



## **BAXTER RESPONDS TO PREEMPTION DISCUSSION, THE QUAID LAWSUIT AND THE CRITICAL ISSUE OF MEDICATION ERRORS**

- I. Prominent, differentiating features existed on the labels of misadministered heparin products; these features aided clinicians in safely administering the products more than 100,000 times a day**
- II. Baxter's packaging is specifically designed to help reduce the possibility of medication errors**
- III. Recalling a safe, efficacious drug because of misuse of a product would deprive other patients of much needed medications**
- IV. Baxter has moved to dismiss the Quaid lawsuit, based on a number of grounds, including preemption**

DEERFIELD, Ill., May 14, 2008 – Baxter commends Dennis Quaid for sharing their twins' harrowing experience in an effort to highlight the serious issue of medication errors during the United States House of Representatives' Committee on Oversight and Government Reform hearing entitled "Should FDA Drug and Medical Device Regulation Bar State Liability Claims?" held today.

"Baxter's first priority is patient safety and the safety of our products, and we sincerely regret that one of our drugs, intended to save and sustain lives, was instead at the center of a medication error," said Francois Lebel, M.D., vice president of Global Medical and Clinical Affairs for Baxter's Medication Delivery business. "It's important to remember that the hospital already publicly stated that these were unfortunate and avoidable events."

- I. Prominent, differentiating features existed on the labels of misadministered heparin products; these features aided clinicians in safely administering the products more than 100,000 times a day**

Baxter's heparin vials have been used safely more than 100,000 times a day, a fact that contradicts the implication that two of the company's vials are indistinguishable from one another.

The two hospitals where tragic errors occurred with Baxter's heparin products reported that these were isolated events resulting from a system failure in the hospital along with human and procedural errors, such as not reading the label. In the Quaid's situation, the hospital's assessment that human error was involved was supported by the California Department of Public Health's findings.

"These tragic incidents illustrate why it is so important that clinicians always read the name and dose of a drug before giving it to a patient," said Lebel. "No label enhancement will ever replace the need for clinicians to put safety first and ensure they are administering the right medication."

## **II. Baxter’s packaging is specifically designed to help reduce the possibility of medication errors**

After learning of the tragedy involving misadministration of heparin in Indianapolis in late 2006, Baxter consulted with the FDA and broadly distributed a Medication Safety Alert to clinicians across the United States to notify them that, although isolated, its heparin vials had been involved in a medication error. Prior to the error, Baxter had never received a single customer report about a perceived similarity between the 10 unit Hep-Lock and 10,000 unit heparin vials. Nonetheless, Baxter began a project to devise an innovative way to label and package its drugs that would reduce the risk of clinician error from failing to read the labels, starting with heparin.

In the months that followed, Baxter conducted extensive market research in multiple cities, seeking information and feedback from more than 100 clinicians about medication errors, their causes, and the new label ideas and prototypes that Baxter was considering. Baxter communicated the results of this research to the FDA. Heparin, as a “high alert” medication (as defined by the Institute for Safe Medication Practices), was the first drug to be packaged in this new labeling and Baxter plans to introduce additional drugs with this packaging beginning later this year.

Baxter ceased manufacturing the heparin vials with the previous labels in September 2007 and, after going through the appropriate due diligence, introduced new vials with a 20 percent font size increase, unique color combination and large cautionary tear-off label reinforcing that the product should not be used as a heparin lock-flush solution. Vials with the new labels were available for hospitals to purchase as of October 2007 and have been well-received and recognized as a market-leading patient safety advancement. However, even these changes do not lessen the importance of reading the label.

## **III. Recalling a safe, efficacious drug because of misuse of a product would deprive other patients of much needed medications**

Baxter didn’t recall the remaining supply of vials with the previous labels for two reasons: the medication errors were unrelated to the safety or efficacy of Baxter’s products; and Baxter’s vials, even before the label enhancement, were better differentiated than other heparin products on the market.

“To trained healthcare professionals who read the labels, Baxter’s vials were very different – different drug names – HEP-LOCK U/P vs. Heparin; 10 units vs. 10,000 units; bright green cap vs. gray cap; light blue label vs. dark blue label; and different font styles,” said Lebel. Medication errors can and do occur with any drug if clinicians do not read the label. If companies recalled a drug product whenever a clinician made an error, this would deprive other patients of much needed medications. At the time of these events, the U.S. relied on essentially two manufacturers for this life-saving medication, and a recall may have disrupted the supply of a safe and critical medication.

#### **IV. Baxter has filed to dismiss the Quaid lawsuit, based on a number of grounds, including preemption**

The Quaid lawsuit is ongoing. In March, Baxter reached out to the Quaid's attorney to ask the Quaid to partner with Baxter and distinguished medication safety experts on a program to reduce medication errors, though a response has not yet been received. Baxter is hopeful that it can resolve this litigation and partner together with the Quaid for the benefit of clinicians and patients rather than continue to litigate this matter in the courts.

On March 4, 2008, Baxter filed a Motion to Dismiss On Ground Of Federal Preemption and Forum Non Conveniens with the Circuit Court of Cook County (Illinois).

- **Preemption**

Preemption is a concept originating from the U.S. Constitution. Federal law preempts state laws where a conflict between the two would make it impossible for parties to comply with both state and federal law.

Preemption shields companies only from lawsuits that would interfere with FDA decisions. For instance, companies could still be sued for manufacturing adulterated or misbranded products. The only state claims that are preempted are those that seek to impose liability on a health care company for doing what was required or authorized by the FDA.

The FDA has broad authority to ensure that prescription drugs are safe and effective for use as labeled and packaged. The Food Drug and Cosmetic Act implicitly preempts any state law claims that interfere with this authority.

Preemption is intended to ensure that a patchwork of inconsistent label requirements isn't created by thousands of judges and juries across the country. This would increase the burden and costs to health care companies, which would ultimately raise health care costs to all patients.

- **Forum Non Conveniens**

Baxter filed a motion to dismiss based upon forum non conveniens because the medication errors occurred in the state of California; the plaintiffs and potential third-party witnesses reside in California; and because the potential witnesses in California are beyond the subpoena power of the Illinois court.

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