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DOCUMENTS ACCOMPANYING TESTIMONY PROVIDED BY THE NEVADA STATE BOARD OF PHARMACY IN SUPPORT OF SB 37

ASSEMBLY COMMERCE AND LABOR
MAY 6, 2005

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BIO

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J1-20

Dangerous

COUNTERFEIT MEDICINE IN AMERICA'S DRUG SUPPLY: In the past five years, diluted, mislabeled and substitute versions of the following drugs have landed in America's pharmacies and hospitals.

LIQUID BIOTECHNOLOGY MEDICINES:

EPOGEN, PROCRIT—Boosts the red blood cell count of patients undergoing organ transplants, cancer treatment, or kidney failure.

- 110,000 low-dose vials relabeled to appear 20 times stronger.

GAMIMUNE—Blood plasma extract that helps patients with immune system disorders fight infections.

- Diluted with a cloudy, bacteria-filled liquid.

NEUPOGEN—Protein that boosts the immune system of cancer patients.

- Replaced with saline.

NUTROPIN AQ—Growth hormone used to treat children with kidney problems or genetic disorders.

- Replaced with insulin, which can cause seizures in patients who don't need it.

SEROSTIM—Human growth hormone for patients with HIV/AIDS that keeps them from losing weight, muscle mass and organ tissue.

- Replaced with a dangerously high concentration of an inexpensive fertility drug.

PILLS, TABLETS & MEDICAL SUPPLIES:

CELEBREX—One of the country's most popular drugs for combating arthritis.

- Replaced with vitamins.

COMBIVIR—Prolongs the life of patients with HIV/AIDS by keeping the virus from reproducing.

- Replaced with Ziagen, another HIV medicine that can cause a fatal allergic reaction.

LIPITOR—America's best-selling medicine that lowers cholesterol and reduces the risk of heart disease.

- Bitter-tasting counterfeits contained a mixture of placebos, unapproved generic and some authentic ingredients.

PROLENE—A surgical polypropylene mesh attached to abdominal walls to repair hernias.

- Unsterile counterfeits caused severe infections in a number of patients.

VIAGRA—Taken by men to treat impotence.

- American counterfeiters manufactured over 700,000 fake pills.

ZYPREXA—Helps prevent hallucinations and delusions in schizophrenic and bipolar patients.

- Replaced with aspirin.

By Katherine Eban • May 2005 • Harcourt, Inc.

Dangerous Doses

THE PROBLEM OF TAINTED MEDICINE IN AMERICA:
Counterfeit medicine, which once reached patients only through Internet and south-of-the-border purchases, has infiltrated the drug supply via homegrown counterfeiters and corrupt distributors.

A GROWING TREND

- Counterfeit versions of at least 11 different prescription medicines, to treat diseases from cancer to AIDS to high cholesterol, have landed on pharmacy shelves in the United States since 2000.

- The Food and Drug Administration saw an almost ten-fold increase in its counterfeit drug investigations, from 6 in 2000 to 58 in 2004. The agency is currently investigating 91 open cases of domestic counterfeiting that span the nation and involve millions of doses of medicine.

- According to a confidential report by the Pharmaceutical Security Institute, a research organization funded by drug makers, in 2004 the United States experienced 76 incidents of counterfeiting, diversion and theft of pharmaceuticals, the highest reported number in the world ahead of even China and Colombia.

COUNTERFEITS REACHED PATIENTS

- The patients who received counterfeit medicine, as described in *Dangerous Doses*, purchased their medicine from legitimate pharmacy chains including CVS and Rite Aid. Counterfeiters relabeled drugs to appear 20 times stronger or replaced them with substances like tap water, insulin, and fertility hormones.

- In July 2003, counterfeit versions of Prolene, a polypropylene mesh used to repair hernias, entered America's hospitals. A North Carolina patient suffered severe infection from the counterfeit and underwent numerous follow-up surgeries to repair the damage.

- A month's supply of cancer medicine for 22,000 people, relabeled to appear 20 times the strength, vanished into the supply chain in Spring 2002 and most likely reached patients. The scheme netted $46 million for the counterfeiter and his associates.

- Distributors recalled more than 18 million tablets of the popular cholesterol-lowering drug Lipitor in 2003, after patients received bitter-tasting counterfeits with little active ingredient. It was one of the largest prescription drug recalls in U.S history

THE NEW MEDICINE DISTRIBUTORS: NARCOTICS TRAFFICKERS, FELONS AND THE MOB

- Drawn to pharmaceutical distribution by exorbitant profits and low penalties, narcotics traffickers and even mafia associates have obtained legitimate state licenses to operate as pharmaceutical wholesalers, selling stolen, mishandled, and counterfeit medicine into the nation's supply.

- In Florida, an offshore bookie became a prescription drug wholesaler to repay a debt to the Gambino crime family. A national mail-order pharmacy, Caremark Inc., unwittingly purchased $1 million in adulterated HIV medicine that the bookie's company had acquired from a narcotics trafficker.

By Katherine Eban • May 2005 • Harcourt, Inc.

24. A Wink and a Nod in Las Vegas

October 2003
Las Vegas, Nevada

THREE MONTHS AFTER MICHAEL CARLOW'S ARREST, JUST AS A federal task force released a report on America's vulnerability to counterfeit medicine, two groups with radically different agendas convened amid the desert's glittering hotels and casinos to determine who would control the nation's drug distribution system. Both groups met in Las Vegas during the same week, just a few blocks apart.

In a conference room at the Las Vegas Chamber of Commerce, the Nevada State Board of Pharmacy convened a public hearing for two wholesalers accused of conspiring to buy diverted medicine that proved to be counterfeit. Such proceedings might have yielded a slap on the wrist in the past. But this case had mushroomed into a full-blown trial with implications far beyond the two companies involved.

