

Celebrity tragedy focuses attention on federal preemption and MICRA limits

Testimony of Dennis and Kimberly Quaid before Committee on Oversight and Government Reform of the U.S. House of Representatives

May 14, 2008

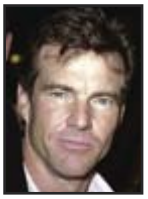
Chairman Waxman and Members of the Committee:

Thank you for inviting my wife, Kimberly, and me here today to share our experience as parents of two infants harmed by the negligence of a prescription drug manufacturer. As I'll explain, our newborn twins nearly died because of a drug company's failure to put safety first. It is our hope that these proceedings will raise public awareness of the issue before the Committee today: When the U.S. Food and Drug Administration (FDA) approves the sale of pharmaceutical drugs, does that preempt the right of consumers to sue the manufacturer if the drug later causes injury or death? This is an issue, I'm sure, most Americans are not aware of, but it is one that could adversely affect all Americans, our family included. As many of you already know, our twins received a potentially fatal overdose of the bloodthinning medication Heparin last year.

Our life-altering story

Thomas Boone and Zoë Grace Quaid were born on November 8, 2007. They were four weeks premature, but healthy and beautiful, and, after three days in the hospital, we took them home to begin our new life as a happy, much-expanded family.

On their eleventh day of life, Kimberly noticed an irritation on T-Boone's belly button and Zoë Grace's finger. Being nervous new parents, we took T-Boone and Zoë to the pediatrician immediately, and, after examining them, he sent us to Cedars-Sinai Medical Center – one of the top hospitals in Los Angeles – for a more


Quaid

in-depth diagnosis. Lab tests at Cedars revealed that both of our twins had a staph infection, and we were told that they would have to be admitted to the hospital to be put on a continuous intravenous drip of antibiotics. Our hearts sank as we accompanied the twins to the pediatric ward, where they were placed in a room to begin their treatment.

At about 11:00 a.m. the next day, a nurse came to the room and said she needed to replace the now empty bags of antibiotic. According to standard procedure, the nurse was supposed to clean the IV lines connected to our twins' little arms with 10 units of a blood thinner medication called Hep-Lock, the idea being that the very small dose of Heparin contained in Hep-Lock allows the IV to flow freely. What was not standard procedure was that she mistakenly injected the twins with a massive overdose of 10,000 units of the drug Heparin, which is *1,000 times* the normal 10-unit dose of Hep-Lock our babies should have received. This happened while Kimberly and I were present in the room.

Unaware of the catastrophe that had just occurred, Kimberly and I spent the afternoon and early evening standing vigil over our twins until our doctor suggested we go home and get some rest. We were exhausted, not having slept the night before. The twins seemed to be resting comfortably, so we decided to go home, but not before leaving express instructions to the doctors and nurses to call us if anything changed in our infants' condition. We had no way of knowing at that point that the potentially lethal quantity of Heparin in their tiny bodies was turning their blood to the consistency of water.

After we left, a nurse on duty noticed that Zoë Grace had an abnormal seepage of blood coming from a place on her foot where blood had been drawn. No alarms were raised. Incredibly, sometime after 7:00 p.m., both babies were injected with yet another 10,000-unit overdose of Heparin. One nurse prepared the medication, and then handed it to the instructor nurse, who then handed it to the nurse in training as the instructor lectured the trainee on how infants must only receive a 10-unit dose of Hep-Lock. They then left the room and continued their rounds.

At about 9:00 p.m., Kimberly and I were at home trying to get some restless sleep when Kimberly was suddenly struck with a hammer blow of overwhelming dread. She became inconsolable, crying out with a mother's intuitive certainty that our babies were in trouble: "They're passing," she said. This did not make sense to me. I had called the nurse's station an hour and a half earlier and had been told that the twins were fine. But, to calm Kimberly's fear, I called again and was put through to the nurse in our room. Kimberly wrote down the time for some reason. The nurse told me in a measured tone that the twins were fine. I was assured. Kimberly became less frantic, and we both eventually fell into a fitful sleep.

