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THE DEADLY WORLD OF FAKE DRUGS

Whether it's phony Viagra or knockoff cancer meds, fake drugs kill thousands of people each day, thanks to counterfeiters in China and India who mix chalk, dust, and dirty water into pills sold around the world. With the Internet becoming the world's dispensary, these poison pills could be coming to a pharmacy near you. | **By Roger Bate**

Suresh Sati, a large and cheerful man from a small city in northeastern India, has been hunting down counterfeit goods for more than half his 49 years. From the moment I meet him at my hotel in Delhi, I can tell that he enjoys his work. Most days, Sati makes the rounds visiting his undercover agents, who live near the main wholesale markets in Delhi, where most fakes are traded. They pass on news and rumors about new dealers and crooked police. As we set off down the road toward one of the city's sprawling markets, Sati smiles nostalgically as he recalls his first anticounterfeit raid, back in 1981, on a small-scale outfit manufacturing knockoff TV antennas. His work has changed a great deal since then; his targets today are far better financed, organized, and dangerous. These days, Sati runs a company called "The Protector," which leads raids for multinational

corporate clients. His bread-and-butter work: hunting for fake drugs.

Back in his basement office the next day, in an unremarkable building in residential Delhi, Sati offers me a glimpse of what he is up against. He lays out the samples of phony drugs he has collected from recent clandestine purchases and the previous week's raid. He places two vials of liquid erythromycin, an antibiotic used to treat bacterial infections, on the table in front of me. One vial is the real thing; the other contains water from a Delhi tap. "Which one is the fake?" Sati quizzes. I can't say. They look absolutely identical.

During the past decade, trafficking in counterfeit drugs has become one of the world's fastest-growing criminal enterprises. The World Health Organization (WHO) estimates that more than 30 percent of medicines on sale in parts of Africa, Asia, and Latin America are fakes. By 2010, the global turnover for phony pharmaceuticals is projected to be \$75 billion, a 90 percent increase since 2005. A sharp increase in drug seizures also points to a mounting crisis. In

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2006, the European Commission reported that customs agents intercepted 2.7 million counterfeit drugs at EU borders—an increase of 384 percent from a year earlier.

The fake drug industry works in much the same way as the counterfeiting of designer handbags or DVDs of the latest Hollywood blockbuster. It provides a superficially reasonable imitation of the real product, manufactures fakes in vast amounts, and relies on economies of scale to make profits. Products are often distributed by the same criminal middlemen

the contents, and then pass off their dangerous wares as the real thing.

A lack of quality oversight and enforcement makes poorer countries the most lucrative potential markets for these counterfeiters. A market like the United States is more difficult to crack, but the anonymity and breadth of the Internet now offers counterfeiters an attractive route around controls. Many so-called Canadian generics bought over the Internet are actually made in China and India, transported by traders via Dubai, Egypt, or

Russia, and then shipped into Europe and North America for sale. In the fall of 2007, British customs officers uncovered a scheme in which millions of dollars' worth of fake Viagra was shipped from India, Pakistan, and China to Britain, where it was repackaged, and then sold online

to customers in 35 countries—including the United States and Canada. According to the WHO, half of all drugs purchased over the Internet fail simple tests for active ingredients.

But the greatest cause for concern may be just how little is being done to combat the counterfeit drug trade, especially in developing countries. Hampered by a lack of resources, most countries find the problem overwhelming. On the day I spent with Sati, his rounds started at 7 a.m. and finished just before midnight. He may not work that hard every day, but he hardly ever stops. That's because he's fighting a losing battle. "I've been busy," he says. "For every faker we shut down, another two or three start up."

OVER-THE-COUNTER COUNTERFEIT

It's hardly surprising that a product like pharmaceuticals might be a target for massive counterfeiting. The price of genuine drugs is high, which pushes the profit margin on fakes even higher, and the global market of potential customers is enormous. What's more, fakes can be difficult to detect. A patient will likely attribute ineffective drugs to the severity of an illness, not to the quality of the medicine. Policies designed to promote domestic generic-drug producers may also permit lower quality controls on exported drugs, creating an opportunity for counterfeiters to sneak their supply into the market.

