

DISCLAIMER

Electronic versions of the exhibits in these minutes may not be complete.

This information is supplied as an informational service only and should not be relied upon as an official record.

Original exhibits are on file at the Legislative Counsel Bureau Research Library in Carson City.

Contact the Library at (775) 684-6827 or library@lcb.state.nv.us.

Even if you fill your prescription at a large, reputable drugstore, the medicine you take could be mishandled, tampered with, even counterfeit.

pharmacy fakes

● Kelly Burke was fooled once at age 17: A trusted high school boyfriend left her with HIV. Now 29 and living in San Diego, Burke has had to juggle a complex medical regimen, file reams of paperwork for disability insurance and fight every day just to stay alive. To do this, she has had to rely on a few things, particularly the medicine her doctor prescribes.

When Burke began suffering from some of the symptoms that afflict people with AIDS, she could only hope for a cure. Her arms and legs had become sticklike and her belly huge, her weight shifting precipitously. Her doctor prescribed Serostim, a human-growth hormone packaged in individual vials that cost \$7,000 a month, thankfully covered by insurance. The drug was like a miracle. She injected it daily into her abdomen and felt better almost immediately. "I started having more energy and sleeping better at night. My mood improved," she recalls, describing how her body seemed to magically reappportion itself.

In late fall 2000, after having used Serostim for almost a year, she took out the familiar-looking vial, injected the medicine and began to feel terrible. "It stung really badly and

caused big welts," Burke recalls. Within days, she was running a fever and vomiting most of her food. Soon she had trouble keeping down even water. But she was reluctant to stop the shots she thought were saving her life. "I kept taking my medicine like a good girl," she says, using the drug almost every day for a month, despite being stricken by diarrhea, sweating and muscle pain. At one point, in despair, she hurled the box of medicine against the wall.

As it turned out, the substance she had been injecting into her abdomen was not pure Serostim at all, but a mystery liquid packaged to look just like the drug that had been helping her survive. The scheme was widespread: Vials of phony Serostim had been discovered in nine states from New Jersey to Texas to Hawaii. And as the drugmaker, Sero, was

alerting pharmacies to the problem, fake versions of medicines from five other manufacturers—including lifesaving treatments for patients with cancer, kidney disease and bipolar disorder—began landing on the nation's drugstore shelves.

● **Like most Americans,** Burke assumed her medicine was safe—that it traveled a straight line from the manufacturer to the pharmacy along a path patrolled by regulators. Those who buy from fishy Internet sites or roadside drugstores in Mexico are obviously courting risk. But she was purchasing a product from a major U.S. drugmaker at a CVS ProCare pharmacy near her former home in Berkeley, California. What could be safer?

