

Protecting Procrit

J&J reacts to outfox counterfeiters trafficking fake vials of its anemia drug

BY DAVID SCHWAB
STAR-LEDGER STAFF

The telephone call that set off a red alert at Johnson & Johnson last year came from Grapevine, Texas, a small town midway between Dallas and Fort Worth that is best known for hosting one of the nation's biggest wine festivals.

Food and Drug Administration agents investigating a Medicaid fraud case had stumbled upon something unusual in a warehouse: 1,004 tiny vials of medicine labeled as Procrit, J&J's blockbuster anemia drug, but none of the proper paperwork.

Later that day, the matter came to John Dempsey, the head of brand security at Ortho Biotech Products, the Raritan-based unit of J&J.

Within days, his worst fears were realized.

Laboratory tests showed the vials were sophisticated counterfeits, a potentially dangerous situation for Procrit patients, many already weakened by cancer.

"Once we got over the shock, and it really was a shock," Dempsey said during an interview earlier this month, "the next question was: 'What do we do?'"

In short order, J&J accomplished something many thought was impossible, according to interviews with company executives who spoke in detail about the incident for the first time.

Working at a feverish pitch during the next month, executives and engineers came up with a high-tech fix by adding a sophisticated seal to the boxes of its most widely used version of Procrit. And the company launched an intensive redesign of the Procrit packaging and added anticounterfeiting features to all its prescription medicines.

How New Brunswick-based J&J — which earned high marks for its handling of the Tylenol tampering incident 21 years ago — responded to one of the most significant counterfeiting threats ever foreshadowed a growing problem for the pharmaceutical industry.

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CRACKING DOWN ON COUNTERFEITERS

After the FDA discovered counterfeit Procrit in a warehouse, Johnson & Johnson made several improvements to the packaging of its anemia drug. Here is a look at some of those changes:



Carton closure seals

The first thing J&J did was change the way it closed its Procrit packages. The boxes are now closed with a seal printed with polychromatic ink, the same used on a \$20 bill. The ink shifts from green to silver depending on the viewing angle. Sales managers can point a hand-held laser at the seal to authenticate it. If a label is removed, it leaves distinctive green streaks.

Color-coded vial caps and boxes

All vials used to have red caps with an aluminum wrap underneath. Now, the cap, the wrap and the box are all color coded to reflect the strength and the amount of the drug it contains.

The strength of the drug is also printed on the aluminum wrap underneath the flip caps.

SPOTTING A FAKE

There were numerous small, but significant, differences between Procrit and what counterfeiters tried to pass off. J&J first discovered vials containing low-dose Procrit relabeled and repackaged as high-dose. Later, the FDA seized a limited number of Procrit vials filled with water.

INITIAL CLUES

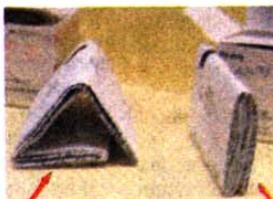
The box

1. Small smudges and black dots occurred when printing the fake boxes, such as the small dot above the "b" in "Albumin."

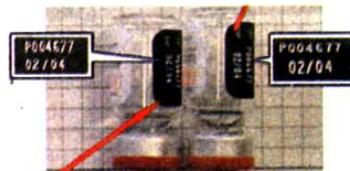


The package insert

1. The insert for the counterfeit Procrit is printed on a heavier paper stock than the real one.
2. The authentic insert is sealed with tear-away glue to keep it closed. The fake has no seal.



OTHER CLUES CAME LATER IN A LIMITED QUANTITY



1. The counterfeit vials are approximately one-sixteenth of an inch shorter, with a slightly larger diameter than the real vials.
2. The black label does not adhere well to the fake vial and may pull away from it.
3. The numbers on the labels are not the same. The font is smaller on the counterfeits and the number "7" has a strike-through that doesn't exist on the real labels.

COUNTERFEITERS RESPOND TO THE NEW SEAL



1. The seal on the real box (top) does not cover the bar code. The seal on the fake box (bottom) often covers part of the bar code.
2. There is no box around the "PHARMACIST Place Label Here" text on the real box.

PROCRIT

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J&J outfoxing counterfeiters

In the wake of the widespread recall earlier this year of counterfeit versions of Pfizer's Lipitor — the nation's biggest selling prescription drug — the FDA is considering measures to reduce the counterfeit threat, including changes to packaging. An FDA task force is expected to present preliminary findings this week.

"If you are not currently looking at implementing some type of anti-counterfeiting technology, you better start looking at it," Dempsey said.

The stakes for J&J could hardly have been higher.

With U.S. sales of more than \$3 billion last year, Procrit is J&J's biggest-selling prescription medicine. Widespread concerns about safety could strike a serious blow to the company's bottom line and its carefully groomed image.

