

Rezulin

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Press Accounts

‘Fast Track’ Drug to Treat Diabetes Tied to 33 Deaths

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By David Wellman

Rezulin: The FDA dismissed warnings on the pill, but it was withdrawn in Britain. Agency and Warner-Lambert say treatment is safe when prescribed and used properly.

WASHINGTON--The Food and Drug Administration dismissed explicit warnings of danger as the agency raced to approve a new diabetes drug that has been linked to at least 33 deaths due to liver injuries, records and interviews show. Senior FDA officials reviewed the drug on a "fast track" while downplaying harmful potential side effects. The drug, a pill called Rezulin, has become a sales sensation since it was launched in March of 1997 by the Warner-Lambert Co., a major U.S. pharmaceutical manufacturer and maker of consumer products such as Dentyne chewing gum.

The first reported deaths due to liver failure prompted the withdrawal of Rezulin one year ago in Britain. The FDA and Warner-Lambert have kept the drug on the U.S. market while instructing doctors on three separate occasions to take additional steps to protect patients with adult-onset diabetes.

But previously undisclosed cases acknowledged by FDA officials Friday show that these precautions have not slowed the pace of patient deaths. The new total of 33 deaths related to use of Rezulin in the United States and Japan is up from the 21 fatalities reported by the FDA as of June.

The FDA's handling of Rezulin is shaping up as a nightmare: One medical officer who opposed the approval of Rezulin was removed as the chief reviewer of the drug.

Two other FDA physicians who recommended approving the drug conceded in interviews that the agency initially overlooked compelling evidence of Rezulin's danger to the liver.

The FDA decision to approve Rezulin without at least recommending that patients undergo precautionary liver testing "was an enormous blunder," said Dr. Curt D. Furberg, a drug testing specialist and head of public health sciences at Wake Forest University.

"The agency failed," said Furberg, who is familiar with the FDA's review and oversight of the drug. "It's amazing that Rezulin is still on the market."

The FDA and Warner-Lambert say that Rezulin is safe for the 1 million or more reported users of the drug when prescribed and used properly.

"We believe this drug brings a unique and significant benefit for patients," said Dr. Randall W. Whitcomb, Warner-Lambert's vice president for diabetes research. "And while it has a risk, [this] is true of all medications."

Adult-onset diabetes affects 15 million Americans and is characterized by high blood-sugar levels that can increase the risk of heart disease and cause other complications. It is distinct from juvenile-onset diabetes, whose victims would die without daily injections of insulin.

The story of Rezulin is a window on the new era of accelerated approval for newly proposed medications. This shift has come amid complaints from pharmaceutical companies and patient activists that the FDA had taken too long to approve medications that could save lives.

The regulation of prescription drugs involves both science and art--the weighing of risk versus benefit. Some patients with AIDS or advanced cancer, for instance, are willing to accept extreme risk for new, experimental treatments.

