

Counterfeit DRUGS

**This growing problem is
endangering lives worldwide**

BY WILLIAM ECENBARGER

IN SOUTHWESTERN China, Hu Zushuang sought relief at a hospital after several days of feeling tired and weak. A doctor prescribed a blood protein called albumin, which Hu purchased from the hospital pharmacy.

An intravenous drip was started; within a few hours the 47-year-old father of one became desperately sick with diarrhoea, laboured breathing and abdominal pains. A day later, on September 20, 2001, he died from toxic shock and multiorgan failure. Police determined the "albumin" was actually

an unknown liquid that was lethal when it entered his bloodstream.

In Brazil, transportation worker Agenor Gomes do Nascimento was diagnosed with prostate cancer and treated with what was believed to be Androcur. But the drug was counterfeit and did nothing to arrest the cancer. Eleven months later, in March 1998, Gomes was dead.

Hu Zushuang and Agenor Gomes do Nascimento are two victims of a global menace. "The proliferation of counterfeit drugs is a fast-rising problem in the developing world," says Erik

Madsen, an Interpol criminal intelligence officer.

In fact, mounting evidence suggests that developing nations are awash in fake pharmaceuticals. The Pharmaceutical Security Institute, an industry watchdog, discovered that 11 percent of pharmacies in the Philippines sold counterfeit medicines. Researchers for Robert Gordon University found an anti-tuberculosis drug in Nigeria that had no active ingredients. Government regulators discovered anti-histamine pills in Colombia were actually dyed cement.

In Mexico, officials of pharmaceutical company GlaxoSmithKline found a counterfeit version of its antibiotic Fortum that had mould spores.

Millions in peril. Most often, counterfeit drugs prolong suffering because they fail to provide a cure. They can also cause further illness because of toxic substances. They also kill.

According to public health authorities, thousands died in Nigeria in 1995 after taking an inactive meningitis vaccine containing only water. In 1997, at least four died in Argentina after taking a fake drug designed to treat Parkinson's disease. More recently there have been fake drug deaths reported in India, China, the Philippines and Brazil.

There are no hard statistics on the scope of this crime because so much counterfeiting goes undetected. Nevertheless, authorities agree that the health of millions of Asians, Africans and Latin Americans is in peril. Says

Dr Lembit Rago, drug coordinator for the World Health Organization in Geneva, Switzerland: "When you look at customs seizures, intelligence reports from law enforcement agencies, investigations by the pharmaceutical companies and the few definitive studies, you have to conclude that in the developing world, anywhere from 10 to 30 percent of the drug supply is counterfeit."

Coma and death. Counterfeit pharmaceuticals are often extremely hard to detect; they also come in a bewildering variety of forms. Fake drugs may contain no true ingredient or too little of the true ingredient. The fakes may be harmless—or they may have impurities, contaminants and even toxic substances. They could be rejected or out-of-date formulations withdrawn from the market by manufacturers.

Sometimes a trace amount of the legitimate ingredient is included to add deception. "The fakers are very smart," says Dr Dona Akunyili, Nigeria's top drug official. "An anti-malarial drug like chloroquine is bitter. If they don't put a little chloroquine in, people will know. So instead of 200 mg, they will put 41 mg. That is what we have been getting from our analysis."

There are 300 million cases of malaria each year, and about one million deaths—and anti-malarials are among the most widely counterfeited drug in the developing world. A study published in *The Lancet*, a British medical journal, found that a breath-



taking 38 percent of the frontline anti-malarial drug artesunate in Southeast Asia was fake. "The result was that a substantial number of malaria sufferers died who would have otherwise survived," says Oxford University's Dr. Paul Newton, who headed the study. One of them, Newton and other public health professionals believe, was Sam Veasna, the internationally respected head of Cambodia's Wildlife

reassembled into an apparently intact and unused product," says Geoff Power, an anti-counterfeiting expert with GlaxoSmithKline. "When we removed the plastic flip-off, we found puncture marks in the rubber plug, confirming not only previous use, but also failure to clean off the degraded residues."

