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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,



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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 pio-

neered 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 emer-

gency basis, just as it should do immediately to correct the recent Supreme Court decision immunizing the makers of defective and mislabeled 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.