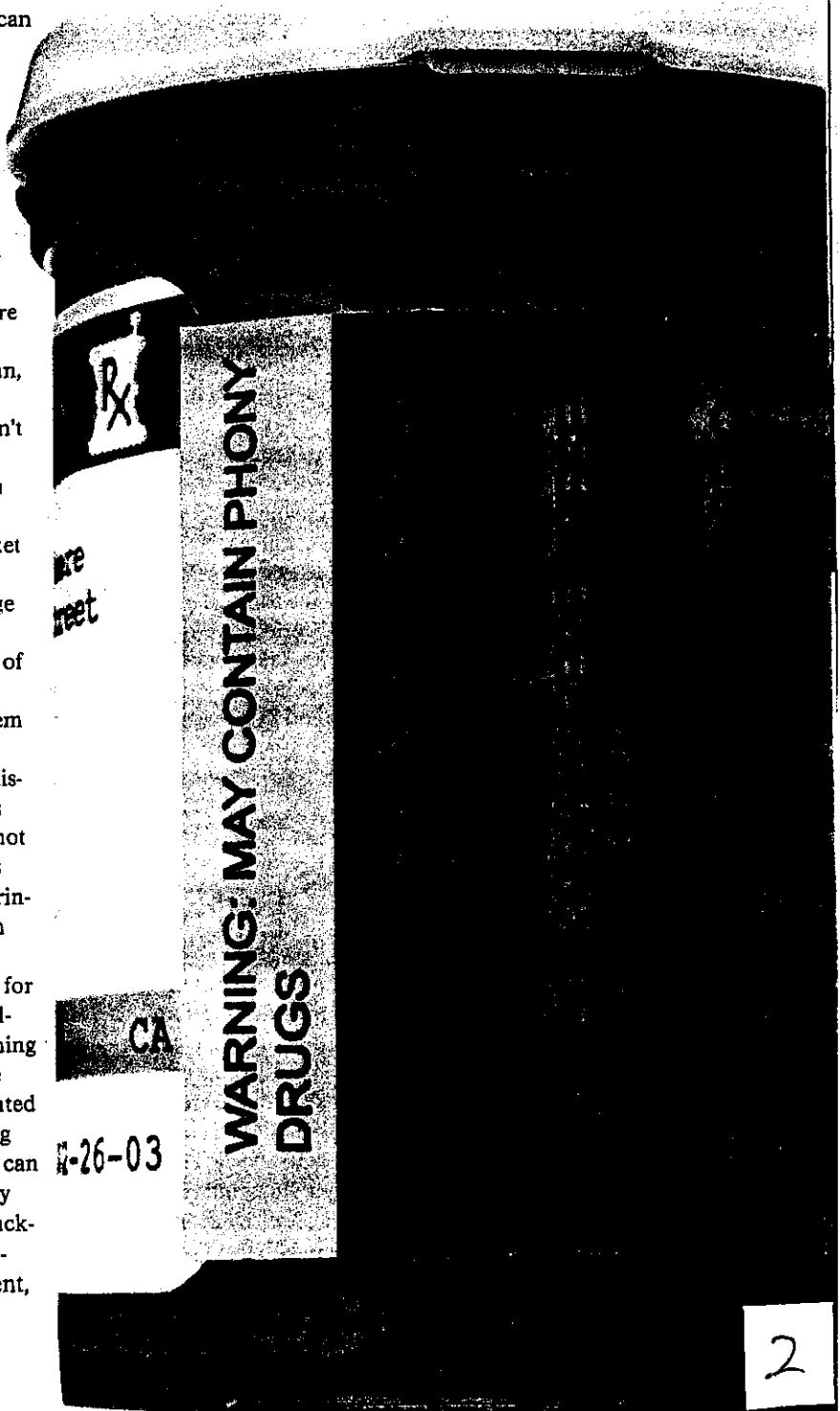
In theory, these assumptions were right. The American drug distribution system—long viewed as the world's most secure—should work like this: Drugs leave the manufacturer and go to an authorized wholesaler, which distributes the medicine to retail pharmacies or hospitals. There, a licensed pharmacist distributes the drugs to you. A 1988 law, the Prescription Drug Marketing Act, intended to safeguard drugs en route, requires states to license wholesale companies and prohibits hospitals or pharmacies from reselling drugs to anyone but patients. Compared with overseas, where counterfeiting is rampant, "the solution we have in the United States works very well," says James Christian, head of corporate security for the drugmaker Novartis. "The distributors are very carefully monitored. There isn't much wiggle room."

A five-month SELF investigation, however, reveals a very different picture. Every day, America's prescription drugs pass through a largely unregulated gray market of wholesalers, some 16,000 companies in all. These middlemen, comprising a \$126 billion industry, range from legitimate companies with pristine warehouses to back offices with bare lightbulbs. Taking advantage of constantly fluctuating drug prices, these companies buy the drugs in bulk at discounted prices and resell them not to pharmacy chains and hospitals only, but also to other, smaller wholesalers for a profit. By aggressively discounting drugs, small wholesalers help reduce prices for mom-and-pop pharmacies and hospitals that may not have the buying power of a large drugstore chain, says Ron Streck, president and CEO of the wholesalers' principal trade organization, the Healthcare Distribution Management Association in Reston, Virginia.

