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## **Did Doctor Test Medicine On Unsuspecting Patients?**

***By Stephen Dean***

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**CUERO, Texas --** The Food and Drug Administration has launched an investigation into a mysterious medicine that was tested on patients in several small towns southwest of Houston, Local 2 Investigates reported Thursday.

The federal investigation centers around a complaint filed by a nurse anesthetist who reported that he witnessed the unapproved drug being given to patients without their knowledge or consent.

With a hidden camera, Local 2 Investigates found the drug stocked in the pharmacy at Cuero Community Hospital, the only hospital in a small Dewitt County town. The pharmacist quickly jerked the medicine away, apparently thinking a KPRC undercover reporter was actually a potential patient getting too close a look at the medicine container.

The drug is called Providex. It has also been marketed and sold under the names "Sore Relief" and "Durable Closure."

The former nurse who reported the testing on humans, Timothy Goosby, said, "If people in that town knew that if they received that medication, that they were being tested on, that they were becoming -- as you say -- guinea pigs -- I think you might find a great public outcry."

Goosby first complained to the Cuero Community Hospital CEO. He then filed complaints with the FDA, the FBI, several state legislators and state regulatory boards.

In some cases, Goosby reported he was present as the medicine was rubbed on cuts and sores of patients at Cuero Community Hospital. In one case, he said the medicine was actually injected into the abdomen of a patient who had just undergone intestinal surgery.

"When I saw him inject it into the patient's abdomen, I was absolutely appalled," Goosby said.

He reported to the FDA that several of his colleagues were concerned about the fact that patients had no idea that an experimental, unapproved drug was being tested on them. His complaint likened it to the infamous Tuskegee Study of the 1930s, when the government experimented with a new syphilis medicine on hundreds of black men without telling them. In the Texas case, he said the only difference is a physician who stands to profit. "He had a great financial involvement. I don't think the Tuskegee people had financial gain," Goosby said.

The CEO of Cuero Community Hospital when "Providex" first arrived, Jim Buckner, admitted he purchased the drug and stocked the hospital's pharmacy for use on patients, having no idea what was in the drug. "The product was touted to us as having been done and researched," said Buckner, who is now CEO of a different Texas hospital. Buckner had access to all patient files when he was alerted to the testing and he told KPRC Local 2 Investigates, "If there was ever a written consent given to a patient to accept the use of this drug, I am completely unaware. I don't think we did at our hospital."

"No consents," said Goosby, who said he was forced out of the hospital for reporting the testing. He said patients were misled into believing they were receiving their usual medicine.

"It was just, 'Hello Mrs. so and so. I have your medication for you,' he said. "That's the way it was being handled, that this is kind of standard protocol, this is one of the medications we use daily."

Barbershop owner Pat Flores lives near the Cuero Community Hospital and he reacted, "I don't think it's right. It's very wrong, because no telling what the consequences to those people or the side effects."

The former CEO said he bought the drugs for his hospital pharmacy in Cuero after hearing a sales pitch from one of his "influential physicians." Dr. Daniel Dugi referred to himself as the drug company's "principal investigator," a point emphasized in an elaborate sales packet that Dugi provided to Local 2 Investigates. Former CEO Buckner said, "When I asked him what was in this product as the active ingredient, he wouldn't disclose it, (saying) 'It's still patent pending, waiting for FDA approval,' and they couldn't share that information with us."

In the promotional literature provided to Local 2 Investigates, Dugi wrote that he had treated "well over 1000 patients" and he reported "a superior success rate" in over 90 percent of the patients he treated. The sales pamphlet then contains 18 separate entries marked "Case Summary," spelling out how the drug performed when applied to those patients' wounds. Some of the documents are marked, "Confidential," but Dugi admitted to KPRC Local 2 that they were all his patients. Photographs and graphs illustrate the healing of the various wounds.

When KPRC Local 2 Investigates approached Dugi for answers, he invited the camera crew into a back room at one of his clinics, but he said very little. "No filming! No filming!" Dugi said. He insisted that the medicine manufacturer would not allow him to answer questions. When asked why a drug company should dictate his silence when talking about his own care to patients, Dr. Dugi said, "my care meets very, very good standards."

"I had informed consent from everybody that we used the product on," Dugi said when asked about whether patients knew they were subjects in a test. He declined to answer when he was asked whether FDA knew he was testing the drug on patients. "You're barking up the wrong tree," he said. "This is an FDA registered product."