For Dempsey and other senior executives in New Jersey, there was no avoiding the magnitude of the problem. A short drive away, inside a huge, refrigerated warehouse in Somerset, pallets holding 2.4 million doses of Procrit were stacked 30 feet high. Until Dempsey and his team found a solution, \$1.2 billion in inventory was stranded.

With a combination of skill and luck, J&J executives borrowed anticounterfeiting technology used on the \$20 bill and developed a tiny adhesive seal to secure the Procrit cartons. Next, they found critical pieces of machinery and erected an assembly line where workers applied the seals. They did in weeks what might normally take many months or even a year.

"J&J pulled off an amazing feat," said Ron Streck, president and chief executive officer of the Healthcare Distribution Management Association, a leading industry organization.

A LUCRATIVE BUSINESS

Though heavily promoted, Procrit isn't in everyone's medicine cabinet. Each vial, about an inch tall, contains less than a teaspoon

full of clear liquid. Typically, a doctor uses a vial to fill a syringe for a weekly injection.

J&J determined the medicine found in Texas hadn't been touched. But someone had washed off the labels on the vials and printed replacements to show they contained the highest dose of Procrit, when they actually contained the lowest.

The trickery could be extremely lucrative. Vials of the low-dose Procrit sell for about \$22 each, compared with \$450 a vial for the strongest and most common dose, which contains 40,000 "units" and was marked with a fluorescent orange 40 on the box.

The forged packaging would fool any doctor or patient. But to the experts at J&J, there were tell-tale imperfections, like a tiny smudge on the front of the box and a slightly thicker cardboard tray inside separating the four vials. J&J officials said they don't know how many of these mislabeled Procrit vials were sold.

Only later would J&J learn about a second, more elaborate counterfeiting scheme involving filling vials with water instead of medicine. The FDA stopped this before any product was sold. Twenty-one people would subsequently be charged in Florida in connection with counterfeit Procrit.

As his first order of business, Dempsey, 49, a resident of Maple Glen, Pa. — whose passion outside the office is tending to the impatiens and other garden perennials — had convened a high-level executive team to consult with the FDA.

They worked until after 10 each night in a conference room in the office of then-Ortho President Gary Reedy, eating meals brought up from the downstairs cafeteria and crowding around the speaker phone in the center of the table.

Their most pressing task was to inform doctors and the public.

By the following Tuesday, June 4, a week after the initial call, Ortho sent 200,000 letters to health-care professionals alerting them to the mismarked vials. Dempsey then turned his attention to packaging.

'WE NEED TO DO SOMETHING'

That afternoon, he called Elizabeth Hansen, a J&J package development engineer who worked in a

building on Route 22 in Bridgewater.

"We need to do something immediately," he told Hansen.

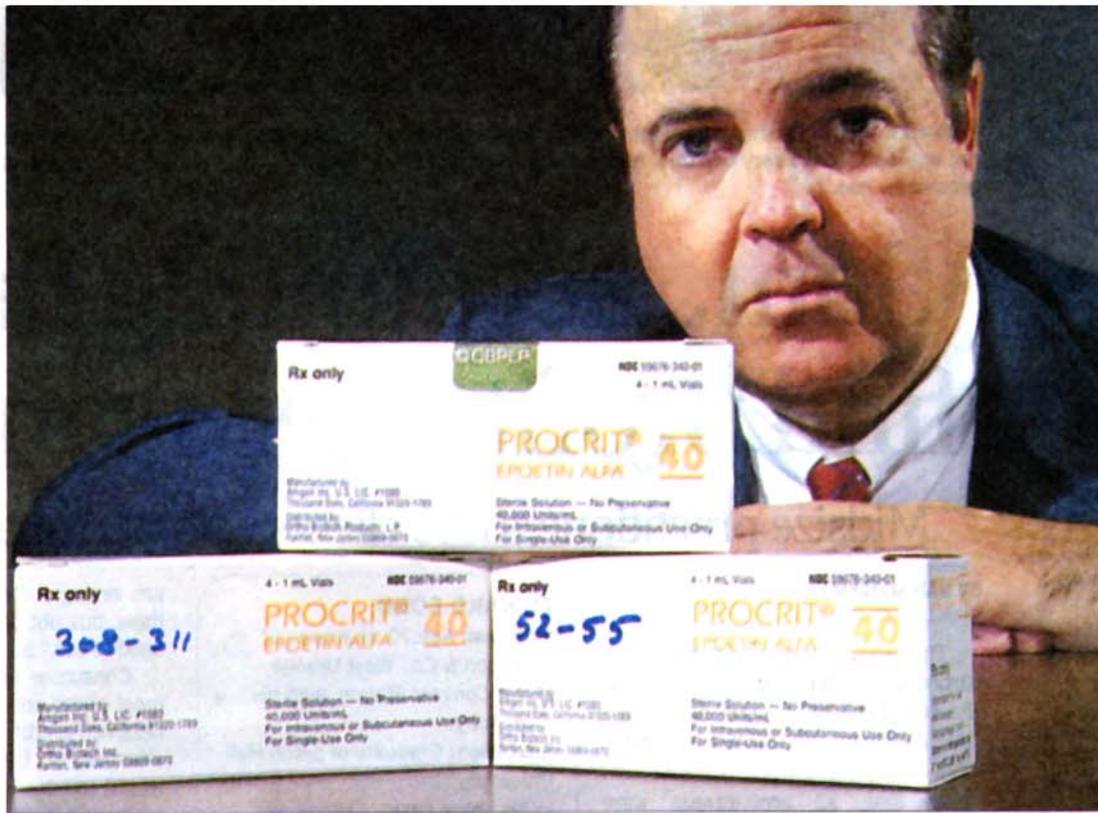
While she had arrived at J&J just a year and a half earlier, she had spent almost 20 years working on pharmaceutical packaging. She had a bachelor's degree in packaging from Michigan State University to go along with her MBA.