But investigators say this system has also allowed for what they call counterfeiting—the dilution, mislabeling or adulteration of prescription drugs. Before reaching patients, drugs may pass through a dozen wholesale companies in numerous states, in largely undocumented transactions that are almost impossible to trace. Along the way, unscrupulous companies have realized they can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging, says Michael J. Mann, a special-agent supervisor with the Florida Department of Law Enforcement, which has spent two years investigating potential

misconduct by as many as 50 of Florida's drug wholesalers.

A SELF review of counterfeit-drug cases, state health department and court records, and interviews with 25 investigators and industry experts found evidence of a recent explosion in domestic counterfeiting. In 2002, the Food and Drug Administration opened at least 30 separate investigations of the crime. Within the past year, federal investigators have seized adulterated medicine in more than a dozen states and tracked the drugs to more than two dozen. And in a single week last year, FDA agents seized \$1.7 million of phony drugs in Texas, \$1 million in Illinois and \$2 million in Florida,



according to a criminal investigator with knowledge of the cases. Troubling as this is, consumers have little protection. The FDA does not require drugmakers to report instances of adulterated drugs. Nor does the agency require wholesalers to document the changing ownership of each drug as it passes through the distribution system. As a result, the ability to trace drugs through the American market remains "significantly compromised," the investigator told SELF. "The industry doesn't like to alarm people because it costs them money, the FDA regulators don't want to say anything because they're not doing their job, and medical professionals and consumers have no idea what's going on."

Young women may be among the most vulnerable: Between the ages of 18 and 44, women are one and a half times more likely than men to take prescription medicines, according to a recent Boston University study. But it's impossible to know exactly who has been hurt by corrupt wholesalers. By taking their medicine, patients unwittingly dispose of the evidence. If they get sicker or die, what actually harmed them remains unclear, because they were sick to begin with. In many ways, this makes pharmaceutical counterfeiting the perfect crime. As Mann says, "inherently, the witnesses will be dead."

● **Kelly Burke may not** have been the only person whose medication wasn't working. In the spring of 2002, Florida health department investigators began to hear reports that an unusual number of cancer patients taking the injectable drugs Epogen and Procrit, designed to boost red blood cell counts, were showing dropping counts instead. Hundreds of thousands of people nationwide take these drugs to counter the anemia caused by chemotherapy, kidney failure and AIDS. The suspicions about patients' poor response fed investigators' concerns that the counterfeiting problem might be getting worse.

It was bigger than they could have imagined. In undercover stings, warehouse raids and inspections, Florida investigators and FDA agents have found at least nine different kinds of adulterated prescription medicines, including some 2,000 vials of Procrit; Combivir to combat HIV; and Zyprexa, which treats schizophrenia and bipolar disorder. In one of the

Lauderdale and saw boxes stacked floor to ceiling filled with fragile cancer and AIDS drugs. Where the medicine had been and under what conditions was anyone's guess. Jemco, a relatively small drug distributor, did a big business—about \$55 million a year, according to investigators. The president, Jose A. Castillo, 40, lives in an exclusive gated community north of Miami with his domestic partner, Brian A. Hill, 34, the company's vice president and secretary.

The warehouse in neighboring Pembroke Pines was a world apart, dusty and sweltering, despite being filled with drugs needing refrigeration. Venema found medicine removed from its original packaging and piled in toaster and computer-scanner boxes. Using lighter fluid and sponges, someone had melted off labels that would have revealed the drugs' origin. The abysmal conditions were in keeping with the company's track record: Days before the raid, agents had caught the company trafficking 1,000 vials of phony Epogen. By relabeling the medicine as a higher dose, counterfeiters had inflated the price from \$528 to \$4,700 a box.