The complexity of the drug supply chain and the pains forgers take to conceal their origins make it extremely difficult to pinpoint the hubs of inter-

Half of all drugs purchased over the Internet fail simple tests for active ingredients.

who deal in other knockoff goods. The difference is that fake drugs can carry a human price tag.

For much of the past decade, lifestyle drugs—erectile dysfunction medicines, painkillers, and anti-anxiety medicines like Valium—were the most common knockoffs, particularly in rich countries. But in the past few years, counterfeiters have moved into far more life-threatening fake pharmacology, manufacturing drugs used to treat cancer, HIV/AIDS, and serious heart conditions. As many as 1 million people a year die as a result of taking these fakes, most of them in the developing world, but an increasing number in wealthy countries, too. In the past year, at least 95 Americans died from allergic reactions linked to Chinese-manufactured heparin, a medicine used to prevent blood clots. Sources at the U.S. Food and Drug Administration tell me that the contaminated heparin was almost certainly counterfeit.

Some counterfeit drugs are simply good copies of brand-name pharmaceuticals—hygienically made with the correct ingredients in the correct proportions. They breach intellectual property rights, to be sure, but they are not inherently dangerous, so long as they are perfect copies. Unfortunately, the motivation for most counterfeiters is profits, not reliable products. So, they are more inclined to perfect the packaging, not

For More Online

Think you can spot the difference between a fake drug and the real thing? Take our interactive quiz at:

ForeignPolicy.com/extras/drugtest.

national drug counterfeiting. That said, nearly every observer and researcher on the hunt for these dangerous fakes will point to two primary culprits: China and India. My own research on antimalarial drugs suggests that 60 to 80 percent of those fake drugs come from these two countries alone. “The overwhelming volume of counterfeit pharmaceuticals originate in Asia,” says Peter Pitts, president of the Center for Medicine in the Public Interest. “Fifty percent is probably a conservative estimate.”

Chinese and Indian counterfeiters come in all shapes and sizes. Some counterfeiters work for legitimate pharmaceutical firms; rogue employees stay after hours to substitute substandard ingredients and then sell the drugs to criminal networks. Other counterfeiting rings are based in slums, with ingredients shoveled into concrete mixers and blended to produce medicines sold on the street. Some producers market chalk as aspirin or lactose as Viagra, putting extreme care into faking a medicine’s packaging so that the drugs can be sold in stores or exported to foreign markets. More sophisticated counterfeiters add small amounts of the right ingredients so their drugs pass simple chemical tests, fooling authorities trying to prevent fakes from entering the distribution chain. “Indians copy everything,” says Vijay Karan, the former chief of Delhi police. “There is more Black Label whiskey sold in India than made in Scotland.”

But when it comes to fake drugs, the Indian government strongly denies that it has a problem. Indian government figures claim, somewhat preposterously, that counterfeit medicines account for just 0.4 percent of all legal drugs on the market there. The WHO says the rate is closer to 20 percent, and other experts place it as high as 30 percent. But the Indian government may not know how bad the problem is because it isn’t looking very hard. Even when drug authorities in other countries do the necessary detective work, banning Indian firms producing counterfeits from shipping drugs to their countries, the Indian government often allows those firms to continue operating.

In January, Sati and I drove for more than an hour down rutted roads in the state of Uttar Pradesh to visit a “drug factory” where some of India’s fake



Vial consequences: Experts believe 1 in 5 drugs sold in India is a fake.

medicines are made. The factory turned out to be nothing more than a small house in a remote village outside of Aligarh, a city of a million people about 90 miles south of Delhi. An industrial cement mixer was blending dust and chalk, which would be compressed into pills and passed off as a local painkiller. The eight or nine people working in the factory were too poor to venture outside the village. They probably had no idea they were doing illegal work or that their product would be shipped to pharmaceutical wholesale markets in nearby cities.