She, too, was dumbfounded.

"I think of our drug supply chain as pristine," said Hansen, a Morristown resident who would become a member of a second group called the "redress" team. "I was horrified."

By 8 the next morning, senior representatives from two of Ortho's suppliers had driven in for what turned out to be an all-day meeting at a J&J Bridgewater office.

Executives decided no more packages of the highest dose Procrit would be released from its Franklin Distribution Center in New Jersey until they found a solution. The center held about a six-month supply.



TONY KURDZUK/THE STAR-LEDGER

John Dempsey, head of brand security for Ortho Biotech, the Raritan-based unit of Johnson & Johnson, with a counterfeit box of Procrit — bottom left — and the real things — an older version, bottom right and a newer one, on top.

That meant they had to act fast. Supplies of 40K Procrit in the market were dwindling. Executives figured they had until the end of the month before those supplies might run out.

Adding holograms to the boxes was ruled out. They are too common, on everything from cereal boxes to trading cards, and are easy to fake.

One of the vendors described a special "color shifting" ink the U.S. Treasury uses on \$20 bills. If you look at the bottom right hand corner, the number 20 looks bright green or silver, depending on the angle. The ink could be used to make a tiny adhesive seal that would secure the top and bottom of the cardboard boxes that contain the Procrit vials.

The room was silent. A decision had been reached.

They would have to conduct many tests before figuring out precisely how to use the ink on the labels.

Further complicating matters, the FDA would have to approve all major changes. J&J also would

have to talk with Amgen, the big biotech company based in California, which manufactures Procrit in Puerto Rico.

IT'S NOT OFF THE SHELF

Now it was up to Henry Passarotti, a senior J&J engineer, who had to find the machines to put the labels on the boxes and wrap them for shipping. "It's not something you can buy off the shelf," he said.

A labeler normally takes up to a year to order from Italy. Passarotti visited one supplier whose jaw dropped when Passarotti mentioned he wanted to find one machine by the end of the week, if not sooner.

Ultimately, they found one in Chicago, though it was an older, slower model that could seal just one side of a package at a time. A bundling machine was found at Ortho's sprawling Raritan campus along Route 202.

Within days, Passarotti set up a packaging line at the distribution center in Somerset, but there were still other hurdles.

Procrit must be kept refriger-

ated at about 41 degrees. Only small amounts of the drug could be removed at a time from the walk-in refrigerator where they were stored. Once sealed, the boxes had to be quickly returned to another "cold box." And all this had to be documented for the FDA.

Finally, Saturday, June 22, the sealing and repackaging operation began. About 15 employees, wearing hair nets, lab coats and booties, worked two 10-hour shifts. By the end of the following week, the FDA gave its final approval. On Monday, July 1, the first sealed Procrit boxes left by tractor-trailer.

"It was exciting," said Prudence Smith, one of those on the line. "We knew we were helping sick people."

All of the 40K vials were sealed and shipped by Aug. 15. To mark the occasion, Hansen stopped for an ice cream cone on her drive home late that night. There would be no celebration; there was still lots more work to do.

SENDING A MESSAGE

During the next months, other safety features would be introduced. Ortho changed the tops and seals on the vials, to make it harder to open and reseal them. Ortho also limited the number of wholesalers who can sell Procrit.

"We wanted to make sure that a message is sent to counterfeiters that we are doing whatever it takes to protect our product," Dempsey said.

In a conference room talking about the episode the other day, neither Dempsey nor Hansen appeared ready to take a break.

They are still busy devising more anticounterfeiting measures. By January, crude copies of their Procrit seal had surfaced.

"We hope to keep one step ahead of them, to make sure even if they do figure out what we have on this label in six months, we will have something different so they won't be able to duplicate that," Hansen said. "We're never done."

James Cohen, associate director for compliance and biologics quality at the FDA, said: "We are encouraged by efforts of manufacturers to quickly develop and use anti-counterfeiting technologies to deter and detect counterfeiting."

Staff writer Susan Todd contributed to this report.