The Florida health department revoked Jemco's permit and fined the company more than \$356,000. (As of late January, no criminal charges had been filed. A lawyer for Jemco said he could not comment on the case because it is pending.) Investigators say soon after, the company moved its business to Yadkinville, North Carolina, under the name Medi-Plus International. A woman who answered the phone there said that Castillo was not available. He did not return a detailed phone message seeking comment.

In January, the state launched a grand jury probe that is expected to produce multiple indictments for racketeering by this spring. Florida's wide-ranging investigation even uncovered narcotics dealers and convicted felons working as drug distributors; these criminals are lured, Mann says, by big profits and what have been minor penalties, often limited to misdemeanor offenses like misbranding a commercial product. The schemes may cost Florida as much as \$500 million a year, mostly in Medicaid payments for adulterated drugs. Says Mann, "These are the Michael Milkens of the pharmacy industry. It's theft on a massive scale."

The Florida discoveries didn't surprise officials in Nevada;

Drug counterfeiting is the perfect investigator. "Inherently, the witnesses

most common schemes, counterfeiters would relabel a low-dose medicine to appear 20 times stronger—and therefore 20 times as expensive. Agents recovered vials of Neupogen, a drug to help chemotherapy patients fight infection, that contained only saline. Insulin had been passed off as the growth hormone Nutropin; the phony packaging was so well done that even experts could barely tell the difference. So far, Florida has seized \$15 million worth of counterfeit drugs and revoked or suspended the licenses of 17 wholesale companies.

Last April, Gary Venema, a special agent with the Florida Department of Law Enforcement, walked into the hot, grimy warehouse of Jemco Medical International outside Fort

it's been several years since they first noted the explosion of wholesale companies moving prescription drugs around the country as if on a Monopoly board. Nevada officials say that before they overhauled state regulations in 2001, many of the state's roughly 40 licensed drug wholesalers were little more than drop-off spots where employees worked from 10 A.M. to noon, when United Parcel Service made deliveries. (One company even did business out of a U-Haul storage shed.) The drugs being delivered to and from these companies were "literally touring the entire country," says Louis Ling, general counsel for the Nevada State Board of Pharmacy. The problem with this, investigators say, is that the more hands drugs pass

FROM TOP: MARISSA ROTH; HAIR AND MAKEUP, ROBERT BENNETT FOR NARS FOR RIGHTIOUS ARTISTS FOR JET-SET; COURTESY OF THE FLORIDA DEPARTMENT OF HEALTH (4); PREVIOUS SPREAD: MICHAEL KRAUS; PROP STYLING, MIA KATOH.

through, the more likely they are to be mishandled or adulterated. In one case, Nevada wholesaler Dalfens, a largely phantom business run from a spartan office, had a pizza parlor next door accept a delivery of fragile medication needing to be refrigerated. The pizza place stored the box beneath its counter for three days before a Dalfens employee picked up the drugs to be resold, Ling says. For Dalfens's many violations, the Nevada board issued a formal ruling revoking the company's license and fining it \$1 million. (A lawyer for Dalfens says the company has appealed that ruling on the grounds it is "riddled with defects and not enforceable.")

The board also found that Dalfens unlawfully failed to keep records of its sales, which reached at least \$35 million, and gave fabricated sales records to investigators. In investigating cases like this one, Ling has become convinced that the secondary wholesale market is an "industry that facilitates" counterfeiting by obscuring the path drugs travel—a process akin to money laundering.

