

Benefits of Rezulin in question

The controversial diabetes drug has been attributed to many deaths

By G. Jaros
Oregon Daily Emerald

Two years ago, a promising new drug for diabetics that lowers blood sugar levels was offered in the easy-to-take form of a pill a day. But the pill, Rezulin, made national headlines when people began to die from complications.

Rezulin caught on quickly with those who have adult onset diabetes and now has about 1 million users. But after Rezulin was approved in March, 1997, a number of people taking it developed life-threatening liver complications.

"This is not to be used ever as a first-line drug for diabetes," said Food and Drug Administration advisor Dr. Jules Hirsch in Business Week in March. Hirsch, of Rockefeller University in New York, said if it continues to be widely prescribed, "in five years there will either be hundreds or thousands of people who will die of liver disease."

The drug's manufacturer, Warner-Lambert Co., sold the drug under the brand name Rezulin, but it was generically known as Traglitazone. The drug is for the treatment of adult onset diabetes.

"People who suffer with [adult onset] diabetes still produce insulin, but they either don't produce enough or their bodies are not using it right," said Julie Norton, University Health Center pharmacy manager.

"This one [pill] works by improving the target cell's response to insulin," Norton said. "So if you're just producing a small amount of insulin, this one helps your body use that insulin."

Adult onset diabetes doesn't usually affect people until their 40s, Norton said.

In March, advisors urged the FDA in an eight to four vote to withdraw the approval of Rezulin as a stand-alone treatment for adult onset diabetes while also

endorsing the drug's continued use in combination with insulin and other medications, according to a March 27 article in The Los Angeles Times.

The FDA is not bound by the panel's recommendations but usually follows its advice.

The vote followed a presentation regarding the liver toxicity of Rezulin by senior FDA epidemiologist David J. Graham. He noted that the FDA has verified Rezulin's role in 43 reported cases of liver failure. He said it would cause liver failure in one of every 1,800 patients. The manufacturers dispute this saying one of every 57,000.

Executives of Warner-Lambert Co. said that Graham overstated the risk of Rezulin. They estimate the number of Rezulin-related deaths at 28.

Some doctors disagree with the evidence presented.

The benefits of the drug outweigh the risks, provided liver toxicity is monitored, said Dr. Sethu Reddy, program director in the department of endocrinology at the Cleveland Clinic in an interview with The Plain Dealer on March 24. Reddy said the evidence isn't there to show Rezulin is dangerous.

Doctors who prescribe it argue that statistically, people are far more likely to die from penicillin than Rezulin.

Rezulin is expensive. Daily dosage of 400 to 600 mg once per day is \$160.20. In clinical studies, a maximum effect may require 12 weeks of treatment. That would cost \$1,946.40.

Thanks to drugs like Rezulin, the U.S. market for diabetes treat-

ments has nearly doubled since 1994, hitting a billion in 1998. Warner-Lambert reported \$748 million in Rezulin sales last year, according to a March 27 article in The Los Angeles Times.

Rezulin has registered sales exceeding \$1 billion and has been prescribed to more than 1 million patients, according to the company. Also reported by Business Week on March 29 was that the FDA's counterpart in Britain announced that it had refused to allow reintroduction of Rezulin after the drug had been withdrawn from Britain in December 1997. The Medicines Control Agency determined that the risks of Rezulin outweigh its benefits.

Since Rezulin was approved in 1997 with no liver testing recommendation, the FDA has changed its labeling three times — recommending additional liver testing in each instance, according to the FDA.

Diabetes affects about 10 percent of Americans, but minorities, particularly Native Americans, are three times as likely to suffer from it, Norton said.

The death rate from diabetes has jumped 50 percent since 1985. According to Business Week, this stems from a number of factors — including a growing number of people who eat too much and exercise too little and the lack of new drugs to overcome those trends.

Diabetes led to an estimated 67,000 amputations between 1993 and 1995, and nearly 28,000 cases of end-stage kidney disease in 1995. It causes as many as 24,000 new cases of blindness each year and an estimated 193,000 deaths annually, according to the Business Week's article.

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