

Oversight and Investigations Subcommittee
“The Heparin Disaster: Chinese Counterfeits and American Failures”
April 29, 2008

Colleen Hubley Statement

I would like to thank you for allowing me to speak on behalf of my Husband, Randy Hubley. I am familiar with heparin not only because my husband was on dialysis for the last 18 months of his life, but also because I have been a dialysis nurse for 7 years.

Heparin is a lifeline for dialysis patients. It keeps the blood from sticking to the blood circuit while the dialyser clears the blood. As a dialysis nurse, I understand the importance of this drug. Now, because of the loss of my husband, I understand even more the importance of making sure that all drugs are safe.

Randy was a beloved father, stepfather, grandfather, son, brother, uncle and last, but not least, my soulmate. As his wife and a RN, I cared for him in every way possible. We were certain that no matter what came our way, we would be able handle it together... after all, I had been in nursing for 25 years, most as an open heart intensive care unit nurse. Despite our hope, this Man died on January 15th at 2 am, while I did CPR over him...in tears, powerless to save him.

Randy started dialysis in May of 2006, when his kidney transplant rejected. We were the first couple in the Toledo area to do “home hemodialysis.” This is a process that is done 6 days a week, 2 ½ hours at a time, in the comfort of our living room, as opposed to “in-center dialysis” done 3 days a week for 3-4 hours at a time. It was one way for us to gain a little more control over his care and also to increase his life

expectancy. We were willing to do anything to keep him alive and well for as long as possible.

However, after undergoing a surgery at the Cleveland Clinic, Randy needed to start “in-center dialysis.” On January 7, 2008, Randy started dialysis at the same Toledo Fresenius clinic as his mother. This was the last week of his life. I wish I could tell you that at least the last few days of his life were good for Randy. I could take some solace in that. However, the weekend prior to his death, was awful.

When he arrived home from dialysis on Friday, January 11, Randy had low blood pressure, severe diarrhea, abdominal pain, jaw pain, his throat was sore and felt “tight” to him, making him feel he needed his inhaler to breathe easier, something he didn’t normally need too often. Because of this, he barely could make it to the restroom. This was not my husband! He lay on the couch this whole weekend, trying to give me a smile when he could.

Monday morning he was too embarrassed to go to dialysis, fearful of having 12 other patients see him having diarrhea right in the chair, because it isn’t a quick process of returning the blood. He was too stubborn and disgusted with the thought of going to the ER and having another, “Well, were not really sure what’s going on” answer. We settled on the couch to sleep, so I could be near him. He promised that he would go if it didn’t subside by morning, but at 2 am I awoke to him clutching his abdomen, unable to breathe and finally grabbing his chest. We had already called 911 before he collapsed, and what seemed like hours I gave him CPR with my son helping me. Even when the paramedics arrived, they could barely get a breathing tube in his throat due to the

swelling. He was taken to the ER and we were notified that even if they got him back, it was hopeless. I watched my husband and best friend slip away before my eyes.

There isn't enough time to make anyone understand what a loss this has been. There is a void that can never be filled. Randy wanted to spend his last years fishing with his family and spending time with his loved ones. He will not get that chance now, and his grandson will never know what a beautiful person he was.

As a nurse, I thought I would be there to save my husband from any errors, but I guess I was naïve. I never thought that the lifesaving medication we were relying on might be contaminated.

Now, after learning that my husband was given contaminated heparin, I understand even more that everything in healthcare is vital, that there should be no "acceptable losses." If citizens are truly going to ever feel safe in this country, going to a hospital, doctor or taking our daily medication, we all have a responsibility to make sure that everything that is given is free from contamination. I understand that the FDA is overworked and understaffed, it is something I deal with everyday as a Nurse, but if you take a deep breath and think for one moment, "What if that was my Mother, My Husband.....what would I want done?"

My husband was a fighter until the bitter end. He would have given anything for one more day, and I know he would want me to make sure this doesn't ever happen to anyone else. Please do not let his death be in vain, We, as a family, need to know that some good can come of this tragedy.

While the FDA and Baxter have failed to perform their duty to provide Americans with safe drugs, there are many Americans who have worked very hard to insure a safe supply.

An article was published last week in the New England Journal of Medicine¹ connecting the symptoms of heparin patients like my husband to the contaminated drugs sold by Baxter. I want to thank those doctors and scientists who wrote that article and who have worked so hard to help unravel this puzzle and prove that these counterfeit Chinese imports were responsible.

And I want to thank this Committee for shining light on these issues and, hopefully, for taking action to insure that our drug supply is safe.

Respectfully Submitted,

Colleen Hubley
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¹ Contaminated Heparin Associated with Adverse Clinical Events and Activation of the Contact System, Kishimoto, *et al*, new England Journal of Med 2008;358, published at www.nejm.org on April 23, 2008.