But the twins were not fine. In fact, they were fighting for their lives. Their now water-thin blood was flowing out of every place that they had been poked or prodded. They faced the very real possibility of hemorrhaging through a vein or

Copyright © 2008 by the author.
For reprint permission, contact the publisher: **www.plaintiffmagazine.com**



The Quaid Foundation

For most of us, the name of Dennis Quaid is a familiar one. We've watched his films for years, starting with *Breaking Away* in 1979, *The Right Stuff* in 1983, and *Vantage Point* in 2008. Good, solid entertainment. We've come to know him as the actor with the easy-going charm, a broad disarming grin, and a mischievous twinkle in his eyes.

When political issues are discussed, his name doesn't come up. One might think of Sean Penn, Alec Baldwin, Susan Sarandon or Tim Robbins, but not Dennis Quaid. Of course, these are actors who have consciously decided to use their celebrity status to promote their viewpoints. Nothing wrong with that, in my opinion. If there is a greater interest in Darfur because George Clooney spoke up about his observations there, or we have keener interest in Africa because of Madonna or Angelina Jolie, well, I am fine with that. Whatever it takes to shed a light on the dark corners of our world.

Some people, and perhaps Dennis Quaid is one of them, do not publicly advocate their positions. For them, tragic events can often trigger an activism that has far-reaching effects. Before Quaid's twins suffered a massive overdose, I couldn't say what Quaid stood for. All that changed on November 20, 2007, when the hospital staff at Cedars-Sinai mistakenly gave the Quaids' twins, Thomas Boone and Zoe Grace, then only 12 days old, one dosage of Heparin, a blood thinner, then a second dosage, that was 1,000 times greater than the common dosage for infants. Heparin is a blood thinner and overdoses had already killed three children in Indianapolis the prior year.

Apparently two pharmacy technicians and a nurse who administered the drug failed to check the concentration level. Quaid claimed the packaging was not distinctive enough when compared with a larger dose Heparin packaged by Baxter Healthcare. In their lawsuit against Baxter International Inc., the Quaids alleged that Baxter should distinguish the package by size and shape, and that in February 2008, Baxter sent a letter warning health professionals to carefully read the labels to avoid a mix-up.

In defending itself against charges of defective packaging and labeling, Baxter has insisted it was "not a product issue. The issue here is about improper use of a product." Since the incident, Baxter voluntarily recalled all supplies, claiming their recall had nothing to do with Quaids' lawsuit but was due to a possible contamination by a Chinese manufacturing plant that may have contributed to 19 deaths.

In a previous interview with *Golf Digest*, Quaid said "There are three things being a celebrity is good for: raising money for charity, dinner reservations, and tee times." Quaid has been involved in golfing for charity for years and lends his name to the annual "Dennis Quaid Charity Weekend" in Austin, Texas. Now he can add a fourth . . . Because of this near-tragedy – Dennis Quaid and his wife founded a non-profit corporation, The Quaid Foundation. For more information, go to www.thequaidfoundation.org. — ***Donna Bader,*** *Editor*

artery, causing massive brain damage or failure of one of their vital organs.

Our babies could have died that night, and we would not have been there for them.

Early the next morning, Kimberly and I arrived at the hospital, only to be met at our babies' room by our pediatrician and hospital staff. We were taken aside and told what had happened. Suffice it to say, it was the beginning of the most frightening day of our lives. It was spent helping tend to our infants who were still bleeding profusely and severely bruised from internal bleeding. They were both screaming in pain, and God only knows what they were feeling. I am not sure even a lab rat had ever received such a high dose of the Heparin that was causing them to bleed out. At one point as the doctors tried to clamp shut a bleeding wound in the remnant of T-Boone's umbilical cord, blood spurted six feet across the room and splattered on the wall. The bleeding went on all day. Although the twins had been administered Protamine, a medication to counteract the Heparin overdose, their blood's inability to coagulate literally remained off the charts all day and into the night. Kimberly and I did a lot of praying.

Finally, after more than 40 hours, their coagulation levels dropped into the measurable scale and continued to fall, eventually back into the normal range. T-Boone and Zoë Grace had survived, apparently with no damage so far, thank goodness. But we have no way of knowing what the long-term effects may be.