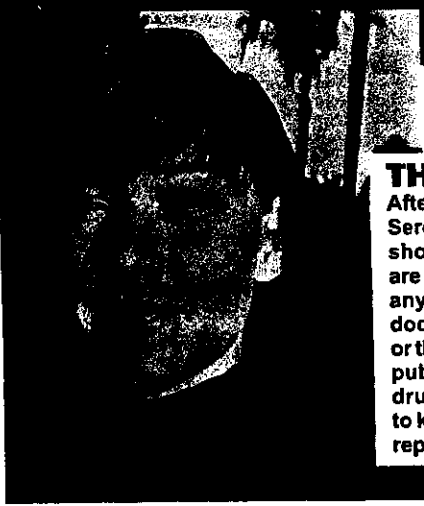
Streck, who leads the association representing the largest wholesalers, concedes that leading distributors often do buy from smaller companies of unknown merit "in order to be competitive" and benefit from their slashed prices. He acknowledges, "There are occasions when it is not safe."

● **Tim, a teenager** in Long Island, New York, found this out after receiving two successive batches of adulterated medicine. Last year, at 16, he had a liver transplant and suffered from severe anemia. "You go through this horrible event [of the transplant] and you have so little control," says his 43-year-old mother, Jeanne (who asked that the family's name not be published). Her son's drug regimen, she thought, was one thing she *could* control. Once a week, she injected Epogen into her son's arm, using the method she learned from a home health nurse. But Tim appeared to be getting worse: He would wake up in the night "screaming in agony," his body racked by radiating pain, Jeanne says. Not realizing her son's painful cramps might be connected to the Epogen, she continued the shots for 10 weeks.

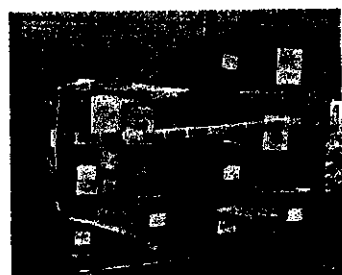
crime, says one will be dead."

And then last spring, Jeanne got a call from CVS ProCare saying that counterfeit Epogen had been circulating. Tim's prescription refill, already on its way, proved to be part of that bad batch. The understandably nervous family then carefully scrutinized a vial left over from Tim's first prescription and found that a degree sign was missing from the label—telltale evidence the medicine was fake. The family had uncovered a second batch of counterfeits that the pharmacy hadn't known anything about.

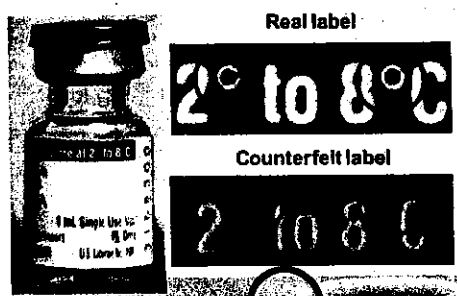
The family says representatives of the drugmaker, Amgen, told them the adulterated product was not dangerous, only ineffective. It was Epogen, but at (Continued on page 191)



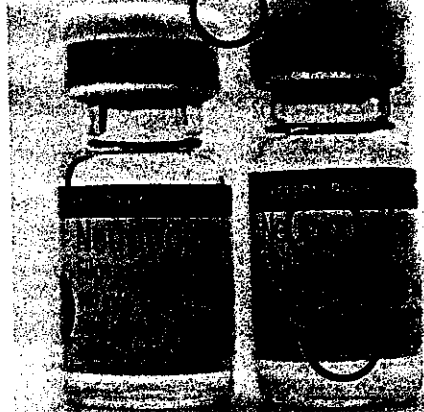
THE VICTIM
After taking counterfeit Serostim, Burke was shocked to learn there are no laws requiring anyone—drugmakers, doctors, pharmacists or the FDA—to warn the public about phony drugs. It's up to patients to keep up with news reports and drug recalls.



THE EVIDENCE Raids and sting operations in Florida turned up adulterated injectable drugs. Some wholesalers had turned a few vials into many by diluting them; others had repackaged drugs with fake labels that made the dose appear higher and pricier.



