Botulism Disaster Uncovers Fake Botox Market

BY BETSY BATES
Los Angeles Bureau

Dermatologists are among the physicians cited by name in federal court documents exposing an underground network to distribute cut-rate botulinum toxin type A to physicians suspected of using it on patients who may have assumed it was Botox.

Four doctors, including the director of oculofacial plastic surgery at University of Kentucky, have been indicted on federal conspiracy charges involving mail and wire fraud and misbranding a drug in connection with what the federal government is calling "a scheme to distribute fake Botox for use on humans."

At least 10 Florida physicians, including several dermatologists, have also had their licenses suspended or restricted because they purchased the unapproved drug, said Lindsay Hodges, a spokeswoman for the Florida Department of Health.

The network was discovered after four South Florida residents were hospitalized in critical condition with botulism, having received catastrophic amounts of improperly diluted raw botulinum toxin purchased from a California laboratory.

The same laboratory also supplied a Tucson, Ariz., company, Toxin Research International (TRI), with 3,081 vials containing botulinum toxin type A, "in a formulation designed to imitate Allergan's Botox" Cosmetic, according to an indictment issued by the U.S. Attorney's Office in the Southern District of Florida.

Botox is the only botulinum toxin type A approved for use in humans in the United States. At least 219 physicians and other health professionals purchased $1.5 million worth of the knockoff botulinum product at about half the price of Botox from TRI, after attending a weekend workshop or being sent promotional postcards or faxes advertising "A Very Stable Clostridium Botulinum Toxin Type A."

In very small print, the $1,250 vials containing 500 IU of toxin noted, "For Research Purposes Only Not for Human Use," according to federal documents.

Assistant U.S. Attorney Carlos B. Castillo said in an interview that physicians who ordered the fake Botox are being investigated by the Centers for Disease Control and Prevention and the Office of Criminal Investigations of the Food and Drug Administration in conjunction with numerous state medical boards.

"This deadly toxin packaged in harmless looking vials, wrapped in the guise of medicine, and used on unsuspecting members of our community, represents a grave threat," said Marcos Daniel Jimenez, U.S. Attorney for the Southern District of Florida in a statement.

A preliminary injunction halted further distribution of the mock Botox in January 2005.

The scandal came to light in late November 2004, when Bach McComb, a 47-year-old Florida osteopath with a suspended medical license, injected himself and three others with improperly diluted amounts of raw toxin obtained directly from List Biological Laboratories, a Northern California research laboratory.

Federal investigators believe the vial contained 20,000 units of botulinum toxin; however, a spokesperson for Allergan said the company's scientists have calculated that the vial may have contained up to 10 million units of botulinum toxin. It is unclear whether Dr. McComb used saline to dilute the product, and if so, by how much.

He and his three patients were hospitalized on ventilators with botulinum poisoning and, months later, are in various stages of recovery. Dr. McComb's girlfriend, Alma "A.J." Hall, remains hospitalized in New Jersey; a Palm Beach County, Fla., couple, Bonnie and Eric Kaplan, are recovering at home, having spent months in the hospital and a rehabilitation center.

Dr. McComb had to use a walker during his arraignment in federal court in Fort Lauderdale in late February 2005, according to the Palm Beach Post.

Also indicted in the case were Chad Livdahl, N.D., and Zarah Karim, N.D., of TRI, and Robert Baker, M.D., professor of ophthalmology, neurology, and pediatrics at the University of Kentucky in Lexington.

The Tucson naturopaths are accused of purchasing thousands of vials of botulinum toxin that were intended for research and then marketing them to physicians, presumably for human use in spite of labeling noting they were research products.

A fax found during a search of TRI headquarters explained to one customer that she could not receive a refund for the botulinum toxin A she returned to the company after she discovered the notation on the vials stating it was not meant for human use. "We must state that for legal purposes to protect ourselves," the fax said. "Our product is simply Botulinum Toxin Type A, which is exactly the same as any Botulinum Toxin Type A that you used in the past."

Federal prosecutors say Dr. Baker promoted and demonstrated the product to physicians at a 2-day workshop in Scottsdale, Ariz., in July 2003. A testimonial letter distributed to physicians bears his name; however, his attorney has told reporters the case is one of identity theft.

