



# We Must Protect Ourselves Now More Than Ever

By Stephanie Feldman Aleong

Florida has dealt a significant blow to the safety of all people who rely on prescription drugs, particularly those patients who need delicate and expensive therapeutics, such as immune globulin: In the 11th hour of the last day of the legislative session in May, both chambers of the Florida Legislature passed HB 371, which significantly weakens Florida's 2003 Prescription Drug Protection Act.

Then, in the last days of June, Governor Jeb Bush signed HB 371 into law, allowing distributors of prescription drugs to avoid their responsibility to provide documentation regarding the source and conduits of prescription drugs, and making it easier for counterfeit prescription drugs to reach your pharmacy shelves.

## From Leader to Laggard

In 2003, Florida was the leader in the nation with its passage of the Prescription Drug Protection Act, which required all distributors of prescription drugs to prepare, authenticate and distribute drug pedigrees, in paper or electronic format, whenever they transacted prescription medication. These pedigrees would document the true origins of drugs and make the distribution of prescription drugs a transparent process that health inspectors could verify. The pedigrees would also provide critical evidence for prosecutors to catch criminals who counterfeit and adulterate prescription drugs that end up on reputable pharmacies' shelves.

Florida's drug protection law was enacted in response to the 17th Statewide Grand Jury of Florida Report, which noted that the legitimate marketplace of drugs in Florida was riddled with counterfeit and adulterated medicine that felons had introduced into the national drug supply through the use of a complex web of shell corporations.

Prescription drugs that eventually found their way to the largest of U.S. drug distributors had passed through hot car trunks, laundry rooms, trailers and numerous hands in South Florida. As noted by the Nevada State Board of Pharmacy, because there is no such thing as a local, regional or statewide drug supply, it was the entire

nation's drug supply that was contaminated by these bad actors.<sup>1</sup> In fact, the book "Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply" reported the rampant proliferation of counterfeit and adulterated drugs in Florida that eventually traveled nationwide.<sup>2</sup>

Florida's pedigree requirement was set to go into effect on July 1, 2006. However, the pharmaceutical industry led an all-out assault on the Prescription Drug Protection Act by encouraging and supporting legislation watering down the pedigree requirement, legislation that eventually became law in the form of HB 371. Now with its enactment, HB 371 eliminates the pedigree requirement as long as drug wholesalers simply "promise" that they buy their medicine from drug manufacturers directly and sell directly to a dispenser, such as your local pharmacist. No documentation of the origin of the drug—including lot number or invoice number—will travel with these pharmaceuticals.

## Is a Promise Enough?

This lack of a traceable number makes it nearly impossible for the drugstore where you buy your medicine to make sure that the wholesaler has in fact bought the drugs directly from the manufacturer. Without an identifying number, this meaningless "promise" merely signifies that at some point a distributor "promised" it purchased a specific unit of a drug from a manufacturer, but, without a pedigree, there is no way for a health inspector or prosecutor to prove that a specific vial of drug was the subject of a fictitious "promise" or a valid one.

Additionally, HB 371 allows distributors to make "intra company transfers" of medicine without providing any pedigrees, which is exactly the type of practice that led to counterfeit medicine being introduced into one of the



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nation's largest distributors, Cardinal Health Inc., when one of its employees took kickbacks from a counterfeiter in exchange for purchasing unsafe, adulterated medicine from a previously convicted felon.<sup>3</sup> The drugs Cardinal's employee bought traveled from warehouse to warehouse at Cardinal and into the nation's drug supply because of intra company transfers.

Without the original protections in Florida's 2003 Prescription Drug Protection Act, patients' health once again depends on the honor of an industry that has successfully refused to provide pedigree documentation for over 15 years and that has allowed counterfeit medication to reach our pharmacy shelves.

### Anyone Can Be Affected

Patients have been injured by the counterfeit and adulterated medicines reaching pharmacy shelves. Most notably, on Long Island, New York, a 19-year-old liver transplant recipient, Tim Fagan, was injected with adulterated Epogen that came from Florida.

Tim's mother had purchased the Epogen from her local CVS and had no reason to suspect there was anything wrong with the vial of medicine. Only later, after Tim had suffered painful convulsions and anemia, did the family eventually find out that the Epogen had passed through 12 different locations and unauthorized, unsafe supply channels before landing on their drugstore's shelves.

Tim's struggle spurred Representative Steve Israel, D-N.Y., to introduce federal legislation that would make pedigree papers compulsory, increase penalties for dealing in counterfeit medicine and give the FDA much needed resources to investigate counterfeiting.<sup>4</sup> Sadly, that bill continues to languish in committee in the House since its introduction in May 2005.

There is some hope for patients, however. The federal government is finally about to mandate that many distributors produce pedigree papers. In 1988, Congress enacted the Prescription Drug Marketing Act (PDMA), which required that distributors of prescription drugs provide pedigree papers with each shipment of prescription drugs. One of the reasons counterfeit and adulterated drugs have continued to flourish since 1988 is that industry successfully convinced the FDA to "stay," or put on hold, the pedigree requirement for 18 years. Instead, a mandatory requirement for pedigree papers became an "advisory opinion," because of the political pressure drug companies brought to bear.

Because of all of the recent publicity surrounding, and

prevalence of, counterfeit drugs, the FDA announced in June that it is lifting the stay on the federal pedigree requirement, effective this December.

This should be our happy ending, correct? Even if the state law on pedigrees in Florida is now gutted, we still have the federal pedigree law to protect us. Right? Not exactly.

The federal PDMA has a large exception to its pedigree requirement: It excludes "authorized dealers of record" of a drug, which it defines vaguely as a wholesaler that has an "ongoing relationship" with a manufacturer to distribute that manufacturer's drug. The PDMA does not define "ongoing relationship."<sup>5</sup> Neither does the FDA define that term in the Code of Federal Regulations.

So, bottom line, industry can still skirt the pedigree requirement, unless the FDA constructs a narrow definition of "authorized distributor" and "ongoing relationship." It is my fervent hope and mission to convince the FDA to construct such a definition.

### What Can You Do?

As a group, patients who take costly injectable pharmaceuticals are particularly vulnerable to counterfeiters because of the incredible profit that entices criminals to move unsafe, adulterated and counterfeit versions of these products into the legitimate marketplace. Current federal and state law is not sufficiently strict to stop this practice, although I am hopeful that continued pressure on the FDA to narrow the definition of who can be exempt from the pedigree requirement will result in better regulation.

For now, you should always check the packaging of your drugs to see if there are any discrepancies, and contact your doctor immediately if you experience any abnormal reaction to your medicine. As a type I diabetic and a cancer survivor, I carefully scrutinize every prescription each and every time I open a new vial of medicine or bottle of pills. I know that, until the government takes the right action, careful observation is our best line of defense. ■

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1 Larry Pinson, Pharm.D, Executive Secretary for the Nevada State Board of Pharmacy, Letter to the Governor to Veto HB 371 (May 9, 2006).

2 Katherine Eban, *Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply* (2005).

3 *United States v. Spence, Carlow*, Case No. 3:06-00047, United States District Court for the Middle District of Tennessee.

4 HR 2345 (2005).

5 21 C.F.R. § 203 (2006).