

## Rezulin

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### Press Accounts

#### **For Recent Victim, Risk Wasn't Known March 18, 1999**

**Los Angeles Times**

By David Willman

*Medicine: Case No. 3174412-0 is Rosa Delia Valenzuela, who took Rezulin five weeks before she died. 'I want this stuff off the market,' son says.*

WASHINGTON—The government death reports provide the barest of details.

Like all other adverse reaction notices filed at the Food and Drug Administration, "Individual Safety Report No. 3174412-0" provided no name or address.

In this case, The Times learned the victim's identity from other documents and interviews: Her name was Rosa Delia Valenzuela. She was 63 and lived in a ranch-style house in Arcadia, at the foot of the San Gabriel Mountains.

To those who made their living at nearby Santa Anita Park, Ismael "Milo" Valenzuela and his wife Rosa were mainstays. The couple had faced the risk of Milo Valenzuela's death every day that he rode some of America's fastest thoroughbred horses. In a span of three decades, he won more than 2,500 races. He twice won the Kentucky Derby, on Tim Tam in 1958 and on Forward Pass in 1968.

But when he and his five adult children take stock of the tragedy that has befallen them, they say they had no idea of the risk Rosa Valenzuela was taking.

The Los Angeles County health department's one-page certificate of death bears stark testament to that risk: Because of her body's "reaction" to the diabetes drug Rezulin, Valenzuela died of sudden liver failure at 6:50 p.m. on Dec. 18 at USC-University Hospital. High weight, alcoholism and her diabetes were cited as contributing factors.

Now, the circumstances of her death raise questions that bear on whether Rezulin can be used safely by the public.

"My mother is not going to die a statistic," vowed her eldest son, Ismael Valenzuela Jr. "She is not going to go down in vain. I want this stuff off the market."

Dr. Jacob Karula, who treated Valenzuela during the last two weeks of her life, is among those who say they are uncertain whether liver-monitoring tests recommended by the FDA and Warner-Lambert are adequate to ensure Rezulin's safety.

Federal studies show that Latinos, blacks and American Indians suffer disproportionately high rates of adult-onset diabetes. The maker of Rezulin has promoted the drug to Latinos in Spanish-language advertising.

When Valenzuela visited her doctor in October, she was optimistic that Rezulin would lower her blood sugar and prevent the need for insulin shots, family members said. Her physician followed the FDA-recommended precaution of checking the liver and found no signs of danger, her family said.

But less than three weeks after she began taking the tan-tinted pills, the youngest of her three sons, Richard, saw that she was too tired to ride an exercise bike.

Three weeks later, even more fatigued, laboring for breath and overcome with dizziness, Valenzuela was taken to Methodist Hospital, across the street from Santa Anita Park.

Richard Valenzuela noticed that his mother's eyes were by now yellowed, her legs and abdomen swollen. She had stopped taking Rezulin a week earlier, in mid-November.

According to family members, doctors said her body had begun retaining fluid and her 5-foot, 3-inch frame swelled to 276 pounds. Blood tests confirmed life-threatening liver damage.

Her ability to survive liver-transplant surgery, doctors suggested, was in doubt.

On Dec. 5, Milo Valenzuela brought his wife two bouquets of red roses to celebrate their wedding anniversary in the hospital. She died 13 days later--one week before Christmas.

Milo Valenzuela reflected on his wife's sudden death after his family had concluded a final rosary, delivered in English and Spanish.

"We had 44 beautiful years of marriage," he said softly. "And this one pill separated us."

Times staff writer Art Marroquin contributed to this story.