CAN YOU SPOT THE FAKE? The differences between real and phony drugs can be subtle. The Epogen label (far left) has a degree sign in the storage information; the fake doesn't. The real Neupogen bottle is 1 millimeter shorter than the counterfeit. Also note the print on the label: The real version is crisp; the fake label has poor-quality printing and crowded type.



PROTECT YOURSELF View safety alerts and drug recalls at www.fda.gov/medwatch. If someone else gives you injections, make sure she is aware, too. If you suspect your medicine is fake, call your doctor, your pharmacist, the manufacturer and the FDA (at 301-443-1240). Keep a sample in case you need to take legal action.

PHARMACY FAKES

Continued from page 183

one-twentieth the strength; unknown counterfeiters had relabeled a weaker solution of the drug. But to Jeanne's mind, this did not explain the side effects. Last September, four months after being alerted, the FDA picked up the family's remaining vials to run the complex analysis that is beyond the capability of ordinary laboratories. The family wants to confirm exactly what the vials contained and find out who adulterated the drugs, which had been shipped from one of the nation's largest manufacturers and passed through one of the largest wholesalers and wound up in one of the most reputable drugstores. It remains a whodunit as to who else had possession along the way.

Jeff Richardson, a spokesman for Amgen, says that "it would be wrong" to alarm patients and depress the value of the company's stock over a few incidents that are local and contained. "I'd hate to have you short the stock," he says. "This is a law-enforcement issue. The drugs are secure when they leave us. We believe they are secure when they arrive."

But Jeanne has learned that almost no one, from manufacturers to government regulators, actually knows where her son's drugs have been. Her faith in the drug supply has been utterly shattered. "It was devastating," she says. "Something that should have been safeguarded was not. And if it could happen to us, it could happen to anyone."

The 1988 federal law designed to protect the drug supply initially specified that wholesalers must document each prior sale of a drug back to the manufacturer, creating what is called a pedigree paper. Such records would allow investigators, and ultimately patients, to track each stop of a drug's journey between the manufacturer and the pharmacy. But wholesalers successfully lobbied to have the FDA put the provision on hold, stating that the requirements would impose an unfair burden of paperwork. As recently as last November, eight trade groups representing wholesalers and drugstores of every size wrote to the FDA requesting yet another postponement of the rule; the groups have argued that "we are unaware of any significant health or safety concerns that would arise from a further delay." Today, 15 years after the law's passage, the protections still have not been

implemented—leaving the path that your drugs take largely a mystery.

SIX THOUSAND AMERICANS TAKE SEROSTIM for HIV, their names and addresses known to pharmacists. Yet Kelly Burke learned about the tampering of her medicine only after her fiancé happened to see a small newspaper article about the problem. Burke says that when she called Serono, a customer-service representative told her the medicine wasn't harmful—but the company needed the vials back and would let her know what they actually contained. She held on to the vials, since they were the only evidence she had.

Carolyn Castel, a spokeswoman for Serono, says the FDA has since told the company that one lot of the phony Serostim contained a growth hormone, but it was not Serostim and was a far lower dose than labeled. Another lot contained a fertility drug: human chorionic gonadotropin, or hCG. Normally, hCG should

even those most in danger, concluding, "There is no factual, legal or public-policy basis to impose an obligation on Serono to issue a nationwide warning." Rick C. Roberts, a 39-year-old from San Francisco who also took adulterated Serostim for AIDS and suffered a bad reaction, says he is shocked he wasn't contacted directly even though both Serono and the FDA knew about the problem. "There was a warning if you happened to be surfing the FDA website for fun," he says.

Burke's suit was settled last spring, although none of the parties admitted liability. A Cardinal Health spokesperson did not return calls seeking comment. A spokesman for CVS ProCare, Todd Andrews, says cases like Burke's and the Long Island family's are rare, and that the industry is taking steps to make them rarer. One key step, he says, is for drugmakers to notify pharmacies immediately when problems crop up. "We wouldn't know there was a counterfeit

When drugmakers know of counterfeits, they are not required to contact anyone, from patients to pharmacies to the police.

be injected twice a month at most, says Daniel Stein, M.D., director of the in vitro fertilization program at St. Luke's-Roosevelt Hospital Center in New York City. Injecting it daily, Dr. Stein says, could cause extreme pelvic pain, swollen ovaries and liver dysfunction.

