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April 5, 2001

Dr. Peter Honig
Director, Post Marketing Drug Risk Assessment
5600 Fishers Lane HFD400
Room 15B33
Rockville, MD 20857

RECEIVED
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MEDWATCH CTU

Subject: Acetaminophen Toxicity
Regarding: [REDACTED]
Date of Birth: January 29, 1961
Date of Death: September 23, 2000

Dear Dr. Honig,

I was given your name from [REDACTED]. We recently lost a member of our family from Acute Liver Failure. At the time of her death [REDACTED] was a relatively healthy 39 year old, with the exception of chronic knee pain stemming from an old automobile accident, and endometriosis and was using the prescription pain medication Vicodin and Esgic Plus as well as Tylenol.

[REDACTED] had been seeing the same family physician for many years to manage the chronic pain she was having and as a result of that she began using excessive medication, and having it refilled more often than normal. We obtained the records from the pharmacies she used and saw a pattern of the medications being filled every 30 days or less and 100 tablets of each prescription.

In 1999 I saw a difference [REDACTED] her moods, she seemed to be under the influence of something and later I would find out that it was the prescription medications I didn't know she was using. I became concerned when I saw that she was having multiple prescriptions filled and I wasn't sure why she needed them.

I had also used the same "family" doctor so I wrote him a letter and expressed my concerns to him, that I thought she may be using too much medication. Needless to say there was no response from him and as of the a few days before her death I know she was still getting the medication.

My family and [REDACTED] husband [REDACTED] also addressed the issues with [REDACTED] and she admitted to using too much medication and started a program at her church for her "addiction." She also mentioned to her doctor that she did not want the medication refilled anymore, and after viewing her medical records we saw that it was documented in her chart that she made that request but they continued to allow the pharmacies to fill the medication.

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[REDACTED] had made several trips to the doctor for flank pain, and had been having trouble with bloating, and her doctor put her on a diuretic. They never discovered the cause but after a few tests (non of them for liver function) decided that the etiology was unknown. She presented several times during the summer of 2000 for vomiting and diarrhea and was given suppositories to control the symptoms.

On September 17 she had a prescription of the Vicodin filled, and after taking a few (3 ?) she tossed the bottle out, feeling guilty about using it. She had severe flu symptoms for 2 days and then 1 day of feeling better. She managed to drink a gallon of Gatorade on Thursday the 21st and by the next day had mentioned she had not been urinating to accommodate for all the liquid she had taken in. My sister saw her on Friday the 22nd in the afternoon, and she said [REDACTED] seemed to have a yellow skin color but [REDACTED] insisted she didn't want to go to the doctor, but assured her if she still wasn't better by the time her husband got home from work she would present to her doctor.

[REDACTED] arrived home and after a few hours [REDACTED] had deteriorated so much she had periods of not knowing where she was or who her family was. [REDACTED] got her to the ER at that point she was never the same. She was combative. The doctors treated her with glucose because of her history of hypoglycemia they thought she may be in shock. They mentioned to us that her liver enzymes were elevated really high and asked if it was possible she took too much Tylenol. We didn't think so and her drug screen came back almost entirely negative except with therapeutic measurements of Acetaminophen.

She was held in the ER for about 5 hours before being sent to ICU at that point she was in a coma. She was intubated and put on life support. Many other things happened and I am not sure of how much detail you need. Finally she was transported via helicopter to [REDACTED]. She arrived there about 1:30 on September and died at 10:30 that night.

She had consultations from many specialists trying to figure out why she was septic and why every vital organ in her body had failed. A few doctors told us that this resembled acetaminophen overdose. We didn't realize at that point in time that this could have been the result of years of taking acetaminophen and that the final "deadly dose" could have even been a small dose like the ones she was using to get relief from the "flu" she was experiencing.

Because the doctor in [REDACTED] could not figure out why a young healthy person could die so suddenly he ordered an autopsy, which was confirmed for necrosis. The coroner talked with me at length of their feeling that this was related to medication toxicity and not an infection. I was concerned that the death certificate didn't specify that in case we pursued litigation and they assured me that the pathology report would speak for itself, and if used in litigation they would testify to that fact.

I am not sure of the impact that [REDACTED] story will make on you or your quest to address the important issues of acetaminophen, but it was a senseless death, and has left a hole in our family. Please feel free to contact me at my e-mail address: [REDACTED] or at my home address: [REDACTED]

I appreciate the opportunity to tell you of our situation and thank the [REDACTED] family for sharing your information with us.

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Individual Safety Report



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