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FEATURES

PHARMACEUTICAL FAKERY

COUNTERFEIT DRUGS THREATEN PATIENTS' HEALTH

Elizabeth Cady Brown (Photos: Wayne Herrschaft) 06/09/2005 12:07 am



Tim Fagan had already been through a lot when the doctors prescribed Epogen for his anemia. Two years before, when he was just 14, Tim had developed a rare liver condition. His legs turned blue; he became lethargic; he vomited blood. Finally, in February 2002, Tim got a donor liver and had an emergency transplant that saved his life. His parents, Kevin and Jeanne Fagan, hoped that Tim would rebound and that the potent cocktail of pills and injected medications that he took each day would help.

Little did the Fagans know that the Epogen they bought at the CVS pharmacy in Deer Park—that Jeanne injected into her son once a week with tragic devotion—was counterfeit.

"It took us several weeks to put two and two together," remembers Kevin. "Several hours after giving him the Epogen, he would suffer full body cramps and scream like I've never heard him scream before. It affected his whole being."

Tim's reaction only started to make sense after a CVS worker called in May to warn the Fagans that the pharmacy had distributed at least one bogus batch of Epogen, which sells for roughly \$500 per dose. For Kevin Fagan, however, comprehension quickly turned to confusion. How had CVS gotten counterfeit drugs? What was in those vials, if not high-dose Epogen? Why wasn't the government keeping the nation's drug supply safe?



Tim Fagan, the teenager who survived taking counterfeit meds after a liver transplant.

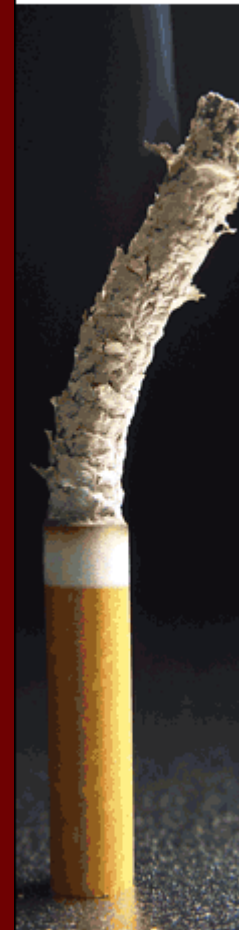
"We are as ordinary as they come," says Kevin, a manager at Con Edison. He and his wife, an assistant principal in Queens, have lived with their three children in Deer Park for 20 years. "I realized, if this could happen to us, it could happen to anyone."

MYSTERY MEDS

The dark world of counterfeiting pharmaceuticals is not well understood. While the Food and Drug Administration (FDA) estimates that less than 1 percent of prescriptions filled in this country are counterfeit, officials admit that this figure is not based on any scientific studies.

"We believe the problem is very small compared to the problem in some developing countries," says Tom McGinnis, the director of pharmaceutical affairs for the FDA. But belief is not the same as knowledge.

Features







And even if the FDA's back-of-the-envelope estimate is accurate, the number of counterfeit drugs dispensed is still potentially enormous. One percent of 3.7 billion, the number of prescriptions filled every year in U.S. pharmacies, is 37 million. Just one phony dose could be deadly or severely debilitating for a patient.

The FDA's own Office of Criminal Investigations initiated nearly twice the number of counterfeit drug cases in 2004 than 2003: 58 compared with 30. The number of such investigations averaged only five a year during the 1990s. But the FDA's McGinnis attributes this not to a rise in counterfeiting, but to increasing vigilance by distributors.

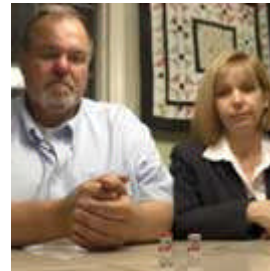
"When they see something that looks suspect, they report it," says McGinnis confidently.

But Katherine Eban, an investigative medical reporter and Rhodes Scholar who just spent two and a half years researching and writing a book about fake pharmaceuticals called *Dangerous Doses*, finds the FDA's response to this public health hazard totally inadequate.

"The problem is enormous," says Eban. "Drug distribution is a minimally regulated system that has been infiltrated by dangerous criminal elements that is having a profound effect on patients."

According to independent pharmaceutical industry monitors such as Eban and the nonprofit consumer-advocacy group Public Citizen, most drugs make it safely from the manufacturer to one of the "big three" national wholesalers, Amerisource-Bergen Corporation, Cardinal Health Inc., or McKesson Corporation. Combined, these companies distribute roughly 90 percent of all drugs manufactured nationwide.