However, the Food and Drug Administration told Local 2 Investigates it has never heard of the drug and no human testing was ever approved. FDA spokeswoman Rita Chapelle said, "We don't comment on pending investigations."

The drug container photographed by hidden camera, along with the promotional packet for the drug, both list a National Drug Control number, or NDC number. The promotional material has "FDA Registered" typed next to the NDC number. However, when Local 2 Investigates entered that number, the drug name and the drug's ingredients into the FDA national database of approved drugs, there were no matches.

Chapelle said by telephone that she checked with several different divisions within the FDA and she found that the number did not exist.

Buckner said, "Nobody really wanted to do much about trying to stop him because he was a very influential physician on our staff." Buckner said he left that position, partly because of the dispute over this drug.

The pharmacist in charge when the drug was first added to the "formulary," or list of medicines being dispensed to patients by the hospital, has now been elevated to CEO of Cuero Community Hospital. Darryl Stefka, Cuero Community Hospital's current CEO declined to answer questions on camera, but he insisted the drug's use was "very legitimate." When asked whether it was tested on patients without their knowledge, he answered, "I'm sure they knew." He was asked why the hospital would stock a drug that is not approved by the FDA, but he did not answer. He said the medicine was not used as part of a trial.

Federal law requires specific, written consent forms for any trial of a new medicine on human subjects. The doctor declined to provide verifiable proof that any such forms existed.

# Drug Company Defends Product Under FDA Investigation

*By Stephen Dean*

POSTED: 8:13 pm CST February 1, 2008

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**HOUSTON** -- The president of a Texas drug firm defended his products Friday after Local 2 Investigates reported they were being tested on patients without Food and Drug Administration approval. The FDA said it had no records on file for the drug "Providex," which Local 2 Investigates found being used on patients throughout south Texas as part of a study.

Cuero Community Hospital physician Dr. Daniel Dugi refers to himself as the drug's "primary investigator" and a sales packet for the drug displays photos of patients that Dr. Dugi admits are his. The sales literature includes a letter from Dr. Dugi touting the "superior success" of the drug. It also includes graphs and measurements of wounds that were treated with the unapproved medicine.

The medicine "Providex" has also been marketed and sold under the names "Durable Closure" and "Sore Relief." Dr. Dugi would not answer questions about his testing or whether he had written consent from each patient as required by federal law for drug testing on humans. "You're wasting my patients' time. You're wasting my time," he said to a reporter. "We're not filming. I told you, no filming," he told the camera crew after inviting the investigative team into one of his clinics in the town of Kenedy, Texas.

The law is clear on drug trials, according to the FDA and experts who operate within those laws every day. Dr. Maurie Markman is Vice President of Research for the world-renowned M. D. Anderson Cancer Center in Houston and said written consent for any new trial is required to include specific information and language. "You have to get that permission," Dr. Markman said. "And that's the way we have to act so that we do always treat people as individual entities with absolute rights as it relates to their body." Markman and other physicians who have participated in authorized clinical trials said any substance that is aimed at treating or curing an actual affliction is defined as a medicine that requires FDA approval for testing and use.

The unauthorized testing caught one patient of Dr. Dugi by surprise. Rudy Cruz found out about the FDA investigation as he was being treated in Dr. Dugi's Kenedy clinic. "It would bother me a lot," he said. "I mean, nobody wants nothing done without your approval, or knowing if it works or doesn't work."

The Texas Medical Board, which investigates physicians, admits it received a complaint about the illegal testing allegations last year. The state agency's enforcement director Mari Robinson said she was **unable to investigate because patient names were not included in that complaint**. Without those names, she said, "We don't have any legal way to get that information. I mean, we really don't." She said that any use of a drug without patient consent would be a violation for which a physician could be punished.

Dr. Dugi said he had "informed consent" from each patient who received the drug, but he offered no proof that any written permission paperwork was ever signed.

KPRC Local 2 Investigates checked further into the claims being made by Dr. Dugi and the drug's manufacturer, The Activ Group of Southlake, Texas. On the company's Web site, some of the products were listed for sale for \$210 for jars of the medicine, which is described as a tissue regeneration product for wounds and sores.