Some drug counterfeiters are like these small-time opportunists. But there is also an international phar-

Officials found a man and woman producing fake steroids and Viagra in a filthy kitchen in Bangkok.

Protection Office. While searching for a rare wild cow in a malaria-infested area, Veasna contracted the dread disease and began taking medicine. Instead of recovering, he fell into a coma and died.

Recycled hospital waste. In March 2001, Royal Thai Police and American customs officials raided a Bangkok apartment. They found a man and woman producing fake steroids and Viagra in the filthy kitchen. She was a prostitute; he was ill with infectious hepatitis. The counterfeits were being prepared for sale on the Internet.

In Ho Chi Minh City, Vietnam, hospital staff workers spotted a batch of suspicious-looking syringes filled with an antibiotic, with yellow stains on the labels. The manufacturer was alerted.

"They had been scavenged from hospital waste, carefully dismantled and

maceutical underworld—more organized, harder to trace and capable of doing damage on a bigger scale.

Typically these counterfeit operations begin, say pharmaceutical industry sources, with unscrupulous wholesalers ordering fake drugs in bulk from factories in China and India.

The wholesalers in turn sell to small manufacturers, who produce the finished tablets and then deal to black marketers, and unsuspecting hospitals and pharmacists. Some of the phoney drugs are sold on the Internet.

The bulk products are shipped with fake labels, often mixed in with legitimate items. Because of the relatively small dimensions of the shipments, they can go by air—sometimes even in the baggage of airline passengers. From China and India they are sent to busy ports like Amsterdam and

Hong Kong, where customs officials can't check every shipment.

Investigators for Bristol-Myers Squibb Company, for example, found fake versions of its anti-inflammatory drugs that originated in India, were sent to several European countries and finally shipped to Mexico. Luckily they were seized by customs officials before they could do any harm.

But that's not always the case. In Haiti, 89 children aged one month to 13 years died in 1996 after taking a counterfeit version of a liquid acetaminophen used to combat high fevers. The glycerine used as a thickening agent in the compound turned out to be sugar and automobile antifreeze.

Investigators determined that the fake glycerine originated at a factory in China, where it was purchased by a German company, which sold it to a Dutch company, which sold it to a different German company, which sold it to the Haitian company that manufactured the toxic product. Each of the firms told the investigators they were unaware of the bogus nature of the product.

No easy technological fix.

Counterfeiters have become extremely sophisticated, duplicating packaging, holograms, company logos and bar codes that even law enforcement agencies and the drug companies themselves can't identify as fakes.

And the payoff is substantial. Last year a counterfeit version of the drug Serostim was reported by its manufacturers, Serono, Inc. A standard 12-

PROTECT YOURSELF

EVEN EXPERTS have trouble telling harmful fakes apart from real drugs, but the following tips can help keep you safe:

- 1 Only buy drugs from licensed pharmacies and drug outlets, and be wary of Internet offers. Don't buy from peddlers or marketplaces.
- 2 Be suspicious of heavily discounted drugs.
- 3 Insist on a receipt.
- 4 Check that the packaging is properly sealed.
- 5 Ensure packaging indicates the batch number, manufacturing date, expiry date and the manufacturer's name.
- 6 Check that the names of the drug and the manufacturer are spelt correctly.
- 7 Report any lack of improvement in your health after taking a drug to your doctor or health worker.

Source: Global Forum on Pharmaceutical Anticounterfeiting

week course of this anti-HIV/AIDS drug costs \$21,000 in the legitimate marketplace. A single pallet of a fake version, worth millions, can be produced for a few dollars and sold at a fraction of the legal price.

"They concentrate their resources on the appearance of the product and its packaging," says James Christian, head of security for the pharmaceu-

tical firm Novartis. "It can be virtually impossible for consumers to tell the difference between a counterfeit and a genuine product. Even pharmacists, doctors and government regulators can be fooled."

Unfortunately, Christian adds, given the present level of technology, "Field tests can determine whether the active ingredient is present, but not whether the active ingredient is present in the appropriate amount, whether there are any impurities or foreign substances in the product, or whether the product is expired."