But after this first sale, the supply chain can grow murky and circuitous. Instead of moving directly from manufacturer to distributor to pharmacy, some medications get diverted into a secondary marketplace of smaller distributors, where they are easily counterfeited, diluted or otherwise contaminated. Unscrupulous and unlicensed merchants target drugs made for the sickest patients, because those drugs are often the most expensive.



Kevin and Jeanne Fagan, showing the vials of fake Epogen that they bought at their local CVS in Deer Park.

They are suing the drug distributors for millions and working to improve regulation of the drug industry.

Counterfeiters may change the labels to indicate a stronger dose, dilute the active ingredients, or replace them with substances like tap water, insulin or fertility hormones—in the process potentially turning thousands of dollars of real meds into millions of dollars of junk.

"It can be done through a whole range of schemes," Eban explains. "Printing technology is now so ubiquitous, you can redo the labels easily. You can buy a used pill-making machine on eBay."

Tim Fagan's Epogen was first sent into the marketplace by its manufacturer, Amgen, which sold it to the mega-distributor AmerisourceBergen. But before it entered his blood stream, Fagan's drugs changed hands at least 11 more times. According to Eban, the drug was handled by three different wholesalers, two pharmacies, four unlicensed go-betweens, and one suspected counterfeiter. His medicine spent time in a Florida strip club, Playpen South, and sat in paint cans at a trailer park.



ADOPT A HOMELESS PET



"What was in Tim's drugs will forever be a mystery," says Eric Turkewitz, the Fagan family's Manhattan lawyer. "It's one of the issues with counterfeit drugs—the evidence is destroyed the second it is ingested or injected."

STOPPING THE MADNESS

The family has a massive civil suit pending against the distributors and pharmacies who sold Tim's Epogen. They are asking for compensatory and punitive damages equal to \$1 for every share of outstanding stock for each corporate defendant, which could add up to more than \$108 million. All the parties to the lawsuit are currently in depositions.

Turkewitz says this is the first time such a stock-linked award has been proposed. He put it in the complaint, he says, in order to draw attention to the issue and "wake up" stockholders to their culpability.

"The shareholders are the ones who hire the management," Turkewitz explains, "and this is one way for the shareholder to understand that they will get caught holding the bag if management recklessly endangers the health and welfare of the public."

While the strategy may score points for publicity, some personal injury attorneys think it's a loser legally. Eileen Buholtz, a practicing attorney and past chair of the New York State Bar Association's torts section, explains that because awards for punitive damages are based on the wealth of the company—which the number of shares is not—calculating the damages this way may be grounds for reversal by the appellate court.

Turkewitz acknowledges that when it comes time for trial he may revise his award request, saying, "I put it in [the complaint] for its symbolic effect, but it is up to the jury to determine damages they believe are fair and reasonable."

No matter what the award, Turkewitz and the Fagans understand that massive personal injury lawsuits by victims of counterfeit drugs are only one way to agitate for change. In fact, as soon as Tim's health stabilized after the Epogen episode, Kevin started his own lobbying campaign to convince government officials about the need for legislative reform.

At one point, Kevin remembers Tim saying, "Better this happens to me than an infant."

"It breaks your heart to think about," says Kevin. "So what became paramount in all our minds was exposing this problem so that no one else has to go through it."

After months of pounding on countless closed doors, Tim's story finally caught the attention of Congressman Steve Israel (D-Huntington), whose district includes Deer Park. Soon after their meeting in 2003, Israel proposed a new federal law to combat



The counterfeit Epogen labels were almost identical to the labels for the real thing, except they did not have the degree symbol written next to the storage temperature.

pharmaceutical counterfeiting. He made the announcement standing on the Fagans' front porch. Although Tim Fagan's Law never got out of committee that session, Israel reintroduced the bill on May 9 and has higher hopes of getting a Republican cosponsor.

"At least now we have the book, *Dangerous Doses*," says Israel, "which documents for the first time all these streams of sale. When my colleagues understand that the meds they take might pass through a strip club in Florida, they are going to want to pass my bill."

Israel's proposal would impose stiffer criminal penalties on counterfeiters, require manufacturers to tell the FDA about known pharm fraud, authorize \$60 million per year for spot-checking on-the-shelf drugs, and give the FDA the ability to issue drug recalls. Right now, the FDA can recall equipment but only "encourage" companies to recall their medicines. And, at the crux of the Israel legislation is the launch of a "paper pedigree" system so that drugs can only be sold with a certificate identifying all prior purchasers.

"FedEx is a perfect analogy," says Israel. "They know every place a package has been and the same should apply to the medicines in our blood streams."

