REAL FEARS OVER PHONY DRUGS

US HEALTH OFFICIALS VIEW SPATE OF RECENT CASES AS EVIDENCE OF RISING TREND

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The complaints from nurses began trickling in to Bayer Corp. earlier this year. Something struck them as odd about the vials of Gamimune N, the company's drug to treat patients with weakened immune systems. The liquid in the vials was unusually cloudy. Bayer recalled one lot of the drug and then another, trying to isolate the problem. By mid-March, the company concluded that someone had tampered with the drug. At least 13 vials - found in warehouses of US distributors and on pharmacy shelves - had been diluted. Bayer's was the first of five cases of adulterated and counterfeit prescription medications that have found their way to US distributors, pharmacies, and patients this year. The Bayer alert was followed this month by a warning from Eli Lilly that criminals had filled at least six bottles with generic aspirin and disguised them as the Indiana company's schizophrenia drug, Zyprexa.

Within days, other warnings were issued. Watered-down vials of Epogen, an anemia drug made by California's Amgen, had been discovered. Bottles of an HIV drug, Combivir, made by Britain's GlaxoSmithKline, filled with another drug and fraudulently labeled as Combivir were found in Maryland, Connecticut, California, and Florida. A phony version of Serostim, a drug made by the Swiss company Serono to treat AIDS wasting, had been found.

Until recently, strict state and federal regulations have kept the flow of counterfeit drugs in the United States to a trickle. But industry and public health officials see the recent cases as evidence of a mounting problem. The regulatory system is straining under the pressures of an increasingly global economy. Counterfeiting techniques are more sophisticated, and the lure of high drug prices is more tempting.

"The vulnerabilities in the system are being exploited more now than in the past," said Donald E. deKieffer, a Washington, D.C., attorney who specializes in international trade regulation. "It's still a small problem. But the scary thing is that they are getting these fakes into legitimate distribution channels. There's not a shred of evidence these five cases are connected, which means five different schemes in two months have succeeded to some point."

The incidents appear to be limited in scope. In all known cases, the companies said, the counterfeits aroused suspicion before they were taken by patients, and no one is known to have been harmed. The diluted vials of Gamimune N came from two lots traced to a single unnamed distributor. The phony version of Amgen's Epogen was found in only one state, which the company declined to disclose. The fake Serostim seems limited to a single phony lot number. In most cases, the companies and government officials decline
to give more details on when and where the phony drugs were found, citing the FDA's ongoing investigation into the counterfeiting.

But the spate of activity has renewed concerns about the safety of the nation's drug supply and a rise in counterfeiting that puts patients' lives at risk. Last year, in what regulatory officials described as an "unusual" rash of reports, three fake prescription drugs found their way into American pharmacies. And though no patients were known to be harmed in those cases, some did get and take the phony drugs.

Counterfeits and adulterated drugs can trigger allergic reactions or cause dangerous interactions with other drugs. In the case involving Combivir, the drug was swapped with another HIV drug, Ziagen, which causes a potentially life-threatening reaction in 5 percent of patients. Even being cheated of a drug can have serious repercussions for people relying on the medicine. In the worst cases, the consequences are deadly. "We're afraid that if this trend continues unchecked, some unsuspecting consumer will wind up dead," said Ken Johnson, a spokesman for the House Energy and Commerce Committee. The committee expects to hold a hearing next month to address the counterfeit-drug problem and evaluate federal enforcement efforts.

Counterfeit drugs have long circulated in other parts of the world. More than 7 percent of the global supply of pharmaceuticals are believed to be phony, according to the World Health Organization. But the fakes have been largely a problem in underdeveloped nations.

"The US is and will continue to be a likely target for counterfeiters," said Tom Kubic, executive director of the Pharmaceutical Security Institute in Virginia. "The population on the whole spends quite a bit of money on pharmaceuticals, and in illegal activity, you're going to go where the money is."

The Food and Drug Administration is investigating the cases involving Gamimune, Zyprexa, Epogen, Combivir, and Serostim. The agency also continues to investigate the three counterfeit cases reported last year involving Serono's Serostim, Amgen's Nupogen, and Genentech's Nutropin.

But, critics say, federal regulators and law enforcement seem woefully ill-prepared to fight the problem. They have released few details about the investigations - it remains unclear whether anyone has been arrested in the year-old counterfeit cases. And, they say, little has changed since FDA officials testified at a congressional hearing last June that the agency lacked the resources to combat growing counterfeit activity.

"The problem is a resource issue," Kubic said. "The global economy, the shrinking world, the ability and speed at which goods move, the breaking down of traditional barriers have all put enormous pressure on regulatory and law enforcement authorities." Counterfeiters use a variety of scams. They get hold of expired drugs, soak the bottles in hot water to remove old labels, and attach phony labels bearing a new date. They buy cheaper generic alternatives and dress them up as more expensive brand-name drugs.
They water down a batch of drugs and double their inventories by counterfeiting labels. They sell bathtub mixtures, ranging from sugar pills to toxic concoctions, as genuine drugs.

And to move their wares into legitimate supply channels, counterfeiters depend on a booming gray market among the nation's wholesalers and distributors. In search of bargains, distributors often ignore laws restricting the reselling of prescription drugs, buying products that have been diverted from nonprofit hospital or nursing-home pharmacies, charities, or foreign countries - all of which get medicines at deeply discounted prices.

Without this gray market, investigators and prosecutors say, counterfeiters would have no place to unload their goods. By ignoring the state and federal regulations, distributors are dismantling the system meant to ensure the safety of the nation's drug supply. Known as diversion, the practice also increases the chances that drugs will be spoiled by improper handling and makes them impossible to find in case of a recall.

The FDA has stepped up efforts in the past year to monitor distributors and prevent the diversion of drugs among wholesalers, a spokesman for the agency said. The agency has also arrested people in the past year involved in counterfeit activity - though the spokesman could not comment further because the investigations are ongoing. He said the FDA is also working closely with drug makers to alert patients about any potential risks.

Kubic supports the agency's efforts. At a time when the pharmaceutical industry also is struggling to prevent such activity, Kubic said, the FDA has shown a willingness with industry to work toward solutions. The industry estimates that it loses about $2 billion a year to counterfeits. The problem, however, goes beyond the scope of either the FDA or industry.

Counterfeiting is a white-collar crime with lesser penalties than those carried by trafficking of illegal drugs or violent crimes in which the risk of physical harm is imminent. Despite the seriousness of the problem and the potential for harm, Kubic said, counterfeit pharmaceuticals remain a relatively rare crime, and as such, it doesn't rise to the top of the agenda for most law enforcement agencies.

"Criminals know this," Kubic said. "These are bright and rational people. They're doing the risk-benefit analysis, and they're choosing to shift to diverting and counterfeiting prescription drugs."

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