Compound Interest

A mom-and-pop pharmacy finds a do-it-yourself way around the high price of a new hep C drug

December 1, 1999 By Maia Szalavitz

There's nothing novel about consumer Davids doing battle with pharmaceutical Goliaths, but patient groups, the FDA and HMOs all lining up on one side against a drug company is unusual indeed. The spark for this strange-bedfellows alliance? A small pharmacy-turned-guerrilla operation that's dramatically underselling the first-line drug treatment for hepatitis C, a potentially serious liver infection faced by an estimated 40 percent of PWAs.

It all started in June 1998 when drug mega-firm Schering-Plough got FDA approval to market Rebetron, a "bundled" product that combines doses of its alpha interferon (Intron A) and ribavirin for treatment of hep C. (The company continues to sell Intron A separately, but not ribavirin.) Not only does the bundle cost a bundle (some $1,600 a month), but it freezes out consumers who want to vary the dose of interferon, use another company's interferon or take ribavirin alone. Patients were pissed.

Enter Fisher's, a Pittsburgh pharmacy. "Not long after the combination came out, we started to have problems," says co-owner Don Kerrish. "Even people with insurance couldn't afford their copayment of nearly $17,000 a year for this drug, and it wasn't long before some owed us $2,000 or more. Plus we had people who weren't qualified for the company's patient-assistance program and had no insurance. For them, it was a death sentence.

"We also had doctors who wanted to use different doses, even of Schering's brand of interferon," Kerrish continues. "Our biggest prescriber wants patients to use interferon five times a week, not the three times that is packaged in Rebetron. What are they supposed to do—buy extra and throw it away?"

After researching ribavirin, Fisher's found that the patent on the drug ran out in July of this year, but generic versions couldn't be manufactured until the year 2000. Meanwhile, they learned, a New York City buyer's club, the PWA Health Group, was importing the drug from Mexico and charging consumers $410 a month. But Fisher's soon realized that they could offer an even cheaper product. Pharmacies have the right to *compound* (make their own versions of) drugs for individual patients—say, for someone allergic to a filler in a brand-name product. Why not compound ribavirin?

Fisher's brought in two attorneys—a patent lawyer and a corporate specialist. "We weren't willing to break the law or violate our ethics," Kerrish says. "And if we'd violated Schering's patent, they would have squashed us like a bug."

Once Fisher's found that it was legal for them to compound the drug—and the FDA had inspected their compounding facility—they started filling prescriptions. The pharmacy is still one of Pittsburgh's largest sellers of Rebetron, but now you can also get just plain ribavirin from Fisher's, either in person or by mail order for $225 a month. Even when adding Schering's $450 monthly price of interferon, the combo is still $925 cheaper than Rebetron.

The term *compounding* brings to mind an old-time pharmacist grinding away with a mortar and pestle, but these days the operation is high-tech. Fisher's uses a "clean area" with a biological safety cabinet to prepare the ribavirin capsules from raw powder. The cabinet has negative airflow and a special filter to protect the pharmacist from stray powder. A hand-cranked machine presses the powder into capsules, and then the pharmacist weighs them on an analytical balance to ensure that the dose is correct.

When news that Fisher's was compounding the drug hit the press, Schering tried unsuccessfully to get the FDA to cite them for illegal manufacturing. "We're not saying Fisher's shouldn't compound ribavirin," says Robert Consalvo, media-relations manager for Schering-Plough. "We're concerned that they not be allowed to circum-vent the regulations and patent laws to manufacture and sell a competing product at a lower price."

Insurers, however, reacted positively to the news. In an unusual development, Fisher's is now being contacted by eye-on-the-bottom-line HMOs seeking to cover the product.

Activists applaud Fisher's efforts to help its customers. And the Hepatitis C Action and Advocacy Coalition (HAAC) is concerned by more than just the high price of Schering's product. They fear that if Schering's bundling is not reversed, it will set a dangerous precedent for future single-company drug combinations. Indeed, at press time, Bristol-Myers Squibb was seeking FDA approval for a bundled combo of two new chemo drugs for cancer.

For more than a year, HAAC has mounted a campaign, including letters, press conferences and meetings with Schering, to seek the unbundling of the drugs—all to no avail. Recently the patient group organized a briefing for congressional reps and FDA regulators. Meanwhile, says HAAC's James Learned, activists hope that growing sales of the compounded product may drain sufficient sales from Schering's $1 billion annual Rebetron market to make the corporate giant rethink its marketing mode. "Compounding alone is nowhere near the answer," Learned admits. "It doesn't solve the access and pricing issues for everyone. But it does keep the pressure on Schering."

He adds, "It's always tricky when you push for access to a drug because it seems like you are pushing that drug. Ribavirin is not the safest, most fabulous treatment for hepatitis C [see Second Opinion, at right]. It will be great when no one has to deal with any of the current drugs, but the ones in the pipeline are at least three to five years away." Until then, people with hep C at least

have an affordable treatment option, thanks to that bizarre alignment of HAAC, HMOs, the FDA and the little pharmacy that could.

Fisher's Specialized Pharmacy can be reached at 888.347.3416, www.spsdrug.com; PWA Health Group, at 212.255.0520, www.aidsinfonyc.org/pwahg/index.html (website includes fact sheets on ribavirin and alpha interferon); and Hepatitis C Action and Advocacy Coalition by email at haac_sf@hotmail.com (San Francisco) or James_Learned@prodigy.net (New York).

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.poz.com/article/Compound-Interest-12241-6500