Fibromyalgia Drug Savella Should Be Pulled From Market, Says Public Citizen Group

January 2010 Petition Letter To FDA Is Sent One Year After The Medication Was Approved For Sale In U.S.

(Posted by Tom Lamb at www.DrugInjuryWatch.com on January 28, 2010; see http://bit.ly/bkCTYv)

On January 21, 2010 the Health Research Group arm of Public Citizen sent its "Petition to Ban Fibromyalgia Drug Milnacipran (Savella)" to FDA Commissioner Margaret Hamburg, M.D.

This Public Citizen letter Petition begins as follows:

> Dear Dr. Hamburg:
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> Public Citizen, representing more than 65,000 consumers nationwide, hereby petitions the Food and Drug Administration (FDA), pursuant to the Federal Food, Drug, and Cosmetic Act 21 U.S.C. Section 355(e)(3), and 21 C.F.R. 10.30, to immediately remove from the market the drug Savella (milnacipran; Cypress Bioscience, Inc. and Forest Laboratories, Inc.) because it has highly questionable clinical efficacy and has been found, in randomized controlled trials, to cause a large number of potentially serious adverse reactions including hypertension, increased heart rate, and increased suicidal ideation. On July 23, 2009, milnacipran's approval for fibromyalgia was denied in the European Union for these very same efficacy and safety reasons....

For some contextual information we turn to a January 20 *Bloomberg* news article, "Forest's Drug Savella Should Be Recalled, Public Citizen Says":

> The FDA approved Savella, also known as milnacipran, as a treatment in January 2009 for fibromyalgia, a disorder characterized by a variety of pain-related symptoms including muscle pain and headaches. In July, European regulators rejected the drug, saying its benefits were marginal and didn't outweigh the risks. Public Citizen said the drug is not effective in treating pain.
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> "The larger issue is this is a new kind of drug for fibromyalgia," Sidney Wolfe, director of Public Citizen's Health Research Group, said today in a telephone interview. "This is the first drug only approved just for fibromyalgia, and it shouldn't have been. There are serious safety risks that outweigh the benefits, and the drug doesn't work for pain alone."

More information is found in Matthew Perrone's January 20 *Associated Press* (*AP*) article, "Group Urges Recall of Drug for Fibromyalgia -- Public Citizen questions benefit of pain pill for fibromyalgia, points to blood pressure risks":

> Since the FDA approved Savella last January, doctors have written more than 250,000 prescriptions for the drug, according to data from IMS Health....
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> FDA has cleared two other treatments for fibromyalgia: Eli Lilly's antidepressant Cymbalta and Pfizer's anti-seizure treatment Lyrica. Both drugs were cleared based on their ability to decrease fibromyalgia pain, though it's not clear how.
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> The cause of fibromyalgia is not known, though some researchers point to abnormalities in how patients with the disorder process pain nerve signals.

We will continue to watch for developments concerning the relatively new fibromyalgia medication Savella, and we welcome any information that you may about this emerging drug safety issue.

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