Proponents argue that imposing a simple paper-tracking system is one of the most obvious and effective ways to prevent counterfeiting. And Congress agrees—or did—having passed the Prescription Drug Marketing Act in 1988, which authorized precisely the sort of paper trail in Israel's bill. But lobbying by drug-distributor trade groups such as the Healthcare Distribution Management Association (HDMA) and other powerful pharmaceutical interests has kept change at bay for the last 17 years.

Instead, drug distributors have focused on fighting counterfeiters by promoting changes to licensing rules. They argue that the most immediate thing the government can do is raise the bar on the credentials required to get a distribution license.

Technically, the FDA has the paper pedigree on hold, and observers say it would take an act of Congress to finally get the system up and running. The FDA says it has delayed implementing the paper pedigree because industry members have expressed so many concerns about the certificate possibly being counterfeited and how much the system will cost. The HDMA and the FDA jointly argue that new high-tech scanning technologies are just around the corner that will be able to track drugs even more effectively and cheaply.

"We don't believe the cost of a paper pedigree system nationwide is worth it with this technology so close," says McGinnis, the FDA's pharmaceuticals director. He could not say when this high-tech tracking would be ready, however, nor put a price tag on using paper in the meantime.

"We don't know," he admits. "We've never costed it out."

Israel and other critics say the agency is overly sympathetic to industry concerns because the FDA has been "infiltrated" by people who used to work for the companies they now regulate.

"I think they know there is no technological solution imminent, so they are using that to stall the paper," Israel says. "The real issue here is that [the wholesalers and distributors] don't want to bear the expense of these paper pedigrees. My response to them is the Fagan family."

It remains to be seen whether that response will be enough to counter the \$200 billion U.S. prescription drug industry. The

combination of the Fagan lawsuit, Israel's legislation and New York Attorney General Eliot Spitzer's recent decision to investigate the secondary drug market is having some impact already. On May 7, Cardinal Health Inc., the nation's second-largest drug distributor, announced that it would no longer trade with drug middlemen.

And on May 24, CVS, America's largest pharmacy chain, said it would no longer purchase drugs from wholesalers that do trade in the secondary drug market. CVS made its announcement on the same day company attorneys were taking Tim Fagan's deposition and, according to Turkewitz, the CVS decision puts an enormous amount of pressure on the rest of the pharmaceutical industry.

"How can the other two large distributors continue to do business in the gray market when the largest pharmacy chain in the country won't do business with them anymore?" he asks.

Kevin Fagan says he'll continue to fight on both legislative and legal fronts until the drug supply chain is secure. And Tim has sworn to carry on another, more private battle: to conquer the fear and take his pills every day, knowing they could save his life—or end it.

"If I don't take the pills, I die," says Tim. "If they are counterfeit, I die. It's a scary thing that will always play on my mind."

LIKELY PATHWAY FOR TIM FAGAN'S EPOGEN

Manufactured by Amgen (low-dose Epogen, 2,000 units per milliliter)

.....

TO AmerisourceBergen, a national wholesaler

.....

TO J&M Pharmcare, a pharmacy in Miami

.....

TO Armando Rodriguez, a Florida middleman

.....

TO José Grillo, an alleged counterfeiter. He packed 110,000 vials of Epogen in paint cans and took them to a Florida trailer park where Silvino Morales, working in a hut in his backyard, doctored the labels. (Now labeled high-dose Epogen, 40,000 units per milliliter).

.....

TO Paul Perito and Nick Just. They bought the vials in the back room of a Florida strip club called the Playpen South and stored them in a beer cooler.

.....

TO Carlos Luis, a middleman. He had a line of customers waiting for meds. Sold more than \$2 million worth to Eddie Mor.

.....

TO Eddie Mor, owns a paper wholesale company in Texas, sold pharms out of his home.

.....

TO Susan Cavalieri, a registered pharmacist in Florida with a license to distribute. Her involvement made it look legit again.

.....

TO Dialysist West, an Arizona-based wholesaler.

.....

TO AmerisourceBergen's Kentucky distribution center. The same national wholesaler where it started.

.....

TO CVS Pharmacy in New York.

For more information, visit these websites

www.fda.gov/counterfeit

The Food and Drug Administration's page about counterfeit drugs.

www.house.gov/israel/issues/counterfeitdrugs.htm

Congressman Steve Israel's page about Tim Fagan's Law.

www.fraud.org/fakedrugs

National Consumers League tips for avoiding fake pharms.

www.dangerousdoses.com

Katherine Eban's web site.

www.ericurkewitz.com/counterfeit-drugs.htm

Tim Fagan's attorney's web page about counterfeit drugs.



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