A Brief History Of Prescription Drug Recalls In The U.S., 1997-2010

FDA Will Consider Next Possible Market Withdrawl During July 13-14 Hearing About Avandia

(Posted by Tom Lamb at www.DrugInjuryWatch.com on June 7, 2010; see http://bit.ly/aAF1ZZ)

At the end of June 2010 reporter Marilynn Marchione wrote an article, "When is a drug too risky to stay on the market?", that was published by the *Associated Press* (*AP*).

This *AP* article provides good background information about how and why an FDA-approved prescription drug would be withdrawn from the market in the United States. Further, this *AP* article seems to be intended as a "primer" for the July 13-14, 2010 FDA hearing on Avandia, the controversial diabetes pill made by GlaxoSmithKline PLC.

This June 2010 article sheds some light on the analytical framework used when determining whether there should be a drug recall or not, as seen from this excerpt:

> The FDA can order a drug off the market, but that can be challenged in court. Usually, a company voluntarily withdraws the medicine at the FDA's request.
>
> Many things influence whether such a request is made, said Dr. Brian Strom, a drug safety expert at the University of Pennsylvania. He is a longtime FDA drug safety adviser who has consulted for Takeda Pharmaceuticals, which makes Actos, an Avandia rival.
>
> Some factors to consider:
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> _ How serious is the illness being treated?...
>
> _ How big is the harm?...
>
> _ How frequent are the risks versus the benefits?...
>
> _ Are there safer alternatives?...

A related *AP* item, "Risky drugs pulled from the market in recent years"", provides us with a history of drug recalls in the U.S. for the period 1997 to the first part of 2010. That item provides this drug recall information, and more, which was compiled by *Associated Press* news researcher Rhonda Shafner:

- 2010: Mylotarg -- Risks: Liver disease
- 2009: Raptiva -- Risks: A rare brain infection
- 2007: Zelnorm -- Risks: Increased risk of heart problems
- 2007: Permax -- Risks: Heart valve damage
- 2005: Cylert -- Risks: Liver problems, including death
- 2005: Bextra -- Risks: May increase the risk of heart attacks and strokes; also may cause rare but serious skin conditions
- 2005: Tysabri -- Risks: Rare, but life-threatening side effect (Note: Drug returned to market in 2006 under a restricted distribution.)
- 2004: Vioxx -- Risks: Heart attacks, strokes
- 2001: Baycol -- Risks: Severe damage to muscle, sometimes fatal
- 2000: Lotronex -- Risks: Intestinal damage from reduced blood flow
- 2000: Propulsid -- Risks: Fatal heart rhythm abnormalities
- 2000: Rezulin -- Risks: Severe liver toxicity
- 1999: Hismanal -- Risks: With other drugs or high dose can cause fatal heart rhythm
- 1999: Raxar -- Risks: Fatal heart rhythm abnormalities

- 1998: Posicor -- Risks: Dangerous interaction with other drugs
- 1998: Duract -- Risks: Severe liver damage
- 1998: Seldane -- Risks: Fatal heart rhythm abnormalities
- 1997: Pondimin -- Risks: Heart valve abnormalities
- 1997: Redux -- Risks: Heart valve abnormalities

For those with an interest in serious side effects associated with unsafe drugs, I encourage you to look at each of these *AP* items using the links provided.

And, of course, we will let you know the fate of Avandia when that is determined.

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