

In Boom for Home Drug Tests, One Runs Afoul of Government

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Back in May, radio psychotherapist Dr. Laura Schlesinger started steering troubled parent-callers toward a little-known line of instant drug and alcohol tests called First Check. By June, First Check was a paying advertiser, running a 60-second spot in which a pharmacist recommended the do-it-yourself kits "when the need to know ... is now."

"Every time that 60-second spot runs, every [phone] line we have lights up for 15 minutes," says H. Thad Morris, president of Worldwide Medical Corp., First Check's Irvine, Calif., manufacturer. "It shows us how concerned parents are."

The U.S. Food and Drug Administration is concerned, too, and last month asked Worldwide Medical to pull the ads from radio, print and television. The First Check drug test isn't approved for consumer use, and Worldwide Medical is selling it illegally, the FDA says. The agency sent the company a letter informing it of "serious regulatory problems" with the First Check drug test that could result in a seizure of inventory, monetary penalties or a court injunction against selling the product.

Worldwide Medical is fighting back, challenging the FDA's authority to regulate a product that is proving to be astonishingly

popular. In the 18 months since introducing the at-home drug kits, Mr. Morris says, Worldwide Medical has sold one million of them. Since its December 1997, introduction, the product has helped fuel a more than sixfold increase in the company's revenue, to \$6.5 million from \$1 million, Mr. Morris says.

First Check is convenient and fast, qualities that make it both popular with parents and controversial with regulators. Parents need just three drops of their child's urine to test for the presence of marijuana, cocaine, heroin and methamphetamines. They get results, on small plastic panels, in less than 10 minutes: Red lines indicate a negative result, and no lines means a positive. Other tests, by contrast, require a wait of days or weeks for results from an outside laboratory.

Since June, [Kmart](#) Corp. has been selling First Check tests, which range in price from \$9.99 for the marijuana kit to \$24.99 for marijuana, cocaine, methamphetamines and heroin. Spokeswoman Mary Lorencz says sales are strong. "Until there's some ruling that it can no longer be sold, we'll continue to carry it," she says.

According to FDA regulations, any at-home drug test that gives immediate results is a medical device and requires clearance, just as other devices do. The agency says Worldwide Medical hasn't adequately tested the First Check kit in home conditions.

Worldwide Medical takes the position that its kits provide only "preliminary" results and that the FDA has already approved the technology, the "underlying panels."

Rivals in the fast-growing market for at-home drug tests complain Worldwide Medical has grabbed an unfair advantage by skirting the FDA's costly premarket approval process. "We'd love to do what they're doing, but we're following the FDA's rules," says Bruce Christie, chief executive of Drug Detection Devices Ltd., a

closely held Georgia distributor of the At Home Drug Test, made by Phamatech Inc., of San Diego.

Phamatech's test is one of just a few consumer drug tests approved by the FDA for home use. It indicates whether any of five drugs is present in a urine sample: If some lines are missing from a dip stick, that indicates the presence of a drug. Consumers must send the sample to a lab and, within three to seven business days, obtain specific results by calling a confidential, toll-free number. It costs \$29.95.

The FDA approved Phamatech's home test in October, and Phamatech says its sales are approaching 100,000 units. "If [the FDA doesn't] discipline people like Worldwide Medical, I don't know why the rest of us should toe the line," Mr. Christie says.

When instant-drug-test kits were introduced about 10 years ago, they raised eyebrows, mainly for privacy reasons. Some critics say because they don't involve a medical professional or counselor, they can be dangerous: Parents are usually emotionally distraught when they get the test results. "I fear the average parent won't know how to react to the information," says Peter Newland, director of the adolescent division for Phoenix House, a New York drug-treatment group.

Still, the tests are proving to be popular with parents of teens. Last year, Gladys Erwin, an Aliso Viejo, Calif., mother, asked her 14-year-old son to take a First Check drug test one night, after he stumbled in late with bloodshot eyes. The results were positive. During months of out-patient counseling and stays in the hospital, Ms. Erwin says, she continued to spot-check him with First Check tests, following up with more-expensive lab testing whenever results were positive. At various points, he tested positive for cocaine, methamphetamines and marijuana. Now the boy, at 15, is being treated at a long-term-treatment facility out of state.

'Essential Tool'

Ms. Erwin says the First Check tests were an "essential tool" on the road to treatment for her son. "You can't run to a lab at one in the morning," she says.

The FDA has approved hundreds of instant drug tests for use by teachers, police officers, counselors and other professionals. But FDA regulations forbid companies to market the same technology to consumers without further review, spokeswoman Sharon Snider says.

The FDA makes an important distinction between "collection" kits, in which parents send a hair or urine sample to a lab for processing and learn the result by phone, and "screening" kits, which give an instant reading. Collection kits are exempt from premarket testing, meaning companies are free to market them to consumers; screening tests aren't.

Worldwide Medical's attorney, Larry Pilot, says the First Check kit doesn't offer a precise diagnosis and therefore shouldn't be classified as a medical device. He also argues that the "underlying technology" -- the white panels -- has already been approved by the FDA.

Steven Gutman, director of the FDA's division of clinical laboratory devices, says Worldwide Medical has been "disingenuous" in its dealings with the FDA and on its product labeling. He says the label doesn't include enough information about false positive readings and what steps parents should take in the event of a positive result.

Mr. Morris says the First Check theory is simple: "By the time you mail a sample to a lab, your child could be dead," he says. "You

need to make decisions right now... . We get hundreds of requests for our product each week -- and hundreds of calls saying thank you."

In 1998, 54% of high-school seniors reported having taken an illegal drug at least once, according to an annual study conducted by the University of Michigan. The recent rise in drug abuse, especially of heroin, among affluent white teens has sent the at-home-test market soaring.

David Moore, a Lake Forest, Calif., single father, says both his teenage children took the First Check test at his request. His 17-year-old son was indignant, Mr. Moore says, but the results were negative. Now, he says, they talk freely about drugs. "I am an old-school parent. I believe you have to question your kids," Mr. Moore says. He keeps two of the kits on his kitchen counter all the time, he says. "This test really works as a deterrent against drug use."