In April 2001, Burke and another California patient sued Serono, CVS ProCare and the major distributors of their drugs—in Burke's case, Cardinal Health, one of the country's largest drug wholesalers. Among the accusations: that Serono waited nearly two months before issuing a press release about the counterfeit Serostim. Castel notes that the company's efforts to inform pharmacies, wholesalers and AIDS service organizations eventually resulted in news items in 50 states. "When we confirmed with the help of the FDA that there was a counterfeit problem, we began to spread that word to alert the public," she says.

But in court papers, the drugmaker argued it had no duty to warn consumers,

unless someone told us," says Andrews. "The counterfeits are expertly done."

Yet when drugmakers know of counterfeits, they are not required to contact anyone—not patients, not pharmacies, not the police. They don't even have to report the incidents to the FDA. While the agency has considered such a rule, "the current thought is that it may not be within our jurisdiction," says Benjamin England, the FDA's regulatory counsel to the associate commissioner for regulatory affairs.

Moreover, the FDA does not perform routine audits to ensure that drug distributors follow the provisions of the 1988 law which *haven't* been blocked, including minimum standards for storage, handling and record keeping. Generally the agency reviews compliance only after a criminal case is opened. Although FDA investigators pursue these cases vigorously, by then, says England, "the horse is out of the barn." In other words, unsafe drugs may have already made their way to patients. (Continued on page 192)

PHARMACY FAKES

Continued from page 191

England says the FDA has been working closely with the drug industry to look for new technologies to help secure the distribution system, such as bar codes, tamperproof packaging with holograms embedded in labels or chemical "tags" within medications that could allow pharmacies to screen drugs for authenticity. But as pharmaceutical executive Christian notes, criminals have proven adept at duplicating security features. England also says there has been an increase in voluntary reporting from manufacturers. Previously, drugmakers were loath to point out to customers that their products were potentially unsafe.

Serono has taken the radical step of requiring that Serostim be delivered directly to authorized pharmacies through overnight mail, with no middlemen involved. While Serono does not rule out expanding this program, spokeswoman Castel says the company will continue to rely on wholesalers to deliver other drugs. "It's the industry standard for how pharmaceutical products are delivered," she says. As industry observers note, the drugmakers have little incentive to change this standard. An overhaul would be a massive undertaking, costing billions. And the drugmakers' ability to sell their entire inventory quickly and efficiently to wholesalers—rather than bit by bit to each pharmacy—improves their cash flow and their Wall Street image as highly productive companies.

FED UP WITH THE CURRENT SYSTEM OF industry self-policing, the states of Nevada and Florida have declared open season on unscrupulous wholesalers, vowing to enforce rules far stricter than the federal standard. Now instead of filling out a two-page form, a prospective drug wholesaler in Nevada must file a 20-page application and undergo a criminal-background check. The state is attempting to restrict the amount of drugs that wholesalers can sell to other wholesalers in an effort to ensure that drugs are not moved endlessly through the gray market. Distributors must have drugs on the shelves, qualified employees and spotless files. "There has to be a real person who really works there who is really responsible to us," says Ling. "We were sick of the game playing."

After the Nevada crackdown, only 8

of the original 40 companies in the state remained. Inspired by these results, Florida officials issued a report last October declaring that they, too, intend to target drug wholesalers. They envision tough new rules that would force distributors to track every pill or vial passing through their warehouses; falsifying these records would become a felony. However, a trade group based in Florida, the Pharmaceutical Distributor's Association, argued forcefully against any more record keeping. They have made the same case to state officials as they have before members of Congress—that the paperwork would overwhelm their small businesses.