We were not alone

How had this happened? The answer became apparent after interviewing the doctors and nurses. We discovered that the bottle of 10-units of Hep-Lock and the 10,000-unit bottle of Heparin – both manufactured by Baxter Healthcare Corporation – were deadly similar in labeling and size. The 10,000-unit label is dark blue, and the 10-unit bottle is light blue. And if the bottles are rotated slightly, as they often are when stored, they are virtually indistinguishable.

We later learned that the similarity of the labels for the two products had led to the overdose of infants at a hospital in Indianapolis little more than a year earlier, in September 2006. Just like with T-Boone and Zoë Grace, hospital staff used the 10,000-unit Heparin product, rather than the 10-unit Hep-Lock, to flush the infants' IV lines. Tragically, three infants died, and three others were severely injured.

More than four months after the Indianapolis incident, Baxter sent out a warning to hospitals concerning the potential for deadly mix-ups in the two products. A full seven months after that – in August 2007 – Baxter submitted changes in the labeling of the higher-concentration Heparin to the FDA.

Copyright © 2008 by the author.
For reprint permission, contact the publisher: **www.plaintiffmagazine.com**



Other speakers testifying before Congress on preemption

Dr. William Maisel, practicing cardiologist at Beth Israel Beaconess Medical Center and Assistant Professor of Medicine at Harvard Medical School also spoke. Dr. Maisel has served as a consultant to the FDA's Center for Devices and Radiologic Health since 2003 and previously chaired its Post-market and Heart Device Advisory Panels.

He testified that "FDA marketing clearance or approval of a medical product does not guarantee its safety" and stressed the need for patients to receive "accurate, timely, easily understood information to assist them in making informed decisions." He concluded that additional consumer safeguards are needed to improve medical device safety and the manufacturer's responsibilities for product safety extend beyond initial FDA approval.

Dr. Maisel discussed the continued distribution of pacemakers manufactured by St. Jude Medical, even after it was learned they were defective. St. Jude revised its design and received FDA approval for the modified device but continued to distribute the faulty pacemakers. Finally, eight months after FDA approval for the modified device and almost 2-1/2 years after learning of the defect, St. Jude recalled 163,000 pacemakers. This story points out the problems in giving patients critical information about medical devices.

Dr. Maisel noted that FDA may have a limited ability during its pre-approval evaluation to identify and predict which products are safe. The approval does not always answer all of the questions that the FDA may have. The FDA may also require a manufacturer to perform post-approval studies as a "condition" of approval after its initial marketing approval. He described problems with this post-approval commitment, including failure to conduct the studies, lost studies, late reports, and overdue reports. Manufacturers may fail to report malfunctions and resulting injuries. He noted that the FDA receives more than 200,000 complaints annually about device-related injuries and malfunctions, including more than 2,000 device-related deaths. Visit http://oversight.house.gov/documents/20080514103743.pdf to read more about his testimony.

(See also Testimony of **Dr. Aaron Kesselheim**, physician in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham & Women's Hospital in Boston at http://oversight.house.gov/documents/20080514104328.pdf for a further discussion on the FDA approval process and the role played by pharmaceutical companies and manufacturers.)

Dr. Kesselheim concluded: "Applying the principle of preemption in these cases would treat FDA approval and labeling decisions as the final word on knowledge about a drug's safety, when substantial experience shows that they are not. Preempting lawsuits against pharmaceutical manufacturers would remove a check on pharmaceutical manufacturers that is essential to prescription drug safety and the public health. Without the possibility of litigation against manufacturers and their executives, we are likely to see greater misrepresentation of safety-related data and more inappropriate use of potentially harmful medications. Manufacturers should not be absolved of blame when they inadequately evaluate or report their products' risks. Manufacturers continue to have a key role in the development and organization of efficacy and safety data about their products, but they also have an inherent conflict of interest when evaluating their own products. In my view, it is therefore important to continue to encourage manufacturers to act responsibly by subjecting their decision making to judicial review."