What must be done. Although counterfeit drugs are beginning to show up in North America and Western Europe, the problem is nowhere as severe as it is elsewhere. This is largely the result of tight regulation, vigorous law enforcement and harsh penalties.

In the developing world, however, drug counterfeiting is not considered a serious offence, according to Dr Harvey Bale, director general of the International Federation of Pharmaceutical Manufacturers Associations.

"Manufacturing, distributing, selling, stocking or exhibiting counterfeit drugs is a criminal offence in India with punishments ranging upto life imprisonment," says Sree Patel, head of GlaxoSmithKline Pharmaceuticals Limited's, legal and secretarial department. "But this is just on paper. In practice, court cases drag on for ever, and even when there is a conviction, the accused usually gets off

rather lightly. Unfortunately our criminal justice system doesn't deter counterfeiters in the slightest."

Two years ago, Chinese authorities discovered that an anti-bacterial drug given to patients after surgery was counterfeit and contained harmful bacteria that could have killed. The seller was given a four-month prison sentence and fined \$6500.

In March 2002, police in South Africa broke up a black market medicine conspiracy that was operated by three pharmacists. It was the largest counterfeiting arrest in the entire nation; several thousand pharmaceuticals worth millions that had been stolen, re-labelled and re-dated were seized. But the three culprits received suspended sentences and fines of no more than \$26,000 after pleading guilty to 34 counts of drug counterfeiting.

Such wrist-slaps are a sharp contrast to the United States: Last year a pharmacist who diluted cancer drugs was sentenced to 30 years in prison.

Law enforcement is also a big problem. In India, "the enforcement machinery is poorly equipped, not trained, bureaucratic and corrupt," according to Ashok Chhabra, general counsel for Proctor & Gamble India. The markets in Agra and Patna are notorious sources of fake drugs, and the market at the Bhagirath Palace in Delhi is widely known as a centre for phoney and substandard drugs. Yet they operate in the open.

In China, according to Jack Chang, an attorney for Johnson & Johnson

in Shanghai, drug counterfeiting cases are assigned to administrative agencies. But they lack enforcement powers and don't have trained inspectors.

In Argentina, the National Medication Institute set up a special programme to combat phoney drugs after people died from a counterfeit drug to treat Parkinson's disease. The government agency currently has only 13 inspectors to cover almost 14,000 outlets.

Before making an inspection, these investigators must seek the approval of local officials—and often this is not granted. Even when the counterfeiters are arrested, they are merely fined and set free in a few hours.

Authorities also told Reader's Digest that regulations keep the retail sales of counterfeit drugs at a minimum in North America and Western Europe.

"Prescription drugs are dispensed under the watchful eye of a licensed pharmacist," says Tom Kubie, a for-

mer FBI agent and now director of the Pharmaceutical Security Institute. "These individuals play an essential role in ensuring the integrity of the medicines they dispense. They are a far cry from the informal street sales of pharmaceuticals found in many regions of the world."

UNTIL STRICT controls are put into place, there will be more deaths among the unwary and grief among their survivors. In Brazil, 36-year-old Ildo Gomes do Nascimento says the death of his father, Agenor Gomes do Nascimento, was an enormous loss. "Dad was very loving."

And in China, Hu Chunlan, the 22-year-old daughter of the late Hu Zushuang, decries the lack of action. "The loss of my father was devastating to our family. Counterfeit drugs are still ruining people's lives. Counterfeit medicine will never disappear unless the central government takes strong measures against it."

SEE ME AFTER CLASS

Professors have discovered that college students can have an interesting view of history. A few examples:

"The Sumerian culture began about 3500 years before Christmas."

"Around the year 1000, people were afraid that an Acropolis was lurking around the corner."

"Men on both sides would have gotten to know each other better if they didn't have to wear uniforms."

"The Confederates were greatly damaged by navel blockage."



ANDERS HENRIKSSON in Non Campus Mentis (Workman)