One such city is Agra, best known as the home of the Taj Mahal, and it has become the center of India’s counterfeit drug trade in recent years. Of the three main wholesale markets where fake drugs are traded in Agra, the largest is Mubarak Mahal, which spans three floors and houses about 500 small drugstores. According to Uday Shankar, a pharmacist with Agra Government Hospital, fake drugs comprise 20 percent of store sales, which are easily in excess of \$5 million a day. In the nearby Fountain market, at least 50 stores trade in generics, but they offer illegal copies as well. But, according



Burn unit: Anticounterfeiting is often left to a brave few, who are hampered by a lack of resources.

to Shankar, it's the market in and around the S.N. Medical College, where at least 180 drugstores operate, that has the highest percentage of fake drugs. "Many doctors at the college will tell patients to buy drugs from particular vendors within the market," he says. "Some [do it] to ensure that these patients buy drugs of decent quality, but others to intentionally direct them to pharmacists supplying fakes." Shankar believes the doctors are probably receiving kickbacks for the referrals.

Some of the markets' supply of fakes will come from big manufacturers such as Rajesh Sharma, who is believed to be an increasingly important counterfeiter from the state of Haryana, just outside Delhi. Sharma allegedly specializes in producing fake drugs to order, allowing the buyer to set the percentage of active ingredients. Some drugs will be chemically similar to brand-name antibiotics and painkillers, but other versions will be little more than placebos with excellent packaging. It all depends on what the buyer wants and what he is willing to spend.

Sharma, who is believed to move millions of dollars' worth of merchandise a year, has a business that is growing and mobile, with production facilities in several locations outside Delhi. But he does not yet operate at the level of the infamous counterfeiter Pavel Garg, whose operation produces millions of fake pills each day. Garg once notoriously told an undercover BBC crew that to keep his operations alive, he had bribed the chief minister of Haryana with a Bentley. (It's worth noting that despite such an admission, Garg's counterfeit drug business continues to flourish.)

Unlike smaller village operations, Sharma and Garg sell a lot of their drugs overseas. When a colleague approached Sharma's network, posing as a buyer for a southern African pharmacy chain, he was offered rifampin, a critical tuberculosis drug, at 15 percent strength. Fifteen percent is "enough to pass color dye tests and much cheaper than 100 percent," Sharma told him. From the point of view of the sophisticated faker, this may make sense. But at that strength, the pill will do little to help the patient and is likely just enough to allow the

bug to become resistant to future drug treatments. (See "The Path of Least Resistance" on page 62.)

THE MISSING INGREDIENT

If the international community thinks that going after men like Rajesh Sharma or Pavel Garg is a priority, it seems to be biding its time, too afraid to engage a politically sensitive issue. The WHO has been vocal about combating fakes, but even it hesitates to embarrass member countries who allow fake drugs to enter the market. Unfortunately, many observers believe it may take large-scale casualties for real action to occur. As one British drug-security expert put it to me in April, "Action against al Qaeda really only took off after September 11."

Making matters more complicated, the governments of some countries where faking is big business, notably China, India, North Korea, Thailand, and Vietnam, often do their best to throw up roadblocks. Although India's counterfeit drug problem

appears to be driven by willful government ignorance and illicit distribution networks, China's is rumored to involve a more official channel: the military. Shanghai- and Hong Kong-based insiders, fearful of retribution if they speak on the record, tell me that a small fake-drug factory in northern China is even housed inside a military base. African health experts tell me that their complaints about fakes to the Chinese government fall on deaf ears, alleging that corrupt Chinese politicians are paid off to not inspect manufacturing facilities. And though Beijing executed the former head of its drug authority last year for accepting bribes, such retribution has not been followed by enforcement of tough penalties against counterfeiters themselves. In nearby Thailand, the Government Pharmaceutical Organization for years produced drugs of suspect quality and dictated that hospitals purchase their more-expensive domestic

drugs over better-quality imports. And in North Korea, where much of the foreign currency comes from counterfeit operations, fake drugs are a sizeable chunk of the revenue stream, British security sources tell me.