David Kessler, Former Commissioner of the FDA, together with his colleague, Professor **David Vladeck** of Georgetown Law School, testified that the FDA product approval and state tort liability should operate in a "complementary but independent manner," giving several conditions that should be met if preemption is imposed. He stated that "the tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients, and the FDA about newly emerging risks." Preemption, he believes, would dramatically reduce those incentives. He concluded, "'[I]t is the manufacturers, not the Agency, that are in a far better position to know when a new risk emerges from a drug or device. And it is the manufacturer that has the ability to make swift changes to a drug or device's warning or product features. Doing away with the incentives to act responsibly and expeditiously to correct potential risks, incentives that are the result of state liability cases, would, I believe, jeopardize the public's health." Read more at:

http://oversight.house.gov/documents/ 20080514104829.pdf.

Professor Vladeck's testimony can be found at:

http://oversight.house.gov/documents/ 20080514123701.pdf (including a history of the Medical Device Amendments of 1976 and a plea to Congress to overrule the Supreme Court's recent ruling in *Riegel v. Medtronic, Inc.,* 128 S.Ct. 999 (2008).

Other speakers included **Gregory Curfman**, executive editor of the *New England Journal of Medicine* (http://oversight.house.gov/documents/20080514124322.pdf), **Christine Ruther**, a medical device engineer (http://oversight.house.gov/documents/20080514124817.pdf), **David Clark**, Majority Leader of the Utah House of Representatives and current Chair of the National Conference of State Legislatures Standing Committees (http://oversight.house.gov/documents/20080514125320.pdf), economist **John Calfee** (http://oversight.house.gov/documents/20080514125818.pdf) and **Dr. Randall Lutter,** Deputy Commissioner for Policy at the FDA, speaking in favor of preemption, at http://oversight.house.gov/documents/20080514125818.pdf.

*— **Donna Bader,** Editor*

Baxter was permitted by FDA regulations to revise its labels, without prior FDA approval, to add or strengthen a drug warning or precaution, or to enhance drug safety by strengthening an instruction about a drug's dosage and administration. So, although the FDA did not approve the changes to the Heparin label until December 2007, Baxter

Copyright © 2008 by the author.
For reprint permission, contact the publisher: **www.plaintiffmagazine.com**



starting using its new labels in October 2007. Baxter described the changes to the Heparin labels as "an increase of 20 percent font size, a unique color combination, and a large cautionary tear-off label" warning that the product is not intended for "lockflush."

Baxter explained that the new labeling was designed to help reduce the risk of medication errors. But, shockingly, Baxter failed to recall the misleadingly labeled bottles that were still on the market and stocked in hospitals ready for use. Kimberly and I think that this was a dangerous, potentially deadly decision, made by Baxter for financial reasons. Companies recall automobiles, they recall toasters, they even recall dog food, but Baxter failed to recall a medication that, due to its labeling, had killed three infants and severely injured three others. More than a year after the Indianapolis tragedy, the same medical nightmare happened to our 12-day-old infants – and all because Baxter had not acted as a responsible corporate citizen.

Baxter knew that an estimated 7,000 Americans die each year as a result of medication errors, knew that 61 percent of life threatening or lethal errors involve intravenous drugs such as Heparin, and also knew that Heparin was among eight high-alert products that were involved in more than 31 percent of all medication errors that caused harm to patients. Yet, even with all of this knowledge, Baxter did not change the labeling of its Heparin injection products until months after the Indianapolis tragedy. And Thomas Boone and Zoë Grace would have to fight for their lives because the new product labeling, introduced by Baxter only one month before, had not yet made it to the shelves of Cedars-Sinai, and Baxter had done nothing to see that the look-alike Heparin products were removed from pharmacy shelves immediately.

Although mistakes occurred at Cedars-Sinai hospital, doctors, nurses, pharmacists, or other staff who make medical errors are not bad people. Indeed, choosing a career devoted to curing the sick and easing the suffering of others is one of life's highest callings. But the overdosing of our twins was the result of a chain of events, and the first link in that chain was Baxter Healthcare. Because of Baxter's inaction, a tragedy was waiting to happen again.

What can be done?

