Factors In Assessing Association Between Valvular Heart Disease And Use Of Dostinex Or Permax

Two Medical Journal Articles Review The Published Research And Suggest Ways To Avoid Cardiac Valve Side Effects

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 12, 2010; see http://bit.ly/cbUv2o)

In March 2007 the FDA announced that Permax (pergolide) would be voluntarily removed from the U. S. market because it had been linked to serious heart valve damage.

In August 2007 Health Canada followed suit and announced the sales of Permax must cease in their country, also.

Pfizer's Dostinex (cabergoline), however, remains on the market despite the January 2007 reports in the *New England Journal of Medicine* that Dostinex, like Permax, was linked to valvular heart disease.

In September 2008 a so-called "Dear Doctor" letter about Dostinex was sent by Pfizer Ltd., but apparently only to doctors in the U.K.

More recently, there have been two medical journal articles which reviewed and summarized the published research regarding the cardiac valve side effects that have been associated with Permax and Dostinex.

The first article, "Dopamine agonists and valvular heart disease", published in June 2009, we get this information:

> RECENT FINDINGS: Off-target action of dopamine agonists at 5-hydroxytryptamine 2B receptors is now recognized to cause cardiac valve disease in several studies in Parkinson's disease patients who received high daily dopamine agonist doses, including [Dostinex (cabergoline)] and [Permax (pergolide)]. Generally, dopamine agonist doses in prolactinoma therapy are 10-fold lower than those employed in Parkinson's disease, although occasionally dopamine agonist-resistant patients require higher doses. Most studies of dopamine agonist use in prolactinoma have not observed valvular abnormalities.
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> SUMMARY: Dopamine agonists are effective in treating prolactinomas. At typical doses, the risk for valvulopathy appears low. Increased risk of cardiac valvulopathy should be considered in patients requiring higher doses or long duration of therapy. Echocardiography should be performed in these high-risk patients, drug holidays implemented and patients withdrawn from these agents if possible.

The second article, "Potential Cardiac Valve Effects of Dopamine Agonists in Hyperprolactinemia", first published online in February 2010, reinforces the findings and guidance of the earlier article:

> Evidence Synthesis: The majority of studies showed no risk of valvular regurgitation associated with [Dostinex (cabergoline)]. However, an increased risk of mild to moderate regurgitation, usually at the tricuspid valve, was reported in a few studies. Only one study suggested a relationship with the mean cumulative dose of [Dostinex (cabergoline)].
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> Conclusions: Although most reports do not show an association between use of dopamine agonists and valvulopathy, caution must be exercised, especially in patients requiring long-term, high-dose medication regimens. Clinicians should recommend the lowest possible doses of dopamine agonists and address the question of echocardiographic monitoring on an individual basis.

We continue to investigate possible drug injury cases involving Permax and Dostinex.

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