Nevada authorities spared no expense as they endeavored to show how counterfeit drugs moved easily through the system's loopholes to reach unsuspecting patients. They invited witnesses from around the country, including pharmaceutical executives, an AIDS patient who had received counterfeit medicine, and Gary Venema. The investigator planned to testify about the Florida companies that sold tainted drugs to the Las Vegas wholesalers.

Across town at the Monte Carlo Resort & Casino, the nation's secondary drug wholesalers gathered for their first-ever national conference, a summit on their industry's survival. They represented more than fifty companies from Kentucky, Florida, California, and elsewhere. They came to talk about the investigations, the creeping regulations, the bad press, the crackdown in Florida, and the lacerating effects of counterfeit medicine moving through their companies. They hoped to restore their image as the small businessmen, rather than the pariahs, of the supply chain. And to do so, they needed to bring a credible public face and more disclosure to their secretive industry.

Their plenary session was entitled "Secondary Wholesalers: Why You're Good Guys Too." Conference organizer Robb Miller, a savvy Las Vegas wholesaler with wire-rimmed spectacles and a goatee, climbed the podium to deliver his positive message. "We are lawful citizens," he began. "We provide many services. We move billions of pharmaceuticals across the country each year. We provide inventory management services. We help new manufacturers."

Expounding on his theme of usefulness, he added, "I would say we are essential to national security." He suggested the small wholesalers would be the front line of defense if terrorists attacked the computer systems of the Big Three. "How will they maintain their orders? Where would the emergency response teams get their drugs?" This was the image makeover he wanted: one that equated small wholesalers with homeland security.

"Without us, loved ones would be lost," he said. "We are in every city across the country. We could be called on."

His colleagues remained divided about the best way to survive the onslaught of negativity. Most believed nothing good could come from a PR offensive and that any public

mention of their names could lead larger wholesalers to cut them off or regulators to probe their businesses. Already they had risked exposure just by coming to a gathering that the FDA and the larger wholesalers' trade group, the HDMA, had canceled their registrations to attend.

In a further effort to influence his colleagues, Miller invited fourteen of the wholesalers to a private club that night on the top floor of the Mandalay Bay Resort & Casino. The Foundation Room, with its guarded entrance, separate elevator, and absence of signs, was a perfect place for a more candid discussion. Miller gathered the men on the balcony for drinks as they awaited their table. Some of his guests were members of the secretive trade group run by Sal Ricciardi in Boca Raton, the Pharmaceutical Distributors' Association, which refused to publish its membership list. Tonight, Miller planned to make his pitch to wrest the leadership of the trade group from Ricciardi.

With a sweeping view of the Las Vegas strip, a blaze of electricity that ended abruptly in blackness at the undeveloped desert, the wholesalers smoked cigars, drank Scotch, and traded stories about how it felt to be treated like criminals.

"Before, it was just fine because it was just a money thing, nobody was getting hurt," said a short man, hair in disarray, who used to work as a techie for a major news network before moving to Las Vegas and finding his way into the pharmaceutical business.

A well-dressed Miami wholesaler who had been on the short end of Gary Venema's wrath joined in. "You have guys come in with badges and guns," said the Miami wholesaler. "They have no idea what business is. All they do is look at an invoice and say, 'That's too much money.'" He concluded, "Well, fuck you."

Fresh from the Florida dustup, he explained that the wholesalers there had been forced to give up everything, with no concessions from the state. He recalled that first pedigree meeting in Tallahassee eighteen months earlier and the speech by that young prosecutor. "She referred to the industry as contaminated rats," he said. "'Rats' was definitely in there. 'Dirty rats' is what she said."

Lance Packer, one of the Las Vegas wholesalers on trial that week, sipped his cocktail and joined the discussion. Packer and his father-in-law faced the prospect that their licenses would be revoked. Now among friends, the thirty-seven-year-old businessman excitedly proclaimed his innocence.

When their table was called, the men headed to a private dining room with its own balcony and a magnificent view of the city's neon forest of casinos. Fresh drinks and appetizers arrived. The talk grew more voluble.

The conversation turned to meetings that Ricciardi's group, the PDA, had held with the FDA months ago, regarding the most contested part of the federal Prescription Drug Marketing Act. The final rule, as it was known, would have required wholesalers nationwide to pass on complete pedigrees with their drugs. In January, the group managed to get yet another stay of the rule, the fifth since it had become law. "How could they *not* issue us a stay?" one of the men asked.

Each guest seated around the table occupied a different rung on the wholesale ladder, their operations reflecting varying shades of the gray market. While the men viewed themselves as operating legal businesses, they understood that their tactics were of interest to law enforcement and probably best left unpublicized. Most also seemed to agree that a real scourge facing their industry was a man named Gary Venema—a "cocksucker," the Miami wholesaler declared with venom as

he described how the FDLE agent had barged into his warehouse and threatened to take away his business.

"You *are* a secondary wholesaler," Ricciardi's deputy chimed in.

The Miami man laughed and joined in the satire. "I can't help myself. I'm a low-life scumbag diverter."

By now everybody was warm with liquor and ready for more cigars. But Miller stood and handed out copies of his eighteen-page proposal to revamp the Pharmaceutical Distributors' Association and replace Ricciardi as its leader. Miller argued that the changes would help preserve what they had worked so hard to build.

With bemused detachment, his dinner companions rifled through the pages. The formality of Miller's pitch—including his suggestions of a mission statement, funding forecast, weekly bulletins, and political action committee—flowed against the tenor of the dinner, which was dark, private, and full of shorthand talk. The men did not appear ready to come out of the shadows.

Later on the balcony with a cognac in hand, Miller put a foot up on the balcony rail, aired out the sides of his Versace suit jacket, and pulled at a cigar. He appeared unbowed by the chilly reception. "I have a romantic notion of justice and I think that what's happening is unjust," he said.