It might seem logical that Western pharmaceutical companies would be at the forefront of anti-counterfeiting efforts, eager as they are to protect their brands. Pfizer, for example, spends a lot of time and effort trying to stamp out illegal copies of its drug Viagra. But going after counterfeiters too hard—or too publicly—can be a double-edged sword. Ultimately, if the public believes a drug is being widely faked, sales of the genuine drug may suffer. As a result, many large pharmaceutical companies have been reluctant to pursue fakes, particularly imitations being distributed in developing countries. In 2005, Oxford University health professor Nicholas White,

Message in a Bottle

Packaging is the quickest route to success in the world of drug counterfeiting. If you can replicate a drug's box or bottle, most consumers won't notice what's inside.

Fake Viagra is a huge global business: Millions of counterfeit Viagra pills are manufactured each year and sold for tens of millions of dollars. But to understand why Viagra is one of the

world's most faked drugs, you have to understand the costs that go into making the knockoff blue pills. In both China and India, a kilogram of sildenafil citrate, the active ingredient in Viagra, costs \$60. Diluted into thousands of fake tablets and slipped into the United States for sale, that single \$60 kilogram can be worth as much as \$300,000. (That's a higher markup than cocaine, with lower penalties for getting caught.) Even if a Viagra counterfeiter in India makes

pills at 100 percent strength, he will still probably spend more on packaging than pills. He can produce a 30-pill bottle for about 33 cents, spending 15 cents on the tablets and 18 cents on a near-perfect label and bottle. Of course, if the counterfeiter uses sugar or chalk instead of the active ingredient, the price of production plummets. Then, packaging might take up nearly 90 percent of manufacturing costs.

It is widely believed that if pharmaceutical companies would simply lower their prices on drugs, counterfeiters would have less incentive to make fakes. Intuitively, it makes sense; smaller profit mar-

gins should be a deterrent. Unfortunately, it doesn't work that way. Counterfeiters can accept tiny margins on each product sold—as long as they move millions of pieces of merchandise. Take a Johnson's bar of soap, like one I saw recently in a Delhi market. The genuine product can be bought in a shop for just 60 cents, but the soap on sale that day was a fake. The bar itself was made of low-grade



Die hard: Fake Viagra can cause nausea, vomiting, and even death.

cleanser; the packaging, however, was nearly identical to the real thing. The counterfeiter may only make a cent or two in profits on each bar of soap, but he will manufacture and sell thousands, perhaps millions, of bars. If counterfeiters will go to this much trouble to fake a bar of soap, the cost of genuine drugs—no matter how cheap—will always make it worth their time.—*R.B.*

one of the world's top malaria experts, lambasted British pharmaceutical giant GlaxoSmithKline for failing to warn patients in Ghana of fake Halfan, the company's pediatric antimalarial drug. Thousands of children were potentially exposed to and harmed by the phony medicines. GlaxoSmithKline denied it had hidden information, but Nigerian and Ghanaian health experts I spoke with confirmed the company's silence. Like governments protecting substandard businesses, pharmaceutical giants often have reason to remain quiet.

Well-intentioned nongovernmental organizations distributing drugs in developing countries may also contribute to the problem. To save money and treat more patients, the groups often purchase copy drugs from China and India that have not been tested properly. Many of those drugs might indeed be of reasonable quality. But those countries' overall record for quality enforcement is poor, and too many substandard medications are allowed to slip into the supply chain, even alongside genuine ones. Desperate to get lifesaving medicines to the world's poor, humanitarian groups are left with a difficult choice: expensive, safe drugs that treat fewer patients, or cheaper drugs that might not work.

With so many standing by doing so little, the counterfeit drug trade has been given time to grow larger and more complex. With free-trade zones and Internet sales offering counterfeiters more options for moving and selling their wares, the fight against fake drugs becomes all the more difficult without concerted and coordinated international efforts. Luckily, that hasn't stopped a few brave individuals from taking on the challenge alone. But their hard-won progress could easily be undone.

