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Good afternoon. Thank you for the opportunity to speak here today.

My mother, Monica George, died of Rezulin-induced liver failure in September 1998. She is one of the sixty-six Rezulin fatalities officially acknowledged by the FDA.

I understand that this committee was created in part as a result of an FDA report on lessons learned from the handling of the Rezulin fiasco.

However, I was very concerned to discover that one member of this committee recently appeared as an expert witness for Warner-Lambert in a Rezulin trial here in Rockville involving my mother's case. In his testimony, he described Rezulin as a "success story" and "a model case." He also stated that from the public health point of view, there was no reason to recommend monitoring liver functions the first year the drug was on the market because that could lead to "warning fatigue."

Rezulin may indeed be the model for how things DO work, but should this be your model for future drugs?

The Rezulin story begins with the very troubling circumstances under which the drug was approved. (For further information, this has been well documented by David Willman in his series of articles on Rezulin in the *L.A. Times*). However, in keeping with today's topic, I'll focus on what happened after the drug was on the market.

As reports of serious liver events began to come in only months after approval, the FDA and the drug's maker, Warner-Lambert, responded by sending Dear Doctor letters calling for increased liver monitoring. It took almost two years for a black box warning to reach the PDR. The question is, how much of this information reached the patients already taking Rezulin?

I can tell you that the answer is very little indeed.

In fact, it reached few doctors. Some of the country's most prominent hepatologists who treated my mother were woefully ignorant of the mounting evidence of Rezulin's toxicity to the liver.

Most troubling was the FDA's reaction to the deaths of Audrey Jones and Rosa Delia Valenzuela, two patients involved in clinical trials of Rezulin. Both women suffered

liver failure in spite of strict monitoring, their liver enzymes rising precipitously only weeks after a normal result. Although this was a clear indication that liver monitoring was ineffective, the FDA never made any public comment on these cases.

My mother began taking Rezulin in November 1997, based on information her doctor received from a drug company salesman a few months before. The doctor stated under oath that he did not read the "Dear Doctor" letters. Would my mother, a registered nurse, have stopped taking Rezulin if she had known of the growing number of reported liver problems?

Although I am confident the answer is yes, the real point today is that she was never given the choice.

The current system penalizes patients who begin a new drug early on, in essence putting them in the position of unwitting participants in a poorly controlled clinical trial. As a consumer, I have a few suggestions for improving this situation.

1. When the safety profile of ANY drug changes, this information should immediately be made available in plain language as part of the patient information leaflet when the prescription is refilled.
2. These changes should be highlighted prominently, in red for example, at the top of the page, and dated. A consultation with the pharmacist should be required.
3. I also suggest that a newly approved drug, especially one approved on the fast track, be identified as such on the label, including a caution that the complete safety profile is not yet known.

I know some argue that this kind of disclosure would only frighten patients, but we should consider who is really being protected when this information is withheld. Doctors would be spared phone calls from worried patients, but any physician or pharmacist who truly values patient welfare should at least be willing to answer questions about medications. Drug companies have also fiercely resisted changes of this sort.

I'd like to return to the Rezulin example for a moment. Three weeks before my mother died in indescribable agony, the drug's maker, Warner-Lambert, held a party. I saw the flyer for it, inviting employees to "Celebrate Rezulin at the Billion Dollar Bash."

This demonstrates the enormous benefits to drug companies if concerns about warning fatigue override concerns about safety. Rezulin would never have earned a total of 2.1 billion dollars if it had only been prescribed to the relatively small population of insulin-dependent diabetics who did not respond well to other

therapies. For these patients, the benefit was clearly worth the risk. It was never worth the risk for a mild diabetic like my mother, who was in good health and had a hemoglobin A-1-c of 7 before she began taking this so-called miracle drug.

Yes, all drugs have risks, but unfortunately, in the current environment where efficacy is misleadingly determined by surrogate endpoints, adverse side-effects are consistently downplayed, and profit is valued over human life to the point that some drug companies offer to indemnify doctors if they are sued for prescribing their drug, as Warner-Lambert did with Rezulin, all the risk falls on the patient, all the more so if we are denied access to crucial information.

As I've done more research about drug safety in the aftermath of my mother's death, I've been horrified to learn that the Rezulin model has in fact been repeated over and over during the past ten years. No one seems to be learning anything.

As members of the Drug Safety and Risk Management Advisory Committee, you are in a unique position of power. You can keep using Rezulin as the model of how things should be done. You can keep information from patients and provide political cover for FDA missteps. You can use your appointment to this committee to make extra income serving as an expert witness for pharmaceutical companies.

Or you can see Rezulin as a cautionary tale. You can advise the FDA to enact changes that will inform and thereby protect consumers. I urge you to use your influence to address the serious systemic problems with the safety of prescription drugs, so that American consumers who take an FDA-approved drug need no longer wonder if they take their lives in their hands.

Thank you.