Since this brush with tragedy, I have found out that medication errors are unfortunately all too common. Approximately 100,000 U.S. patients die every year because of medical errors in hospitals alone. It's a toll we would never tolerate in aviation, nearly the equivalent of a full 747 crashing every single day.

I have also learned a lot about the legal system – and it was surprising, I have to tell you. Like many Americans, I believed that a big problem in our country was frivolous lawsuits. But now I know that the courts are often the only path to justice for families that are harmed by the pharmaceutical industry and medical errors. Yet the law is stacked against ordinary people. For instance, in my home state of California, a 1975 law caps compensation to malpractice victims. The cap has never been raised for inflation. The practical effect is that people without the wealth to pay legal fees up front are unable to get their cases before a judge or jury.

Now we face something with potential to be even more sweeping and even more unjust: federal preemption. The Supreme Court is about to decide whether to bar most lawsuits over drugs and their labeling, as long as the drug was approved for marketing by the FDA. After many years of rejecting arguments that FDA actions should preempt lawsuits involving injuries from products regulated by the FDA, White House appointees at the FDA reversed that position in 2002, and now argue that FDA approval immunizes the manufacturers of dangerous products from liability for the deaths and injuries they cause.

We sued Baxter Healthcare Corporation in November 2007. Baxter has filed a motion to dismiss the case, relying on the same preemption argument that the drug industry and the FDA has made before the Supreme Court – that when the FDA allowed its Heparin drug onto the market, it gave Baxter the government's seal of approval – a "get out of jail free" card that denies us the right to hold the company accountable. (Of course, Baxter never mentions the FDA regulations that encourage and sometimes require manufacturers to fix their drug labels immediately, without getting the FDA's permission first.) So, says Baxter, our suit may not be heard by a judge or jury.

It is hard for me to imagine that this is what Congress intended. You tell me, Mr. Chairman: When it passed the Food, Drug, and Cosmetic Act in 1938, did Congress intend to give appointed bureaucrats at the FDA the right to protect a drug company from liability, even when the company cuts corners and jeopardizes our safety?

A federal ban on lawsuits against drug companies would not just deny victims compensation for the harm they experience. It would also relieve drug companies of their responsibility to make products as safe as possible, and especially to correct drug problems when they are most often discovered – years after their drugs are on the market.

Permitting bureaucrats who are under pressure from their bosses and the drug companies themselves to yank our access to the courts is incomprehensible. We have all heard about understaffing and backlogs at the FDA, and about drug-safety scrutiny that is patchy at best. If the Supreme Court rules in favor of the drug companies, it will eliminate one of the most effective deterrents to letting the bottom line win out over public health and safety.

I am in the entertainment industry, but what happened to us, and what is happening in the courts of our country,

Copyright © 2008 by the author.
For reprint permission, contact the publisher: **www.plaintiffmagazine.com**



is no fiction. It is all too real. That is why I have decided to speak out and try to do something.

Kimberly and I have established a non-profit foundation to call attention to medical safety issues and seek ways to improve medical safety from the bedside up. Everybody gains from a safer health care system – from patients to nurses and doctors to hospitals and insurance companies.

We are meeting with experts from all over the country to formulate a strategy for safer health care. Americans pioneered the safest aviation system in the world; though highly complex, it is 99.9 percent error free. The human body is also very complex and hard to perfect. But we should strive for perfection, and we know that at the very least we can do much better.

We can hope that the Supreme Court will not put more barriers in front of patients who are harmed by drug companies. But if the Court goes along with the FDA and rules for the drug companies, I respectfully ask this Congress to pass corrective legislation on an emergency basis, just as it should do immediately to correct the recent Supreme Court decision immunizing the makers of defective and mislabled medical devices. We Americans need some balance on the scales of justice in our country.

My family blessedly survived a huge drug error, triggered by the misconduct of a drug manufacturer. Others are not so fortunate. If they are denied access to our courts, they will have no compensation for their injuries, and society will lose one of the most effective incentives for safer drugs.

Copyright © 2008 by the author.
For reprint permission, contact the publisher: **www.plaintiffmagazine.com**