THE OTHER DRUG WAR

Dora Akunyili, a 54-year-old pharmacy professor, knew she had her work cut out for her when she took the helm of Nigeria's drug-watchdog agency seven years ago. Back then, in 2001, the WHO estimated that 70 percent of the drugs on sale in Nigeria were counterfeit or substandard. But little was being done; government corruption was rampant. Akunyili only got the job when she impressed the former president with her honesty, returning leftover funds from a medical operation paid for by the state. But Akunyili always had a more personal reason for fighting drug counterfeiters: Her sister died from taking fake diabetes medicine in 1988. Since taking office, Akunyili has collected volumes of shocking

The Path of Least Resistance

Billions are being spent on disease-fighting drugs in poor countries, but millions are still dying. Why? Because what doesn't kill a virus only makes it stronger. | By Rachel Nugent

Never before has there been such a generous and concerted global effort to fight the diseases that afflict poor countries as there is today. More money is being spent, more research is being conducted, and more governments and organizations have pledged to eradicate the illnesses that kill millions in the developing world each year. Between 2001 and 2006, annual assistance for health programs in developing countries more than doubled, from about \$6 billion to \$14 billion. Roughly half of that total is dedicated to reducing infectious diseases, with several billion spent each year on drug treatments. The vast sums of money are coming from governments in both developed and developing countries, as well as from well-funded private groups and charities such as the Bill & Melinda Gates Foundation.

Despite these colossal efforts, the battle against infectious diseases is not yet being won. Cases of both malaria and tuberculosis (TB), two diseases that have been singled out for donor attention, are on the rise. Together, these diseases kill more than 3 million people each year, and many millions more suffer bouts. About 402 million cases of malaria occurred worldwide in 2004, up 47 percent from 1998. Meanwhile, new TB cases rose nearly 30 percent between 1996 and 2006, from 7 million to 9 million. Other infectious diseases, such as cholera, shigellosis, and *Streptococcus pneumoniae* infections, most of which are largely eradicated in the rich world, remain common killers. What's worse, these diseases are becoming increasingly difficult to treat.

How can we be working harder than ever against these ailments but making so little headway? Because the microbes we are fighting are adapting faster than we are. The drugs used to treat many diseases in the developing world are becoming less effective at killing the viruses, bacteria, and parasites that cause illness. Microbes are constantly evolving organisms, and many are proving to be impervious to the drugs designed to combat them. Hardy viruses, capable of mutating faster than we can kill them, can wipe out years of research

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tales about phony drugs and government complicity. “People have been dying in this country from fake drugs since the early 1970s,” she says.

According to Akunyili, corrupt Nigerian officials extort money from legitimate drug manufacturers and accept bribes from counterfeiters in exchange for access to the market. In 1995, when the Nigerian government tried to help neighboring Niger battle a meningitis epidemic, more than 60,000 vaccine doses were distributed before all of it was found to be fake. Some 2,500 patients died as a result. But most troubling for the country is the widespread counterfeiting of antimalarial medicines. Some 2.6 million people are afflicted by malaria in the country each year; roughly 5,000 succumb to the disease. My own research shows that a third of

new antimalarial drugs are fakes. Thousands of Nigerian mothers have watched their children die because their meager savings bought imitation drugs.

Akunyili has made impressive strides in fighting counterfeit drug rings in the country, securing the convictions of more than 60 counterfeiters, with as many cases pending. In 2006, her office shut down a market in the southeastern city of Onitsha in a raid that netted more than 80 truckloads of counterfeit drugs with convincing labels. Public awareness campaigns have also had notable successes, with \$16 million worth of fake drugs seized or voluntarily handed over in 2005. Akunyili’s efforts have brought the country’s proportion of fake drugs down from 70 percent in 2002 to just 16 percent last year. She recently told me that this year, it is close to 10 percent. “Not good enough, but a lot better than before,” she says.