The Miami wholesaler agreed. "It makes no difference whether you sell paper clips or Procrit, you have a right to exist," he said. "I think it's wrong that you punish everyone for the bad acts of a few."

As the evening devolved, so did the sanctimony. Long after midnight they went their separate ways, each returning to his own little trade war with regulators and each other, not knowing that their nemesis, the "cocksucker" Gary Venema, was in town, too.

TWO NIGHTS EARLIER, VENEMA HAD BEEN TOO EXCITED TO SLEEP when he arrived in Las Vegas. He walked the strip of megahotels until 1 A.M., barely noticing the garish casinos, the dancing jet sprays from fake lagoons, and the amusement park rides that towered above the neon billboards for show girls. Instead, he was thinking about the Horsemen and the surprising ripple effects of their work. Breathing in the desert air, he declared to a companion, "Finally, I feel that I have accomplished something of relevance in my life."

Since Michael Carlow's arrest, the Horsemen had become a more integral part of a growing cross-country network. In Georgia, Connecticut, New York, Florida, California, and Nevada too, drug security executives, state investigators, regulators, and patients had begun to work together. These were individuals who really understood the issues involved and who were obsessed with safeguarding the nation's medicine. They attended the same hearings and registered the same complaints. They were dissatisfied with the FDA's sluggish pace and its tepid explanations of problems. They viewed the drugmakers as complicit through their secrecy and pricing schemes, which they believed encouraged diversion. They believed the Big Three wholesalers had made a devil's bargain in their quest for discounted medicine. And they wanted to see the entire system rewired so that patients came before profits. While most had never met each other, they were committed to fighting what they saw as a sellout of America's patients.

The nation's drug supply had long been governed by an unspoken covenant: Americans pay the highest prices in the world in exchange for the highest manufacturing standards and a guarantee of purity. When drugmakers emphasized that foreign medicine—which could be riddled with impurities—threatened the integrity of our own supply, they reinforced

the connection between higher prices and greater safety at home. Consumers who went to Canada or Mexico in search of cheaper drugs were seen as abandoning the essential protections of our blue-chip supply.

But sky-high prices had not made us safer. Instead they made America the go-to market for counterfeiters and the prescription business a lucrative draw for criminals—as even an internal report prepared for drugmakers by their own research organization, the Pharmaceutical Security Institute, pointed out.

The drugmakers fought bitterly against importing cheaper medicine from abroad, calling it a grave threat to public health. Yet their internal report stated that the United States experienced fifty-four counterfeiting incidents in 2003—more than any other nation in the world. Each incident posed a serious potential threat to thousands of patients, as the Lipitor counterfeiting and Grillo's uplabeling of Epogen had shown. The report stated that increased reporting of incidents and a free press in the United States were only partial explanations for the larger numbers. The size of the nation's prescription market, the high demand, and the increasing pressure to find lower-cost medicine had helped create a market for counterfeiters—and made it likely the number of incidents would increase, the report stated.

Sure enough, by the first half of 2004, the number had risen. The United States had experienced twenty-eight counterfeiting incidents, behind only Colombia, with thirty incidents during the first six months of the year, according to the internal report. India was third, with nineteen incidents.

The Pharmaceutical Security Institute report showed the hidden costs buried deep in the nation's drug distribution system. Even patients who got medicine from pharmacies or hospitals had no way of knowing whether their medicine had

been recycled or sent on dangerous journeys that left it subpotent, adulterated, or outright counterfeit.

"In the final analysis, this is a fraud against the consumer," said Oscar Gelpi, the assistant statewide prosecutor who took over Operation Stone Cold. "What kind of moron pays Rolex prices for a knockoff?" Americans, he said, "are paying top dollar for what they think are legitimate drugs."

Before the Horsemen came along, state prosecutors and drug inspectors had only weak laws to use against those who tampered with medicine. But the Florida task force had convinced the legislature that adulterating medicine was as bad as trafficking in cocaine. At least cocaine addicts knew they were buying a harmful product. But cancer patients were unwitting victims and might never know the difference once they dispensed the evidence of tainted medicine into their veins. Remarkably, despite all the obstacles, the Horsemen's efforts had made Florida's drug supply the most strictly guarded in the nation.

Other state pharmacy boards looked to emulate Florida's 2003 law. Drugmakers, too, began to tighten their networks, threatening to cut off large distributors who bought their products from the secondary market.

By the end of 2003, everyone, it seemed, had a five-point plan or a task force to improve the safety of the drug supply, and invitations poured in for the Horsemen to speak out about what they had discovered. Venema flew to Delaware, Boston, and Chicago to present his findings. He and a CIA agent were the featured speakers at a meeting of the Pharmaceutical Biotechnology Security Council, a working group of drug security experts that met every few months around the country. When Venema went to testify in Nevada, he landed at a critical moment in the state's battle for control of its drug supply.

THE NEVADA PHARMACY BOARD'S GENERAL COUNSEL, LOUIS LING, a youthful reformer, and its executive director, Keith Macdonald, a patrician silver-haired pharmacist, had been fighting the state's drug distributors for thirteen years. By 2000, the two men realized that many of the distributors were phantom businesses with few employees. One company operated from a U-Haul storage shed. Another had its inventory delivered to a pizza parlor. The men pushed through regulations in 2001, requiring Nevada companies to employ real people in real offices and keep real business hours. As a result, the number of in-state wholesalers dropped from fifty to eight. Those who remained detested Ling and Macdonald and waged a battle against them that became bitterly personal.

In January 2003, Ling had received a call from Gary Venema about a Nevada drug wholesaler called Dutchess Business Services. Venema explained that Dutchess had been buying medicine from Crystal Coast, a Miami wholesale company suspected of selling counterfeit AIDS medicine. Eager to help, Ling sent a detective to Dutchess, where an angry Lance Packer announced that he wouldn't provide any "fucking records" and that he was tired of the state trying to put him out of business. It took Ling seven weeks to get the records. As soon as he saw them, he suspected that Dutchess had bought and sold a huge quantity of counterfeit Serostim.

