Serostim Sabotaged!

In a chilling first-ever, counterfeiters strike at a U.S. AIDS drug. Julie Hantman asks whodunit.

June 1, 2001 By Julie Hantman

AIDS drug makers may have to redouble their product-safety measures after counterfeiters hit Serono, the world's third-largest biotech, in December. While the scandal -- the first such incident in the history of AIDS -- caused no apparent harm, it reveals holes in the U.S. drug-safety system that could spell trouble for med-taking HIVers.

The saga began last fall, when Serono's switchboard lit up with calls from panicked PWAs about their supply of Serostim, a pricey human growth hormone -- $21,000 for a 12-week supply -- that arrests HIV-related wasting. It looked different -- powdery, not cake-like -- some callers complained. Others had just injected the drug and reported that they were having an allergic reaction to it. So, the Massachusetts-based biotech made a call of its own -- to the Food and Drug Administration (FDA), the federal overseer of drug safety -- to report a pharmaceutical nightmare: The substance causing the stir was a fake. "Our investigators are under the impression that we've collected most of the product," says FDA rep Richard Klein.

And it's a good thing, too. If Serono hadn't acted swiftly by issuing an industrywide alert to wholesalers and pharmacists last December, the counterfeit -- which has so far turned up in California, Florida, Ohio, Kentucky, Michigan, Missouri and New Jersey -- could have reached many more of the 6,000 Serostim-takers nationwide. "We take the integrity of our products very seriously," says Serono spokesperson Carolyn Castel.

The bogus batch, discovered in lot MNK612A, was distributed alongside authentic Serostim bearing the same number. The counterfeiters produced a total product imitation -- the drug and the packaging -- and found an illicit route into Serono's distribution chain. Fortunately, Castel says, the counterfeiters' handiwork had flaws. Besides the suspicious look of the drug, the expiration date on the box and Serostim vial should have read 08/01 (August 2001) *not* 08/02. (For additional details, call Serono at 888.275.7376.)

While the FDA is investigating the Serostim incident, the agency has come under sharp criticism for its lax counterfeiting controls. Last June, according to a CNN report, the House Commerce Committee blasted the FDA for not monitoring overseas wholesalers that sell drug ingredients to the U.S. in bulk. Although counterfeit substances can slip into the distribution channel at a number of points -- an overseas ingredient supplier, a U.S. manufacturer's warehouse, or even at a local pharmacy -- critics blame the agency for failing to inspect overseas manufacturing plants. As of

June 2000, fewer than a third of the 6,000 overseas ingredient manufacturers had been FDA-inspected.

Activists say that the FDA is also sluggish at addressing HIVers' concerns about the Serono shake-up, including providing a detailed analysis about what was in the bum product. "The FDA's pace has been abhorrently slow," says Project Inform's Brenda Lein, who has called the agency repeatedly on behalf of victimized PWAs. The FDA finally told Lein that the mystery powder contained human chrionic gonadotropin, or HCG, a benign hormone used by bodybuilders, but provided no answers about whether the substance contained contaminants. Until the investigation is closed, the agency and Serono will likely remain mum. Meanwhile, HIVers should inspect all drug packaging and call their pharmacist about peculiar pills and potions.

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