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J&J Kept Quiet About Risks Of Antibiotic: Suit

By **Shannon Henson**

Law360, New York (August 29, 2008) -- Following a call from the U.S. Food and Drug Administration for a boxed warning on Levaquin, Johnson & Johnson faces legal accusations that the antibiotic drug causes tendon injuries.

In a lawsuit filed Wednesday by the U.S. District Court for the District of Minnesota, Rosette Rubins accuses J&J and its units Ortho McNeil Pharmaceutical Inc. and Johnson & Johnson Pharmaceutical Research and Development LLC of not telling her or her doctor that she risked a degradation of her tendon by taking the medication.

The suit accuses J&J and its units of negligence, strict product liability and breaches of express and implied warranties.

Levaquin is approved for the treatment of a variety of serious infections. The suit says that the defendants marketed it as a first-line therapy for common bronchitis and sinusitis infections even though safer antibiotics were available.

Levaquin, also known as levofloxacin, causes a higher incidence of tendon injuries, including tendon rupture, especially in people 50 and older or in those who are on corticosteroid therapy, according to the suit.

A review of the FDA's adverse event database from 1997 to 2005 shows 1,044 reports of tendon injuries and 282 reports of tendon rupture from those taking Levaquin, the suit says.

Since 2003 when a rival drug went generic, Levaquin has been the most popularly prescribed fluoroquinolone antibiotic in the U.S. It has since become the most prescribed antibiotic in the world.

However, the increased popularity led to more adverse events reports, the suit says. Nearly 150 tendon-related injuries in 2006 and 107 in the first quarter of 2007 were reported to

the FDA.

In July, the FDA called for a boxed warning on Levaquin and a similar drug.

"Since it was first approved for marketing, the Levaquin label has included warnings about tendonitis and tendon ruptures," J&J said in a statement at the time. "We are now revising our labeling ... to include a boxed warning as it relates to the risk of tendinitis and tendon ruptures."

The FDA's announcement came after several requests from the consumer advocacy group Public Citizen to add warnings to fluoroquinolone antimicrobials.

The group petitioned the FDA in August 2006 to put new warnings on the medications, also asking the regulator to send warning letters to doctors outlining the risks of the drugs.

In January, Public Citizen sued the FDA in the U.S. District Court for the District of Columbia claiming the agency had ignored its petitions.

The lawsuit filed Wednesday by Rubins alleges that J&J's failure to document or follow up on the known defects of its product constitute fraudulent concealment that equitably tolls the applicable statute of limitations. J&J suppressed reports and failed to disclose known defects to physicians, the suit says.

Rubins, who was 57 when she was prescribed the medication, started suffering from left Achilles tendonitis while using it. She suffers from tendon ruptures, toe deformities and adverse muscle mass as a result, the suit says.

Her suit joins several other related cases. A representative for J&J did not immediately respond to a request for comment Friday.

Rubins is represented in this matter by Lockridge Grindal Nauen PLLP and Pogust Braslow & Millrood LLC.

Counsel for J&J was not immediately available.

The case is Rubins v. Johnson & Johnson et al, case number 08-cv-05033 in the U.S. District Court for the District of Minnesota.

--Additional reporting by Christine Caulfield, Jesse Greenspan and Erin Fuchs

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