As Ling investigated Dutchess, Packer, his father-in-law Paul DeBree, and others were investigating him. In March, five wholesalers—including Dutchess and Robb Miller's company, Caladon Trading—sued Ling and Macdonald personally, claiming that the state officials had interfered with, and slandered, the wholesalers' businesses. The companies had been cut off as suppliers for Cardinal Health, they alleged,

after Ling raised questions about their buying practices with Cardinal executives. The lawsuit alleged that Ling and Macdonald aimed to drive *all* secondary wholesalers from Nevada. As proof, it quoted Ling as having told their lawyer that he would "continue to piss in your clients' soup until they get out of Dodge."

Five months later, in August, Ling and Macdonald filed a fifty-six-page complaint against two of the companies, Dutchess and Legend Pharmaceuticals. It alleged that the two companies—run jointly by Lance Packer and Paul DeBree—conspired to profit by purchasing diverted and deeply discounted medicine from companies not licensed in Nevada. It accused them of using pedigrees that perpetuated the false representation that their suppliers were authorized distributors, and of continuing to buy from them for more than a year after their medicine proved counterfeit.

The complaint sought to challenge in advance the defense wholesalers had used over the years: that they were innocent companies misled by corrupt suppliers. The complaint portrayed willful blindness as part of a conspiracy among wholesalers and alleged that if they didn't know the medicine they were buying was bad, they should have. And that is where Venema came in. He would testify as to how convicted felons in Florida used the thinnest of pretenses to make their dangerous drugs appear good—pretenses the Las Vegas wholesalers accepted without question.

ON THE MORNING OF OCTOBER 13, A PANEL OF BESPECTACLED pharmacists gathered in a conference room at the Chamber of Commerce to hear the case against Dutchess and Legend. Venema, who had arrived in black jeans and a polo shirt with

a lightning bolt on it that said "Phi Zappa Crappa," surveyed the roomful of people in sober business attire. He muttered, "I should have worn a suit."

Ling and Macdonald were missing, but not by choice. They were huddled with their own lawyer in a courtroom across town, fighting an eleventh-hour defense motion seeking to bar both men from setting foot in the hearing. Ling was the state's prosecutor on the case. Another lawyer, Mary Boetsch, stood by to present the case in his stead.

Lance Packer sat amid the few spectators in the conference room. His father-in-law, Paul DeBree, a diminutive man in loafers and sportswear, sat primly near several of his lawyers. Together, the two men ran Dutchess, DeBree as its president and CEO and Packer as its day-to-day manager. Legend, a new and separate company established by DeBree, shared the same office and interchangeable staff. DeBree was an old hand at regulatory battles and even criminal investigation: After his last wholesale company became implicated in the diversion scheme perpetrated by Bindley Western in the late 1990s, another of his sons-in-law who helped run the company pleaded guilty to conspiracy.

As the hearing began, DeBree and Packer's lawyers presented legal objections to the proceedings that the pharmacy board's president, Larry Pinson, listened to with strained patience and overruled. He then directed prosecutor Mary Boetsch to call her first witness.

Rick Roberts took his seat at the witness table. An adjunct communications professor at the University of San Francisco, Roberts was an AIDS patient whose prescriptions included Serostim, an injectable growth hormone that reversed the sudden weight loss suffered by those with HIV. A month's supply of the drug cost $7,000.

He testified that in late 2000, he began to feel a stinging sensation when injecting his Serostim. When he went to his drugstore and inquired, the pharmacist told him, "You should go home and check. You may have gotten some of the fake stuff."

Roberts took the bus home, his head swimming. "When I got home I convinced myself that I must have misunderstood," he said. "It didn't make any sense to me."

As he took out all his vials and compared them, he noticed tiny variations. On one, the ink appeared slightly darker. On another, the cap was a slightly different blue.

He went online and found an article describing how counterfeit Serostim had been found in seven states and the FDA had launched a criminal investigation. One of his lot numbers matched that of a counterfeit lot.

Roberts testified that once he called the manufacturer, an executive there had urged him to send all the counterfeit medicine back and the company would replace it free of charge. But Roberts—seeing clearly that the vials remained his only evidence that he'd been the victim of a crime—decided that he wouldn't give them up until he could learn what had been in them. "I wanted to know what I had injected," Roberts told the board. He didn't know what the solution contained and he feared that it could kill him.

The counterfeits turned out to contain a far less expensive fertility hormone, human chorionic gonadotropin, which the counterfeiter had likely chosen because its packaging resembled that of Serostim. Another lot turned out to contain a pediatric dose of growth hormone not approved in the United States. Roberts had injected both.

As Roberts was about to end his testimony, the wholesalers' principal lawyer, Steve Gibson, swept into the hearing room. A district court judge had agreed to temporarily bar

Ling and Macdonald from the hearing. Gibson began a new debate over whether to continue the hearing at all.

As the witnesses and board members adjourned for lunch, they encountered Ling and Macdonald outside, looking dejected. Now under a court order, the two men kept their distance, not wanting to jeopardize the outcome of the hearing.

Over lunch they talked about the frustration of taking on the industry's well-paid legal team while their own defense came from a tired and overwhelmed state lawyer who represented the men in addition to his usual duties.

"I can't afford to fight Steve Gibson at $300 an hour," said Macdonald, staring into a glass of iced tea as he contemplated losing a lawsuit that could strip him of his home and other assets.

"We're getting our butts kicked," said Ling.

