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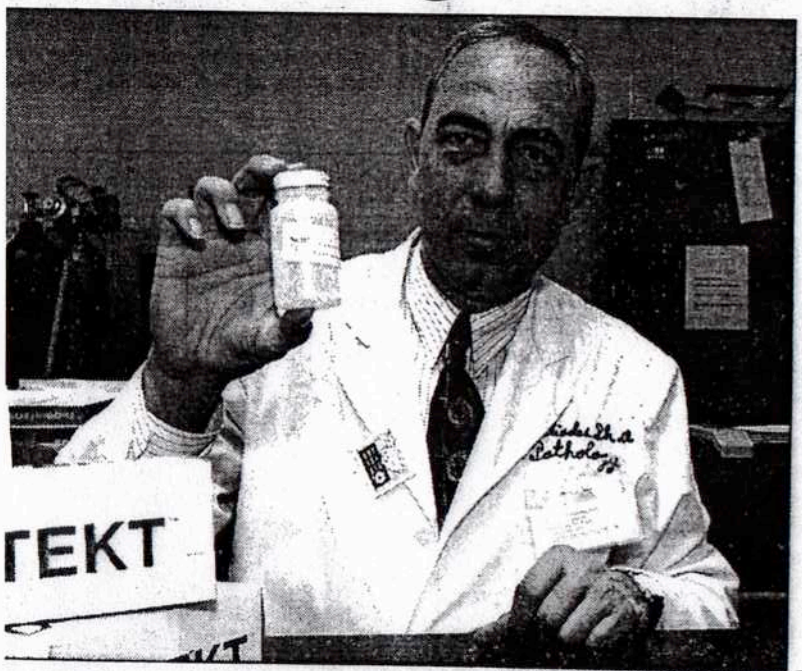
Home Drug Test Kit OK a Decade Late for Omahan



JEFF BEIERMANN / THE WORLD-HERALD

RUG TEST KIT: John Vasiliades, director of Toxicology Labs, with D-Tekt, the me drug testing kit marketed by his company.

BY JOHN TAYLOR
WORLD-HERALD STAFF WRITER

The recent announcement by the Food and Drug Administration that it had approved the first home drug test that doesn't require a prescription had an Omaha toxicologist shaking his head.

To John Vasiliades, director of Toxicology Labs Inc., 7701 Pacific St., the details of the successful company's test kit sounded familiar.

The reason, as it turned out, was that it was similar to the home test kit that Vasiliades had tried unsuccessfully to market 10 years ago.

And the reason he couldn't market it was that the FDA wouldn't permit it, he said in an interview.

The FDA's announcement last month represents a reversal of the policies that blocked Vasiliades' kit, called D-Tekt, as well as others, from being sold. With the relaxation of regulations, Vasiliades said he plans to resume marketing his kit — 10 years late.

On Jan. 22, the FDA said that a Silver Spring, Md., company could begin selling a home drug testing kit — Dr. Brown's Home Drug Testing System.

The kit is simple. It consists of a kit for urine collection — a paper cup for collection and two plastic tubes with screw-on lids into which the urine is poured for storage and shipping.

The tubes are placed in a plastic pouch, which is inserted into a bubble bag for shipment to a laboratory. The kits have an identification number which is placed on the urine specimen.

To find out results, people have to call a toll-free number and identify themselves by the identification number.

The FDA's reversal of its policy came four months after it had blocked the marketing of a similar test kit by a Georgia company — much as the agency had halted the Omaha company in 1987. After some members of Congress protested, the FDA said it would allow the kits to be sold as it developed a new policy.

Vasiliades said the FDA's action amounts to "an Omaha idea resurrected 10 years later."

When he tried to market his kit, the FDA told him it fell under the same regulations as kits for home pregnancy tests.

Because the FDA called the relatively simple kit a medical device, he said, the agency said he would have to do a feasibility study.

"We pulled it (off the market)," he said. "As a small business we just couldn't afford it."

Vasiliades said he has written the FDA, telling the agency that he wants to register as a vendor to market the device. For Vasiliades, some of the paper work has been completed and it's just a matter of the FDA's updating documents.

While the FDA is writing new regulations, an interim policy is in effect that permits companies like the Omahan's to market the kits without FDA clearance.

Vasiliades said his laboratory has been certified by the required federal agencies.

"The way I look at it," he said, "is that I'm in the business now. I'm doing drug testing right now — for companies, [illegible] doctors, lawyers."