to treat anemia in patients with chronic kidney disease (CKD) because of the increased risks of cardiovascular events such as stroke, thrombosis, and death....
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> The modified recommendations are being added to the Boxed Warning and other sections of the package insert in response to clinical trials showing an increased risk of cardiovascular events, such as heart attack and stroke, when ESAs are dosed to achieve a normal or nearly normal blood hemoglobin level. In addition, ESAs have not been shown to improve quality of life, fatigue, or patient well-being.

In fact, we have been covering some of the developments concerning the safety of Epogen, Procrit, and Aranesp over the past six years, as seen below:

Anemia Drugs Procrit And Aranesp May Increase Twofold The Risk Of Potentially Fatal Blood Clots -- Results From Large Long-Term Study Show Association Between These Erythropoiesis-Stimulating Agents And Venous Thromboembolism (**September 2009**)

Procrit, Epogen, And Aranesp: New "Black Box" Warnings Only First Part Of FDA's Safety Re-evaluation -- Popular Anemia Drugs Have Increased Risk Of Death, Blood Clots, Strokes, And Heart Attacks, Especially In Context Of Off-label Prescribing And Use (**March 2007**)

Amount Of Epogen And Procrit Given To Patient Tripled Since Early '90s -- Higher Levels Of Popular Anemia Drugs May Increase Risk Of Heart Problems And Death (**November 2006**)

Hopefully this *Washington Post* news report about Epogen, Procrit, and Aranesp will produce some changes at the FDA and with the pharmaceutical industry (aka "Big Pharma) such that we will not see this type of apparent disregard for the health and welfare of patients again in the future.

Attorney Tom Lamb 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