BY THE SECOND DAY OF TESTIMONY, GIBSON'S EXHAUSTIVE CROSS-examinations had slowed the proceedings to a crawl. Several witnesses had already given up and flown home, as the board acknowledged that it would likely have to convene at a future date to complete the hearing. Venema, this time wearing a suit, went off in disgust to see the Hoover Dam.

Pamela Williamson-Joyce, the vice president of regulatory and quality assurance for Serono Inc., testified that as a result of the counterfeit Serostim, the company had put a unique hologram on the boxes the vials came in, shrunk its customer list, and required all authorized distributors to accept being audited at any time. As well, each box bore a unique identifier, a number that would never be repeated.

On cross-examination, Gibson asked why the company didn't do more sooner.

Williamson-Joyce snapped back that he was talking about "the concept of the ideal. It is not humanly possible for any professional organization to eradicate what someone may choose to do in their basement."

While Williamson-Joyce went on to assert that counterfeits are not a "commonality," only Serono knew for sure how many patients had received counterfeit Serostim. She balked at revealing the number.

"More than ten?" Gibson asked.

"Yes."

"More than one hundred?"

"I don't know," she said.

"More than fifty?"

"Honestly, I'd have to go back and check." Only three patients who'd received it, including Roberts, had come to public attention. Two had settled confidentially with Serono and the major distributors. Roberts had not yet sued anyone because the counterfeiter had never been caught and he didn't know whom to blame.

All the procedural dueling absorbed three days of testimony. Venema took the stand briefly. He rattled off his credentials, including his years as a homicide detective. This caused a detective for the pharmacy board to nod approvingly, as though glad to have a murder investigator working this case. Venema did not get far in his testimony and the board resolved to resume the matter in January 2004.

Venema got back to Florida just in time for the arrests of Maria Castro and Jesús Benitez, the owners of the Miami pharmacy J&M Pharmacare. They pleaded not guilty to charges of organized fraud and the unauthorized sale of prescription drugs.

BY THE TIME VENEMA RETURNED TO LAS VEGAS IN JANUARY, A major stress in his life had been lifted: His son Kevin had returned from Iraq unharmed and was honored with a bronze star for leadership. The case against the Las Vegas wholesalers actually had grown stronger. The corrupt Florida wholesaler who had supplied them with counterfeit Serostim, Bill Walker, pleaded guilty to seventeen felony counts of racketeering, fraudulent use of personal identification, and violations of the health statute 499. Ling and Macdonald had won dismissal of the restraining order against them and were back on the case.

On the stand again, Venema described the criminal networks they found running through the pharmaceutical trade.

He detailed the investigation of Crystal Coast in Miami and the arrests of its principal officers, Bill and Elinor Walker, who had sold the counterfeit Serostim to Dutchess and Legend. A former narcotics trafficker and Norwegian national who was wanted by Interpol, Walker, who used an array of aliases but claimed that his real name was Per Loyning, operated six different wholesale companies. One was called Rekcus (Sucker spelled backward).

Venema detailed the crimes of the Walkers, the winding path that their medicine took through a series of shell companies, and how he found memos between them and DeBree arranging pharmaceutical buys.

This time, lawyer Steve Gibson embarked on his cross-examination of Venema, eager to establish that his clients were no worse than anyone else in the secondary market. He asked Venema whether he had encountered a "stretching of the rules" in the way wholesalers used their status as authorized distributors to disguise the true origin of the medicine they sold. "What I've encountered is more cheating" than stretching the rules, said Venema. "It's out and out lies."

He then testified about the unstated "Don't ask, nobody

has to tell" style of the wholesale market, in which buyers don't ask where medicine came from because they don't want to know. Even the Big Three participated in this system, he said, buying at least two 2 percent of their medicine from the secondary market, as long as the paper looked legitimate. "I personally think they are out of their minds," he said.

Gibson then asked: Had the Big Three conspired with the secondary wholesalers to move cheap, substandard medicine into the supply chain?

"I'm not saying it is a conspiracy on a grassy knoll with the guys who blew away Kennedy, but there are shenanigans going on," he said.

By revealing the seamy source of DeBree and Packer's medicine, Venema proved to be a damaging witness. But he was not nearly as damaging a witness as DeBree himself. Under questioning, the soft-spoken DeBree offered the most vivid and honest admission to date about the profit motive of the secondary market and the exploitation of the loophole that allowed authorized distributors to erase a drug's real pedigree.

DeBree explained that in doing business with Crystal Coast, his due diligence consisted of checking to see if the company had a license. "As far as priority is concerned," he said, "it has nothing to do with the quality of the product." Even after the manufacturer circulated a warning about the existence of counterfeit Serostim and two wholesalers in succession returned the Serostim, DeBree testified that he resold the drugs to a third company and never confronted Walker.

"It never entered your mind that he sold you fake drugs and it never occurred to you that he was a crook?" asked Boetsch.

"I was obsessed about economics and to be made whole," he responded.

As Louis Ling took over the questioning, DeBree explained that he had wanted to exploit the loophole of the

authorized distributor, namely that "it washes" the pedigree, he said, allowing him not to list the trail of companies through which the drug had passed.

Though Crystal Coast claimed it was an authorized distributor, it refused to give DeBree any proof of this claim. When asked why he kept buying medicine from Crystal Coast anyway, DeBree paused and the room fell silent. "That's a good question," he said, finally offering, "Economic advantage?"

IN CLOSING STATEMENTS, THE PROSECUTORS TOLD THE BOARD that under Nevada and federal law, DeBree and Packer did not have to know the medicine was counterfeit to be held accountable for it.

DeBree made no effort to know because he was focused on money, not patient safety, Boetsch said, adding that there was "a nod and a wink and a smirk to the side between all these wholesalers.

"They say, 'They didn't know.' That doesn't matter. It doesn't save them." She continued, "He doesn't have to know it's counterfeit. He has to make sure it's not."