The active ingredient on the Web site and on the jar that was photographed with a Local 2 Investigates hidden camera both list the active ingredient as "Benzethonium Chloride." Not only was the substance not listed in FDA's database of approved drug ingredients, Local 2 Investigates checked with numerous doctors and pharmacists and none had ever heard of the ingredient. The FDA database also showed no listing for The Activ Group or any of its drug names. It also did not include a National Drug Control number, an FDA serial number for approved drugs, which appeared in the sales literature and on the medicine bottle.

Ron Gourley, president of the Activ Group, declined to answer any questions on camera, but he sent several e-mails to Local 2 Investigates to defend his product. He wrote, "There is no new drug. There is a Product which makes nutrients available to damaged tissue to help the body promote healing." He asserted in his e-mail that since FDA had previously approved each ingredient individually, that meant the product itself is "FDA registered."

Gourley's e-mail said, "The Activ Group, Inc. manufactures and distributes its products under the strict guidelines set forth by the FDA under the Over The Counter Monographs and the Cosmetics Act."

The e-mail stated there were "questionable motives" involved with the former Cuero Community Hospital CEO who described getting a hard sales pitch on this drug before he bought it for distribution for patients. The e-mail also questioned the motives of the nurse anesthetist who filed complaints with the Texas Medical Board, the FDA, the FBI, the Texas Board of Pharmacy and several state legislators.

That nurse, Timothy Goosby, is now licensed to practice in Minnesota. He said he surrendered his Texas nursing license and was forced out of his job at Cuero Community Hospital in retaliation for reporting the drug testing. He surrendered his license for failing to disclose two drunk driving arrests when he applied for his Texas license. He told Local 2 Investigates the infraction was only discovered when the people involved in the drug testing started filing several accusations against him in response to his being a "snitch."

Other e-mails to KPRC Local 2 Investigates from the Activ Group president stated the company is "dedicated to cost effective solutions to a growing medical problem." A third e-mail also said the company does possess "registration forms" proving it was "registered with the FDA."

Local 2 Investigates posted the complete text of all three e-mails sent by the company below.

The sales packet for the drugs also included numerous claims about success of the drug with highly regarded institutions such as UTMB in Galveston or the Baylor College of Medicine. Local 2 Investigates contacted each of those entities and every physician listed by name, but the claims could not be verified.

**Complete Response From Drug Company:**

- [E-Mail 1](#)
- [E-Mail 2](#)
- [E-Mail 3](#)

# New Laws Proposed After Illegal Drug-Testing Claims

*By Stephen Dean*

POSTED: 12:24 pm CST February 8, 2008

UPDATED: 10:24 am CST February 9, 2008

**CUERO, Texas** -- The elected hospital board over Cuero Community Hospital has voted to launch an internal investigation into claims of illegal drug testing, Local 2 Investigates reported Friday. An Austin law firm was hired by the board in an emergency meeting this week to handle the inquiry. The U.S. Attorney's office for the Southern District of Texas issued a subpoena to gather information on the case, but federal prosecutors would not discuss their investigation.

Hospital board chairman Richard Weber told Local 2 Investigates, "I do not suspect any wrongdoing by the hospital or our staff." He said no personnel had been suspended or instructed to change any treatments.

Local 2 Investigates reported last week that a drug known as "Providex" or "Durable Closure" was being stocked in the pharmacy for patients at Cuero Community Hospital. The drug and its accompanying sales literature, stated the drug was "FDA Registered" but an FDA spokeswoman said her agency had never heard of the drug and had never approved testing on humans. The drug maker displays a special serial number assigned by the FDA for all approved drugs, and yet the FDA spokeswoman told KPRC Local 2 that the number does not actually exist.

In complaints to the Food & Drug Administration, the FBI, the Texas Medical Board and the Texas Board of Pharmacy, former Cuero Hospital nurse anesthetist Timothy Goosby said he witnessed the drug being tested on patients without their knowledge or consent.

The hospital's former CEO Jim Buckner said an influential doctor at Cuero's Hospital was keeping extensive records on how the drug performed on each patient. He said it seemed like a conflict of interest, but he was unaware of any patients being harmed.

The physician, Dr. Daniel Dugi, declined to answer questions about his use of the drug, but he insisted all patients had consented. In promotional material for the drug, Dr. Dugi bragged of positive results after trying the drug on more than 1,000 patients.