To prosecutors, the need for a better paper trail could not be clearer. Without a way to retrace the path of bad drugs, says Venema, "we wouldn't be able to prosecute a single case." Mann draws a parallel with another multibillion dollar Florida industry: Because citrus canker can affect the entire orange crop, every single tree sold in the state is registered so that an outbreak can be traced.

But Florida and Nevada officials admit even the strongest state laws cannot fully address what is a national problem. Faced with a crackdown in one state, counterfeiters simply move to another. For the moment, Gregg Jones, who manages the investigators of the Florida Bureau of Pharmacy Services, compares efforts to combat these criminals to "shoveling sand on the beach—in a hurricane."

TODAY, KELLY BURKE STILL HAS HER OWN uphill battle: to survive until her wedding day. About as optimistic as one can be in her condition, she says, "Last year, they told me I'd be lucky to see August, and I'm still here...I'm in love and I'm happy." Yet the symptoms she once fought off with Serostim have begun again, her arms and legs growing thin, her abdomen distended.

While she continues to take two antiviral medications, Burke says she is too terrified to take Serostim despite Serono's claims that the company can guarantee the product's safety. She says that she will just tough it out until her symptoms become too severe to ignore, and pray in the meantime that a new cure is found. "The whole idea of taking the drug scares me so much, I don't think I could," says Burke. "Going through that again could kill me." ■

Katherine Eban, an investigative reporter in New York City, writes on medicine and public health for many national magazines. Additional reporting by Shannan Rouss and Dana Sullivan.

SELF CHALLENGE CONTEST RULES

(Continued from page 190) failures of any sort. All entries become the property of the Sponsors and will not be acknowledged or returned. Acceptance of prize constitutes consent to use winners' names and likenesses and winning entry for editorial, advertising and publicity purposes without further compensation, except where prohibited. Winners may be required to sign an Affidavit of Eligibility and winner and guest a Liability/Publicity/Permission release, which must be returned within fourteen (14) days from date of notification or an alternate winner may be chosen. Void in Puerto Rico, outside the United States and where prohibited. The contest is subject to all federal, state and local laws and regulations. Income and other taxes, if any, are the sole responsibility of the winners. All decisions of the judges are final and binding in all respects. Entrants agree to be bound by these official rules and the decisions of the judges, and to hold harmless Sponsors and/or Contributors and each of its officers, directors and employees from all liability arising from or related to participating in the promotion or use of any prize. For winners' names, send a self-addressed stamped envelope to either 10,000 Giveaway, Monthly Giveaway, Finishers Giveaway, Grand-Prize Sweepstakes, Prize-a-Day Sweepstakes or Bring a Friend to Fitness Contest Winners List at P.O. Box 1023, New York, NY 10108-1023, after August 1, 2003.

Contributors to the SELF Challenge Prize Packages include: The Kapalua Bay Hotel & Ocean Villas, Olay, Pria, Nike, Colgate, Boca Burger, Aveeno, Fox River for Women, The Goddess Workout, In-Sport International, Maxx New York, Rite Aid, Speedo, Performance Inc., THOR•LO Inc., Lee Jeans, Sally Beauty, Isis, Alex & Ani, Active.com, Mavi, Champion, Smith. Log on to www.self.com for the contributors to the Prize-a-Day Sweepstakes.

FINESSE GIVEAWAY RULES

NO PURCHASE NECESSARY. You must be a legal U.S. resident at least 18 years of age as of the date of entry. Call 877-995-4492 on March 19 at noon EST. If you are one of the first 500 callers, you will win one Finesse Curl Hydrating Shampoo, one Finesse Curl Hydrating Conditioner and one Finesse Curl Defining Mousse. The approximate retail value for the set of three products is \$9. Employees of The Condé Nast Publications and Finesse and their families are not eligible. One product set per person. Please allow six weeks for delivery after the offer has ended.

6