But Akunyili’s work has not come without steep personal costs. In 2003, her car was ambushed; a

bullet grazed her head and a member of her staff was killed. The following year, her government offices were burned down. She now has bodyguards with her around the clock. Akunyili is a target partly

because she successfully pushed for harsher punishments. Prior to her taking office, drug counterfeiters faced at most an \$80 fine and three months in jail. Most of the accused never saw the inside of a courtroom, let alone a jail cell, because they paid off police. Today, the penalties still do not rival those dealing in narcotics, but fines are increasing—many exceed \$1,000—and jail time is measured in years, not hours. Despite these successes, Akunyili thinks unscrupulous local businessmen and politicians would like her out of the way so they can go back to business as usual. And she faces a daily battle dealing with officials



Pick your poison: Each year, 200,000 kids die after taking bad malaria meds.

from India and China, the two countries that supply most of her country’s fake pharmaceuticals. “Neither government is really trying to stop production and export of fakes,” she says.

In India’s case, the troubles stem partly from toothless laws. As far as my research shows, counterfeiting was not even successfully prosecuted as a criminal offense until last year, and today there is scant enforcement. In a small sign of progress, the Indian cabinet approved a bill in July that increases counterfeiting fines from \$250 to \$25,000 and jail sentences from 5 to 10 years for the worst offenders. But much more needs to be done. Cases still rarely make it to court. Police are often bribed to look the other way. Waiting in Sati’s office one day, I watched the local police come by to talk about a pending prosecution; they spent 10 minutes trying to persuade Sati to drop the case.

A PRESCRIPTION FOR REFORM

As noble as the efforts of people like Dora Akunyili and Suresh Sati are, their hard work will be meaningless against global drug counterfeiting if the major sources of the product are not pursued. That will require far more effective international drug testing and oversight, and most importantly, the nerve (and necessary budgets) to see good intentions through. At the very least, the struggle against these fakes should not be left to a courageous few. After all, what is to say that Nigeria's progress against dangerous fake medicines won't be reversed if the next bullet aimed at Akunyili hits its mark?

As the fake-drug sector continues to grow in speed and sophistication, the global situation will get worse before it gets better. China and India may be the major producers today, but several countries are hot on their heels. Russia's counterfeit drug industry is estimated to be worth \$300 million a year. Small-time producers in Argentina and Brazil are growing rapidly. Egypt has become a major hub for Chinese counterfeits en route to Europe and the United States. Even terror links have become part of the equation: In March 2006, the U.S. FBI busted a

counterfeit ring with associates in Brazil, Canada, China, and Lebanon. The ring was funneling money to Hezbollah.

The good news is that new technologies are making random quality testing easier and faster.

When it comes to deciding between untested drugs or no drugs at all, we may have to go without—for our own sake.

Hand-held spectrometers can assess drug potency in a matter of seconds. If more of these devices are made available to customs agents, imported fakes can be found rapidly and destroyed. But technology can only be one facet of the response. Governments that protect counterfeit drug industries must be named and shamed, and aid agencies should only purchase and distribute drugs that have undergone rigorous testing. That may mean that when the moment comes to decide between untested drugs or no drugs at all, we go without—for our own sake. That's the approach Dora Akunyili believes in. "Better to have lack of access," she says, "than access to counterfeits and substandard medicines." In the end, it may be the only sensible remedy. **FP**

[Want to Know More?]

For more analysis on the global threat of fake pharmaceuticals, read Roger Bate's *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade* (Washington: AEI Press, 2008).

The World Health Organization offers counterfeit drug fact sheets, traveler warnings, and tips for spotting fakes on its Web site. More information on anticounterfeiting efforts can be found at the Web site of IMPACT, a coalition of pharmaceutical companies, NGOs, and national drug authorities. See the Web site of Africa Fighting Malaria, a health nonprofit, for information on how counterfeit drugs are complicating the fight against malaria.

Katherine Eban's *Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply* (Orlando: Harcourt, 2005) is the riveting story of a crack team of investigators exposing a counterfeit drug ring in South Florida. Dora Akunyili, head of Nigeria's drug-watchdog agency, is profiled in the BBC documentary on counterfeit drugs, *Bad Medicine*. FOREIGN POLICY Editor in Chief Moisés Naím explores how the global trade in fake goods is transforming the world in *Illicit: How Smugglers, Traffickers, and Copycats Are Hijacking the Global Economy* (New York: Doubleday, 2005).

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