

counterfeiting crackdown

patient protection is paramount

From the outside, it looked like an ordinary print shop. On the inside, authorities verified their hunch that it doubled as a counterfeit drug-label printing operation. The August raid by South American government agents uncovered 6,000 phony labels for an Abbott medication.

It was the largest confiscation Abbott's Global Product Protection group has made since it began operating in May, and Director Doug Frazier promises war. "We want to send a strong message that you cannot mess with Abbott product," he said, "and if anyone does, we'll hit back. We're going to protect the public's supply of medicines."

The numbers are staggering: The World Health Organization (WHO) currently estimates sales for all counterfeit drugs at \$32 billion. The U.S. Food and Drug Administration (FDA) estimates more than 10 percent of medicines sold internationally are fakes. In developed countries, the most frequently counterfeited products are "lifestyle" medications such as hormones and steroids. According to WHO, people in Third World countries are often sold counterfeit drugs to treat life-threatening conditions such as HIV/AIDS and malaria. No matter where counterfeits and diverted products surface in the world, they have widespread implications for unsuspecting patients and legitimate pharmaceutical manufacturers.

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Abbott investigators found counterfeit Reductil, Abbott's anti-obesity medication, sold through an Indonesian on-line pharmacy and are tracking down its origin. The authentic capsule is on the left, and the two on the right, without crisp and clear print, are impostors.

In China, a mixture of starch and water masked as baby formula is believed responsible for malnutrition in 229 infants earlier this year. Twelve babies died. The tragedy did not involve Abbott formulas, but the incident led reputable manufacturers to increase protective measures.

"On a personal level, we want patients to be safe," said Steve Lichter, divisional vice president of Global Supply, Global Pharmaceutical Operations. "On a business level, we won't tolerate any threats to our brand integrity. To ensure patient safety, we are scrutinizing our products—from the ingredients used to make them, to the moment they get that final scan when the customer buys them at the register."

Supply Chain Sealed Off

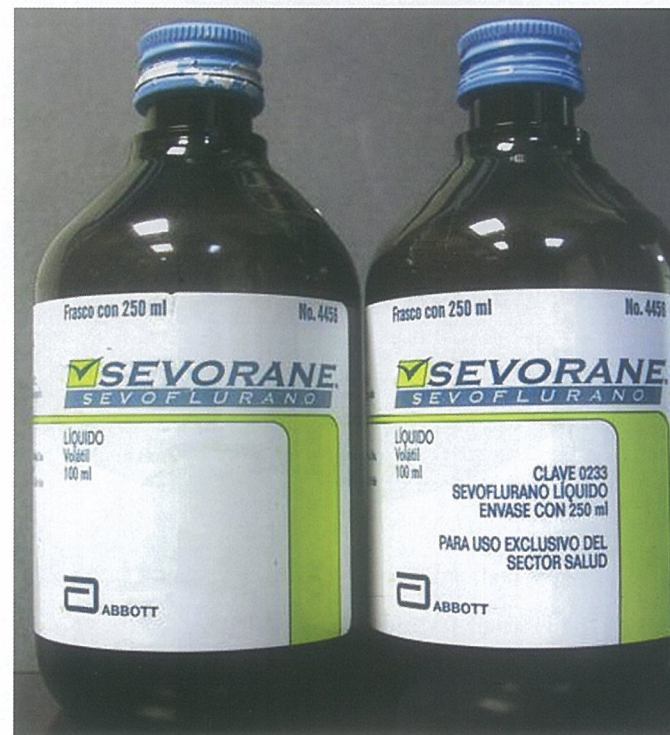
Cheap drugs may not be the bargain they appear to be. Knock-offs often contain little or no active ingredient, the wrong ingredient, or contaminated, expired medicine. "The biggest goal we've got is securing the supply chain," Frazier said. "If we can keep making progress in securing the supply chain, we are going to prevent problems from occurring." A key move to prevent product theft was finalized in June. All Abbott distributors and wholesalers for pharmaceuticals and diabetes care devices in the United States signed agreements to buy Abbott products directly from the company.

Technologies Distinguish Abbott Product

This summer, Abbott introduced smart computer chips using a technology in which the FDA has a keen interest—Radio Frequency Identification (RFID). The sophisticated microchip will stump even the most cunning counterfeiter. It contains an algorithm (information code) virtually impossible to duplicate and other data specific to each unit of product. Several pieces of data on each unit must match Abbott records. "When we make a batch of products, typically there is only one bar code identifying the entire lot of product," said Richard M. Johnson, director of the Quality Center of Excellence for Drugs in Corporate Regulatory & Quality Science. "With RFID, we can actually assign a unique serial number to every single bottle or package."

Abbott is involved in two RFID pilots now, including Ross nutritionals and Schedule II (restricted) medications sold to Wal-Mart. A third pilot is being conducted by a group of major pharmaceutical manufacturers, distributors and retailers testing the chips and software to track product as it moves.

"RFID is an excellent solution for controlling Ross products with huge customer bases. If there's a problem, we will spot it faster. Quick verification of phony product can be critical in catching people who steal or counterfeit," said Jim Hughes, divisional vice-president, Corporate Regulatory & Quality Science.



A counterfeit version of the inhalation anesthetic Sevoflurane was discovered in a Mexican hospital. It is bottled for government use, but the missing writing on the left label was an instant tip-off that it was counterfeit.

Special markings recently introduced give Abbott products unique characteristics. Overt markings include color-shifting inks and tamper-evident labels, among others. Covert markings not visible to the naked eye are also being placed on units, but exactly what they are remains proprietary information known only to Abbott. HUMIRA, for rheumatoid arthritis, is the first Abbott product to have these anti-counterfeit measures. The company's top 21 pharmaceuticals are scheduled to have these same markings by 2005.

Industry-Wide Effort Needed

Abbott can't stop counterfeiters alone. The momentum is building to conquer this problem as Abbott works with peer manufacturers and groups like the Pharmaceutical Research and Manufacturers of America (PhRMA) to develop industry-wide strategies to thwart counterfeiters and thieves. "We will never be completely rid of these people," said Lichter, "but Abbott is putting tough controls on our supply chain that will cripple their illegal activities."

Any suspected cases of counterfeit, tampered or diverted Abbott product should be reported immediately. E-mail information to globalproductprotection@abbott.com and include as much of the following information as possible:

- What occurred
- When it was discovered
- What products are involved
- What are the lot numbers of the products
- What is the location of the occurrence (city, country, province, etc.)
- Name(s) of key players (pharmacies, wholesalers, distributors, hospitals, individuals, etc.)