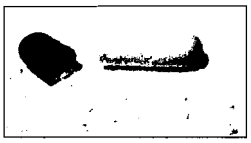
Gibson then argued that the prosecution had not provided "an iota" of evidence of a conspiracy between DeBree and Walker. Admitting that his own client's testimony gave him queasy feelings in his stomach, he concluded that DeBree had been conned by Walker, just like the Florida regulators who licensed Crystal Coast. "Did he exercise the best business judgment all the time? No." Gibson then asked for the board's mercy.

It took about thirty minutes for the board members to reach a verdict. They found the two companies guilty on all counts, revoked their licenses immediately, and fined Dutchess $1 million and Legend almost $400,000.

T13-28

Outside, on the corner of Tropicana and Sands, Venema celebrated. On the day he served a search warrant on Bill Walker, his boss at FDLE had been furious, complaining that Venema should stay focused only on Michael Carlow and stop chasing bad medicine all over South Florida. But without his scattered pursuit, which had led to Walker and his customers in Las Vegas, DeBree and Packer might still have their licenses. To Venema, this signaled a revolution born in Florida beneath his hands. *The Horsemen are few*, he thought to himself, *but they ride like a thousand.*

Acerity Corporation



- **Are you concerned about patient safety, reimportation & Internet sales?**
- **Are you feeling pressure from State & Federal mandates or pedigree information?**
- **Are you losing revenue from counterfeiters & diverters while protecting your product & image?**

If any of these questions concern you, Acerity Corporation has developed a set of solutions to effectively stop counterfeiting and diversion of pharmaceutical products while incorporating pedigree information by using patent pending processes, security software systems and Radio Frequency Identification (RFID) technology to effectively address these issues. Acerity Solution Components consist of **AuthentiTrak™**, **Trusted Source Inspector™** and **Pedigree-On-Demand™** Systems. These systems work together to support the smooth flow of pharmaceuticals down the supply chain while adding strong protection for the safety of patients and the interests of corporations while satisfying State and Federal mandates for pedigree information.

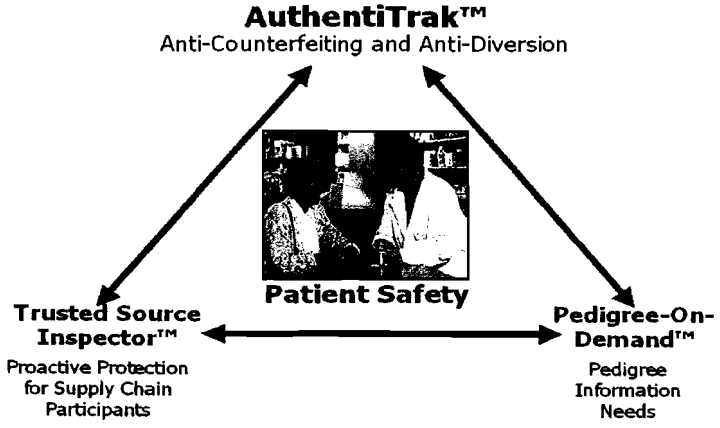
AuthentiTrak™ performs electronic wrapping of outgoing packages. It can function as a stand-alone system to prevent counterfeiting and diversion while performing authenticity verification of incoming packages. The system supports applications which include:

- Covert authentication of products at the item level
- Electronic wrapping of packages to assure package integrity when packages have to be handled by multiple parties (e.g. in freight forwarding)
- Anti-tampering of packages
- Electronic labeling to facilitate accurate materials movement
- Provides basic authenticity verification of incoming packages in a reimportation, Internet sales setting.

Trusted Source Inspector™ (TSI) Protects supply chain participants. The TSI acts as an independent, neutral, trusted entity that verifies and electronically seals repackaged pharmaceuticals before shipping. As part of a larger system, the TSI and AuthentiTrak™ work jointly but independently together for a proactive industry-wide supply chain solution for the pharmaceutical industry, providing a proactive anti-counterfeiting, anti-diversion process. TSI works independently and yet in conjunction with AuthentiTrak™, it provides a very strong system for authenticity verification of incoming packages in a store to store transfer, reimportation and Internet sales setting.

Pedigree-On-Demand™ satisfies the need for pedigree information that State and Federal officials require without divulging information throughout the supply chain. AuthentiTrak™ together with the TSI already provides a strong and proactive anti-counterfeiting and anti-diversion process. However, the system offers:

- State and Federal officials an easy, responsive and effective means to perform detailed pedigree investigations
- No accumulation of paper or electronic pedigrees as the pharmaceuticals travel down the supply chain
- Eliminates tremendous information burdens and unnecessary exposure of data for corporations.



With Acerity Solution Components on site, patient safety concerns, corporate interests, State and Federal mandates are met without the need for a costly and burdensome centralized database approach.

CONTACT US FOR A LIVE DEMO!

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Pharmacies and Drugs Affected by Drug Diversion Operation

April 28, 2005

On April 28, 2005 the United States Attorney for the District of Utah announced a series of indictments concerning an illegal drug diversion operation occurring in several states throughout the country. Although the operation appears to be limited in scope, FDA is providing as much information as possible to the public about the distribution of these illegal drugs to help patients and health providers determine if they might have been affected.

Below is a list of potentially affected drugs and pharmacies. It is important to note that **unless the listed drug was purchased at one of the pharmacies listed below it can be presumed to be safe and effective. If you have purchased a listed drug from one of these pharmacies, do not use the drug but instead immediately notify your health care provider. Pharmacies that received drugs from any of the listed distributors are urged to check their inventories for any remaining products, stop dispensing any of these products, and notify any patients who may have purchased these affected drugs.**

The distributors named in the indictments are:

- PDRX, also operating under the name of Pharma Discount, located in Salt Lake City, Utah;
- Empire Pharmaceuticals, Newbury Park, California;
- DRX Medical, also operating under the name of Defonte Trading, Aberdeen, New Jersey;
- PRNY Enterprises, AC Global, AC Healthcare, and Afro Caribbean Healthcare, all located in Floral Park, New York.

