

How Safe Is the U.S. Pharmaceutical Supply Channel?

And Why You Should Care!

By Kit-Bacon Gressitt

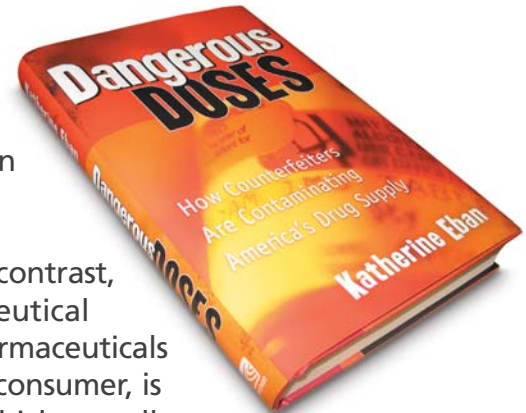
In 2002, investigative reporter Katherine Eban received a tip from a government source, urging her to look into how counterfeit drugs were making their way into U.S. pharmacies.

In May 2005, Harcourt published Eban's book, "Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply."

On November 1, 2005, the House Committee on Government Reform's Subcommittee on Criminal Justice, Drug Policy and Human Resources held a hearing on "Sick Crime: Counterfeit Drugs in the United States," at which Eban testified.

From reporter to author to expert witness is an unusual path. In contrast, what Eban ultimately learned from that first tip is that pharmaceutical counterfeiting is *not* unusual. The supply channel our nation's pharmaceuticals follow, from the manufacturer to the pharmacy to the healthcare consumer, is often convoluted and rampant with vulnerabilities, any one of which can allow counterfeit drugs to enter the supply chain—and end up in your medicine cabinet.

Eban spoke with IG Living about "Dangerous Doses," its genesis and the growing response to it.



Q: Who is the most important audience for "Dangerous Doses"?

Eban: Anyone who takes medicine. What "Dangerous Doses" and my reporting reveal is that Americans who have gone to their pharmacies and paid top dollar for their medicine have been getting adulterated, recycled, stolen and even counterfeit medicine.

Q: How did you discover the counterfeit drug problem?

Eban: I'd been an investigative medical reporter for nine years, and I got a tip from a longtime government source who said I should investigate why counterfeits were landing on pharmacy shelves. His statement really surprised me. When most people think of counterfeits, they think of the Internet or Mexico, but this was a situation in which actual counterfeits were reaching our nation's supply, which is assumed to be secure, closed and inviolable.

I did one story on counterfeiting for *Self* magazine. At the time, I wasn't thinking it was an enormous story, but as I began my reporting [on the situation in Florida], I could see just how huge it was. There were layers of complicity. Major wholesalers seeking discounts buy in the secondary market from small, rogue wholesalers. The investigators who were trying to solve the problem

were encountering terrible bureaucracy and apathy. You had situations where Florida bureaucrats were giving licenses to convicted narcotics traffickers, who then became pharmaceutical wholesalers.

Once we realized the magnitude of the story, we went to "60 Minutes." They took our reporting and did a segment on it. I realized pretty quickly that there could be an extraordinary book here, in part because of not only the magnitude of the corruption, but because of this group of investigators in Florida, who called themselves the Horsemen of the Apocalypse. Their struggle was like a movie in the making.

Q: Why do you think it is so easy for criminals and careless distributors to participate in the pharmaceutical supply channel?

Eban: Consumers just don't know. They have no idea. Most patients who have gotten caught in the crossfire, who have gotten counterfeit medicine, didn't even know that there is a supply chain. They didn't know that their medicine was in the hands of middlemen, between the manufacturer and the pharmacy.

The end result is that they are getting substandard medicine, medicine that may have lost its potency because it was in the trunk of someone's car in hot temperatures,

it was mishandled, and a lot of this medicine is very expensive. It's for patients who need it the most. So, if their medicine is subpotent and it doesn't work, they don't know why it hasn't worked. Most assume it's because they're pretty sick. They don't stop to consider the efficacy of the medicine.

Q: What can consumers do?

Eban: In order to ask informed questions, consumers need to understand how the supply chain works. They need to understand what the risks are that their medicine faces. Try to determine if your pharmacy has an agreement to buy from a wholesaler that pledges that they purchase all their medicine directly from the manufacturer. Disclosures of the medicine's origin to patients are inadequate. I support the drug pedigree's being passed on to the patient, because if you said to a mom, "You can either get a medicine that's guaranteed safe for your child or you can get a discount on medicine that may have been handled by a narcotics trafficker or moved in the back of a car," who would buy that for their kid? Nobody.

Q: What needs to be done to secure the channel?

Eban: I think that drugs should make only one stop between the manufacturer and the pharmacy, and that stop should be documented with a pedigree. Everyone who had their hands on our medicine should be regulated, subject to inspection.

Part of the solution is old-fashioned: stronger laws and more enforcement, so that someone who counterfeits

medicine could be prosecuted for attempted murder instead of for misbranding a commercial product and then spend 18 months in jail and pay a nominal fine. The current laws don't clearly outline criminal penalties for adulteration, which is mishandling, exposing the medicine to risk, as a distinct category of misconduct.

Q: Has the government responded effectively?

Eban: No. We don't have any information as to the size of the problem. The FDA has made guesses, but done no studies. It has capitulated to wholesalers who don't want to reveal where they buy their medicine. With the absence of clear federal guidance, each state has gone off and made their own laws, most of them, until recently, fairly weak.

There needs to be a national solution. The pharmaceutical supply is only as clean as its dirtiest link. So long as there are places in any state where bad medicine can enter the supply chain, then every consumer in the country is at risk. We need uniform standards nationwide.

Q: This issue has led you along an interesting path. Where do you go next?

Eban: A team of movie producers is exploring the possibility of "**Dangerous Doses**" the movie. If all goes well, we may see it in the theaters. ■

"Dangerous Doses" is published by Harcourt Books and can be ordered through www.dangerousdoses.com.

What you can do about counterfeit drugs

Watch what you take

- Be familiar with your medicine. Examine its shape, color, and size.
- If your medicine is in pill, capsule or tablet form, put it in the palm of your hand and examine it under a light before taking it.
- Look for altered or unsealed packaging, or changes in design.
- Make sure the packaging is pristine and has no sticky residue, which can indicate the drug was previously dispensed.

Observe your symptoms

- Be aware of new or unusual side effects.
- Be concerned if your medicine stops being effective.
- Be suspicious if an injectable drug stings or causes a rash.

Look for the latest warnings and announcements

- Visit MedWatch at <http://www.fda.gov/medwatch/>, the FDA's website that lists information on drug safety, label changes and voluntary recall announcements.
- Visit your drug manufacturer's website for information on current recalls.

If you think your medicine is counterfeit

- Tell your pharmacist, your doctor and the manufacturer. Most manufacturers have phone numbers or email addresses for patients with questions and concerns.
- You or your doctor should submit a report to the FDA on the MedWatch site. The form can be found at <http://www.fda.gov/medwatch/report/consumer/consumer.htm>.
- Keep a sample of your medicine as evidence, even if the manufacturer asks you to send it all back.

Other advice

- Buy only from a reputable and licensed seller. You can check credentials through your state pharmacy board or the National Association of Boards of Pharmacy at www.nabp.net.
- If you are buying online, look for approved Internet pharmacies posted at <http://www.nabp.net/vipps/consumer/listall.asp>.
- For more information and articles on counterfeit medicine, visit: Partnership for Safe Medicines: www.safemedicines.org/who/ National Consumers League: <http://fraud.org/fakedrugs/>.

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