State Rep. Garnet Coleman, a Houston Democrat who is ranking member of a House Health Committee with oversight over hospitals, is proposing two pieces of legislation in response to the Local 2 Investigates reporting. "Individuals who do not have FDA approval for a drug trial, or using a drug on an individual, can be arrested," he said. "It would be a criminal offense for doing so."

He also plans to introduce a bill that would better protect whistle-blowers at hospitals. The nurse who reported the drug testing allegations said he lost his career for exposing the wrongdoing. He forfeited his license to practice in Texas for failing to report a drunk driving arrest -- a misstep that he said was only discovered as hospital leaders retaliated against him for filing complaints.

Coleman said, "You can provide whistleblower protection for any employee that is in a medical situation that reports fraud so they will not be fired." He said a similar bill failed in the last legislative session, but this case could show his fellow lawmakers that this law is needed.

On another front, the same law firm that was retained by the hospital board to investigate the matter has sent a letter to Local 2 saying the drug was never used on patients as a trial at the hospital. The letter said "Providex" was no more a mystery drug than aspirin, as FDA over-the-counter regulations allowed it to be used on patients.

The FDA said it cannot comment on the status of its investigation into the matter.

# Drug Removed From Market After Local 2 Investigates Report

*By Stephen Dean*

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UPDATED: 8:10 am CST February 21, 2008

**HOUSTON** -- Drugs have been removed from the market nationwide as part of Food and Drug Administration action that was prompted by a series of Local 2 Investigates reports on human drug testing.

The Activ Group's Web site had offered its drugs, "Durable Closure" or "Providex," for sale on its Web site, which proclaimed, "some 'Rules were meant to be broken' and that's just what we did." Local 2 Investigates found those drugs being stocked in the Cuero Community Hospital pharmacy, just northwest of Victoria, Texas, as a former nurse reported to the FDA and other agencies that the unapproved drugs were being tested on unsuspecting patients throughout south Texas.

The FDA told Local 2 Investigates it had never heard of the drugs and had never approved any testing on humans. The FDA and other federal officials now report the drug maker agreed to pull it from the market as part of the growing federal investigation.

Former Cuero Community Hospital Chief Executive Officer Jim Buckner said he is unaware of any patient being harmed, but he had concerns about the testing years ago when he was at the helm of the publicly funded hospital. "It's not that we shouldn't do testing on human subjects," he said. "It should be done according to proper technique and subject to academic review."

Buckner said he never saw any written consent forms that are required by the FDA. The drugs were administered by a Cuero Hospital physician, Dr. Daniel Dugi, who referred to himself as the "principal investigator" for the drug company. He admitted that he was an investor in the company.

"He was keeping data and research at his clinic," said Buckner. "I know he used it on patients at our hospital on a regular basis."

Attorneys for the drug company and the taxpayer-funded Cuero Hospital Board insist no testing was conducted on patients, but Dugi listed a "case summary" along with photographs of some of his patients in the drug company's marketing brochure that he provided to Local 2 Investigates. He wrote about "superior success" with "over 1,000 patients."

In an earlier broadcast, Dugi declined to answer questions about his use of the drug, saying, "It's FDA registered, which is what has to be done." Federal officials said the drug was removed from the company's Web site and the Cuero Hospital's pharmacy, but hospital board members did not return calls for comment about that move.

The drugs in question were sold with the words "FDA Registered" and listing an NDC number, which is a serial number the FDA issues to all drugs that are approved. FDA officials told Local 2 Investigates they had never heard of the drugs and the NDC number was not on file in the FDA's registry of all NDC numbers.

CRNA (nurse anesthetist) Timothy Goosby reported to the FDA, the FBI and the Texas Medical Board that he witnessed the unapproved drug being tested on patients' wounds and sores without their knowledge or permission when he was employed at Cuero Hospital.

Lawyers for the drug company insist the firm followed all FDA rules and they did nothing wrong. The company claimed it has documents to prove it, but when Local 2 Investigates asked to review copies of those documents, the company did not reply.

The FDA declined to comment on the status of its investigation, and the U.S. Attorney's Office for the Southern District of Texas declined to comment after issuing a subpoena to gather evidence as part of a criminal investigation.

## Previous Stories:

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- February 1, 2008: [Drug Company Defends Product Under FDA Investigation](#)
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