For more details, see related FDA talk paper.

Pharmacies

Name	Address	City	State & Zip
702 Pharmacy	406 W Putnam Ave	Porterville	Ca 93257
A&W Pharmacy	1121 McDonald Ave	Brooklyn	NY 11230
Aalpha Pharmacy	174 South Alvarado Street	Los Angeles	CA 90057
AAUSHADH Inc	4615 5th Ave	Brooklyn	NY 11220
Adams Square Pharmacy	1122-A East Chevy Chase Drive	Glendale	CA 91205
Agra Pharmacy	537 Claremont Pkwy	Bmx	NY 10457
All in One Pharmacy	24404 S Vermont #310	Harbor City	CA 90710
Almarc Drugs	507 Main St	New Rochelle	NY 108016305
Alpha Drugs Pharmacy	1240 S Magnolia Ave	Anaheim	CA 92804-5116

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Alpha Pharmacy	515 S Beach Blvd	Anaheim	CA 92804-1812
Alvin's Pharmacy Inc	115 Cedar Lane	Teaneck	NJ 07666
Arlyn Pharmacy	753 Commack Rd	Brentwood	NJ 11717
Ashland Pharmacy	123 Dekalb Ave	Brooklyn	NY 11217-1237
B N Pharmacy Inc	107-45 Guy Brewer Blvd	Jamaica	NY 114332351
Balaji Targee Pharmacy Corp	519 Targee St	Staten Island	NY 10304-3501
Bello Pharmacy	179 St Nicholas Ave	Brooklyn	NY 11237
Bethel Pharmacy, Inc.	301 Osborne Terrace	Newark	NJ 07112
Beverly Hills Medical Plaza Pharmacy	150 N Robertson Blvd #104	Beverly Hills	CA 802112143
BN Pharmacy Inc	107-45 Guy R Brewer Blvd	Jamaica	NY 11433
Brownsville Community Pharmacy	592 Rockaway Ave	Brooklyn	NY 11212
Calexico Pharmacy	420 E 2nd St	Calexico	CA 92231
California Pharmacy Association Inc	315 N 3rd Ave	Covina	CA 91723
Camp Drugs, Inc	850 18th Ave.	Irvington	NJ 07111-2756
Care Drugs	505 N Mollison Ave	El Cajon	Ca 92021
Care Rite Pharmacy Inc	3500 Broadway	Long Beach	CA 90803-5907
Century Pharmacy	159 E Broadway	New York	NY 10002
Charlie's Pharmacy	1101 Fillmore St	San Francisco	CA 941154711
Coney Island Pharmacy	2720 Mermaid Ave	Brooklyn	NY 11224
Corby Chemists	988 1st Ave	New York	NY 10022
Eagle Scripts	401 N 4th St	Indiana	PA 15701
East Village Prescription Center	72 Avenue A	New York	NY 100097239
Economy Drug Inc	22121 Jamaica Ave	Queens Village	NY 11428
El Camino Pharmacy	6356 Vineland Ave	No Hollywood	CA 91606
El Molino Pharmacy	6652 Front St	Forestville	CA 954369688
Express Drugs	9 Butler St. NE	Atlanta	GA 30303
Express Pharmacy Inc	752 E Arrow Hwy	Los Angeles	CA 91767
Global United Pharmacy	179-42 Hillside AVE	Jamaica	NY 11432
GN Pharmacy	119-01 Jamacica Ave	Richmond Hill	NY 11418
Goodman Plaza Pharmacy	3250 3rd Ave	Bronx	NY 104566743
Georgetown	134-07 Liberty Ave	Richmond Hill	NY 11419

Grant Pharmacy	1340 Edward Grant Hwy	Bronx	NY 10452
Health Fair Pharmacy	305 Willow Avenue	Hoboken	NJ 07030
Hunts Point Drug	2799 3rd Ave	Bronx	NY 10451
Justin's Pharmacy	1168 Summit Ave	Jersey City	NJ 07307
Kennedy Pharmacy	42 E Laurel Rd STE #1900	Stratford	NJ 08084-1350
Khanh Pharmacy	4575 El Cajon Blvd #C	San Diego	CA 92115-4316
L M Caldwell Pharmacy	1509 State St	Santa Barbara	CA 93101
LA Votre RX Inc	25848 Hemingway Ave	Stevenson Ranch	CA 91381
Lark Drugs Pharmacy	16251 Main St	Guerneville	CA 95446
Laurel Pharmacy	13686 Van Nuys Blvd	Pacoima	CA 91331-3616
LaVotre RX Inc	25848 Hemingway Ave	Stevenson Ranch	CA 91381-2319
Liss Pharmacy	794 MT Prospect Ave	Newark	NJ 07104
Little Five Points Pharmacy, Inc	484 Moreland Ave NE	Atlanta	Ga 30307
Medical Center Pharmacy	161 Clinton St	Watertown	NY 13601-3675
Medicine Cabinet Pharmacy	8828 Parsons Blvd	Jamaica	NY 11432-3842
Metta Pharmacy	7037 Linda Vista Rd	San Diego	CA 92111
Midtown Drugs	581 Kearny Ave.	Kearny	NJ 07032-2737
Midway Drugs	10410 Lower Azusa Rd	El Monte	CA 91731
Newark Drug	673 Broad St.	Newark	NJ 07102
Nishi Pharmacy	850 Amsterdam Ave	New York	NY 10025
Nu Look Pharmacy	188-06A Jamaica Ave	Hollis	NY 11423
Nutree Pharmacy	2080 W County Line Rd	Jackson	NJ 08527
Oals Park Pharmacy	205 Prospect Park West	Brooklyn	NY 11215
Owl Rexall Drug	5634 N Figueroa St	Los Angeles	CA
Oxford Pharmacy	3516 1/2 W 8th St	Los Angeles	CA 90005
Professional Prescriptions Center	265 Central Ave	East Orange	NJ 07018
Rite-Way Pharmacy LLC	1603 Westchester Ave	Bronx	NY 10472
Riverside Pharmacy	2920 8th Ave	New York	NY 10039
RX Unlimited San Francisco	901 Castro St	San Francisco	CA 94114
Sicomac Pharmacy	300 Sicomac Ave	Wyckoff	NJ 07481
Sidney	519 Targee St	Staten Island	NY 10304-3501
Silver Pharmacy & Medical Supply	15243 Roscoe Blvd	Panarama City	Ca 91402

