Drug Injury Watch: Gilenya PML Warning Label Change Made In August 2015

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 3, 2011; see) http://bit.ly/fLoNXu)

SUMMARY: We get some general context on this emerging drug safety issue from this August 4, 2015 *Reuters* news report, "FDA to revise Novartis' Gilenya label to reflect brain infection risk":

> [Progressive multifocal leukoencephalopathy (PML)] has long been a concern associated with the long-term use of MS drugs. Sales of Biogen Inc's Tecfidera and Tysabri had been affected by reports of the rare brain infection.
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> Caused by a common virus that is harmless for most, PML tends to trouble patients with weakened immune systems, including those taking immunosuppressants.
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> The infection causes symptoms such as vision problems, confusion, as well as changes in personality, memory and orientation – potentially culminating in severe disability or death.
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> Gilenya was approved in 2010 to reduce relapses and delay disability progression in patients with relapsing forms of MS.
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> The drug raked in sales of about $700 million in the Swiss drugmaker's latest quarter.
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> The FDA had said in August 2013 that it was investigating a case of PML in a patient taking Gilenya, but could not conclusively link the infection to the drug as the patient had been treated with other drugs as well.

On August 4, 2015 the FDA posted on its web site this Safety Alert, "Gilenya (fingolimod): Drug Safety Communication – FDA Warns About Cases of Rare Brain Infection", from which we get this preliminary information about this Gilenya label change:

> **ISSUE**: FDA is warning that a case of definite progressive multifocal leukoencephalopathy (PML) and a case of probable PML have been reported in patients taking Gilenya (fingolimod) for multiple sclerosis (MS). These are the first cases of PML reported in patients taking Gilenya who had not been previously treated with an immunosuppressant drug for MS or any other medical condition. As a result, information about these recent cases is being added to the drug label.

More detailed information about this latest safety issue concerning Gilenya is found in this document, "FDA Drug Safety Communication: FDA warns about cases of rare brain infection with MS drug Gilenya (fingolimod) in two patients with no prior exposure to immunosuppressant drugs".

Specifically, the August 2015 Gilenya – PML warning label change information is found at this part 5.3 — “Progressive Multifocal Leukoencephalopathy” — of the current drug label.

We will continue to monitor the safety profile of Gilenya as regards PML and the other serious side effects this Novartis MS drug has been associated with in recent years.

[Read this article in full at original source]

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

- Another Blood-Clots Warning Label Change For YAZ Coming?
- FDA May Require New Onglyza Drug Label For Warning About Heart Failure
- Federal Court Zofran MDL Motion; Generic Cases Filed In State Courts
- Invokana Lawsuits Filed While FDA Investigates Side Effects Reports
- Farxiga / Jardiance / Invokana: Ketoacidosis and Kidney Failure

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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.
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