A December 2004 affidavit from a special agent for the FDA's Office of Criminal Investigations quotes attendees of the workshop as saying that Dr. McComb injected volunteers with hyaluronic acid, whereas Dr. Baker demonstrated botulinum toxin injections using the TRI product.

A nurse who attended was quoted as saying that Dr. Baker made it a point never to use the word "patients," as if he were avoiding it. Instead, he used the words, "When you inject your specimens."

The affidavit included comments from many physicians who attended the workshop, bought the product, or both.

In Florida, dermatologists, plastic surgeons, family physicians, and a pathologist who performs cosmetic procedures are being investigated by state medical board authorities for allegedly purchasing unapproved product and using it on their patients. ■

To read the complaint filed in U.S. District Court, Southern District of Florida, visit www.usdoj.gov/usao/fls. Use search word Botox.

'Fake Botox' Timeline

2003

Early 2003: Dr. Livdahl and Dr. Karim order 3,081 vials of full-strength, raw botulinum toxin from a California laboratory.

April 14, 2003: Dr. McComb's medical license is suspended in Florida for reasons relating to the prescribing of narcotics.

May 2003: Dr. Livdahl and Dr. Karim incorporate TRI in Tucson.

July 19-20, 2003: Health professionals attend TRI-sponsored workshop where botulinum toxin type A is promoted and allegedly demonstrated.

2004

October 2004: Cosmetic surgeon in Tennessee notifies FDA about possible fraudulent TRI business scheme to market a Botox-like product; FDA investigation begins.

Nov. 26, 2004: Dr. McComb injects himself and three others with raw botulinum toxin from the same lab. All are hospitalized on ventilators within days.

Dec. 4, 2004: Federal agents search TRI offices in Tucson, finding marketing materials and 134 vials of botulinum toxin.

Dec. 15, 2004: Federal agents begin contacting physicians listed in TRI files.

2005

Feb. 3, 2005: Federal grand jury in Florida indicts Dr. McComb, Dr. Livdahl, and Dr. Karim. All later plead not guilty and Dr. McComb is freed on bond.

Feb. 24, 2005: Federal magistrate in Florida denies bond to Dr. Livdahl and Dr. Karim.

March 22, 2005: Dr. Baker is indicted.

March 29, 2005: Dr. Baker pleads not guilty and is released on bond.

Sources: Media reports and documents from U.S. District Court, Southern District of Florida

Unauthorized Cosmetic Products a Legal Landmine

BY BETSY BATES
Los Angeles Bureau

WAILEA, HAWAII — Leaders in cosmetic dermatology at the annual Hawaii dermatology seminar offered words of caution about the use of unapproved products and cut-rate versions of Food and Drug Administration–approved materials and medications.

"Beware," warned David J. Goldberg, M.D., J.D., a dermatologist with a specialty practice in New York and New Jersey. A recent scandal in Florida involving the paralysis of four patients with an improperly diluted, unapproved formulation of botulinum toxin type A led to a federal investigation of a network distributing what authorities called "fake Botox" to physicians across the country. (See story on this page.)

Physicians face possible suspension of their licenses following injection of patients with the unapproved toxin, and the repercussions aren't likely to stop there, speakers said at the meeting.

Michael H. Gold, M.D., a dermatologist in a specialty practice in Nashville, Tenn., noted that unapproved products can be "easily obtained" in Canada and elsewhere. "Be careful about where you get your products and how you do it," he warned his colleagues at the seminar, sponsored by the Skin Disease Education Foundation (SDEF). "Just be reminded that if something goes wrong, you have no leg to stand on."

Because of recent cases, "the FDA and, more frighteningly, the FBI are considerably more aware of the dangers that can occur to the American people as a result of illegal importation [or use] of material," noted Alastair Carruthers, M.D., who is credited along with his wife, Jean Carruthers, M.D., with pioneering the cosmetic use of Botox.

Dr. Carruthers, who disclosed financial ties to Allergan Inc., the manufacturer of Botox, said in a later interview that he thinks many physicians may be taking undue risks. "We've lost sight as a group that these regulatory processes are there for a purpose," said the Vancouver, B.C.–based dermatologic surgeon.

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