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Sims Pharmacy Corp	1711 Pitkin Ave	Brooklyn	NY 11212-6601
Sunny Pharmacy	42-02 B Greenpoint Ave	Sunnyside	NY 11104
SVRH Pharmacy	161 Smith St	Brooklyn	NY 11201
TDI Pharmacy	452 S Main	Pittsburgh	PA 15220
The Community Pharmacy	1524 27th Ste 302	Bakersfield	CA 93301
Toluca Village Pharmacy	4201 W Alameda Ave	Burbank	CA 915054142
Total Remedy & RX Center	1245 Wilshire Blvd	Los Angeles	CA 90017
Tripharm Drug Inc	200 Port Richmond Ave	Staten Island	NY 10302
Valley Pharmacy Inc	23800 Sunnymead Blvd	Moreno Valley	CA 92553
Varsha Pharmacy	239 Boyle Rd	Selden	NY 11784
Wards Pharmacy	653 Long Beach Blvd	Long Beach	CA 90802
Whittier Goodrich Pharmacy	5417 Whittier Blvd	Los Angeles	CA 90022
Wible Pharmacy Inc	2400 Wible Rd Ste 1	Bakersfield	CA 93304

Drugs

MANUFACTURER	DRUG
ABBOTT LABS	KALETRA
ASTRA ZENECA	SEROQUEL
BOEHRINGER INGELHEIM	VIRAMUNE
BRISTOL MYERS SQUIBB	AVALIDE
BRISTOL MYERS SQUIBB	AVAPRO
BRISTOL MYERS SQUIBB	PRAVACHOL
BRISTOL MYERS SQUIBB	REYATAZ
BRISTOL MYERS SQUIBB	SUSTIVA
BRISTOL MYERS SQUIBB	VIDEX
BRISTOL MYERS SQUIBB	ZERIT
ELI LILLY & CO.	ZYPREXA
GILEAD SCIENCES	EMTRIVA
GILEAD SCIENCES	TRUVADA
GILEAD SCIENCES	VIREAD
GLAXO SMITH KLINE	COMBIVIR
GLAXO SMITH KLINE	EPIVIR
GLAXO SMITH KLINE	LEXIVA
GLAXO SMITH KLINE	RETROVIR
GLAXO SMITH KLINE	TRIZIVIR
GLAXO SMITH KLINE	ZIAGEN
JANSSEN PHARMACEUTICA	RISPERDAL

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MERCK	PROSCAR
MERCK	SINGULAIR
MERCK & CO.	CRIXIVAN
NOVARTIS PHARMACEUTICALS	DIOVAN
ORTHO BIOTECH	PROCRIT
ORTHO-MCNEIL	LEVAQUIN
PFIZER INC.	CELEBREX
PFIZER INC.	LIPITOR
PFIZER INC.	LIPITOR
PFIZER INC.	VIAGRA
PFIZER INC.	VIRACEPT
PFIZER INC.	ZITHROMAX
PFIZER INC.	ZOLOFT
PFIZER INC.	ZOLOFT
ROCHE PHARMACEUTICALS	COREG
ROCHE PHARMACEUTICALS	INVIRASE
SANOFI AVENTIS	LOVENOX
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Cardinal to stop drug-trading business

Report: Drug wholesaler says move 'a business decision,' will move to fee-for-service model.

May 6, 2005: 7:21 AM EDT

NEW YORK (Reuters) - Drug wholesaler Cardinal Health Inc. plans to discontinue its pharmaceutical-trading business, which bought and sold drugs among secondary wholesalers, *The Wall Street Journal* reported Friday.

Cardinal (Research) called the move "a business decision" motivated by shifts within the industry, the article said.

The decision comes after Cardinal and the other two leading drug wholesalers, AmerisourceBergen Corp. (Research) and McKesson Corp. (Research) -- which account for about 90 percent of the prescription drug sales in the United States -- were last month subpoenaed by New York state Attorney General Eliot Spitzer. The subpoenas are likely tied to buying practices that may have led to counterfeit drugs entering the system, often through secondary markets, the *Journal* said.

Dublin, Ohio-based Cardinal said its pharmaceutical-trading business has accounted for about $180 million to $190 million in revenue so far this year -- a small fraction of its pharmaceutical distribution business, which has about $36 billion in revenue this year.

The major wholesalers, which buy most of their drugs directly from the manufacturers, have tried to reduce purchases from the secondary market. Cardinal in April said it buys less than half of 1 percent of its drugs from the secondary market.

The drug wholesale industry is in the midst of a change in the way it earns profits as drug manufacturers move to control inventory supplies. The wholesalers used to buy vast quantities of medicines and hold them until prices rose, making profit on the price difference. Cardinal and others are now moving to a fee-for-service contracts model.

Click here for Cardinal Health's quarterly earnings report. ■

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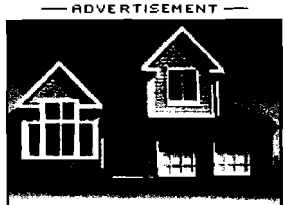

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