

Family Indicted for Fountain of Youth Fraud

by Marian Segal

A randomly detained shipment of drugs from England, mislabeled as curtain rods, sparked a two-year joint investigation by FDA and the U.S. Customs Service that led to a major federal indictment exposing an international black market in illegal “Fountain of Youth” drugs.

A federal grand jury in San Diego last March 16 returned a 198-count indictment charging five individuals and five corporations with smuggling and distributing more than 15 tons of unapproved anti-aging drugs worth more than \$5 million.

The indictment charges David Halpern, 38, of Pebble Beach, Calif., with heading an operation that used sham companies and mail drops registered in fictitious names to illegally import and distribute these products, promoting them to treat a variety of medical conditions often associated with aging. The “Fountain of Youth” products included three classes of drugs:

Procaine hydrochloride derivatives (sold under various names, including Gerovital H3, GH 3, KH 3, and Zell H3). Touted as the most popular rejuvenation product in the world, procaine hydrochloride's only approved medical use in the United States is as a local anesthetic. Halpern allegedly promoted the products, available as tablets, capsules and injectables, to improve the physical or mental status of elderly patients, and to treat serious conditions such as Parkinson's disease, hypertension, neuritis, and arteriosclerosis. Procaine hydrochloride can cause allergic reactions, including potentially fatal anaphylactic shock.

Zumba Forte. According to its promotional literature, the main ingredient in Zumba Forte tablets is related to vegetable substances discovered by primitive native inhabitants of tropical jungles and reportedly used by them to preserve and enhance male potency. The drug is billed as a “sexual tonic” and sold primarily as an aphrodisiac for men. Zumba Forte contains the unapproved substance yohimbe and the controlled substance methyltestosterone. Yohimbe, derived from the bark of the West African yohimbe tree, acts as an adrenergic receptor blocking agent and can cause serious problems in people with kidney disease. It also causes dangerously low blood pressure. Methyltestosterone, a chemical derivative of the male sex hormone testosterone, can cause liver cancer, hepatitis, jaundice, testicular atrophy, prostate cancer, and edema. Both substances are particularly risky for the elderly.

Cellular Therapy. In cell therapy, ribonucleic acid (RNA) is isolated from the organs and tissues of young sheep or cattle, or the fetuses of these animals. The products were sold mainly

in injectable form and promoted for more than 100 different medical conditions. Originally offered as a rejuvenator that counteracted ailments associated with old age, the product is now promoted for treating such conditions as Graves' disease, hypertension, heart attack, arteriosclerosis, menopause, Down syndrome, colitis, acne, radiation damage, senility, and sterility. The animal tissues used in these products can carry animal viruses and bacteria that can cause brucellosis, Q fever, and possibly a type of cow encephalitis known as "mad cow disease." They can also cause allergic complications, anaphylactic shock, and death.

At a press conference in San Diego announcing the indictment, FDA Commissioner David A. Kessler, M.D., said, "Despite these claims of a miracle panacea, no one has ever submitted to the FDA any well-controlled clinical investigations which demonstrate either the effectiveness or safety of cell therapy for any medical purpose." In fact, none of the products sold by Halpern's organization have been proven safe or effective for the uses promoted.

"The case was set in motion in July 1990," says Dennis Degan, the coordinator of FDA's National Drug Diversion Unit, "when U.S. Customs agents followed the delivery of a package from England that had come to a San Diego mail drop. The package was labeled as containing curtain rods, but in fact, it contained drugs."

Search warrant in hand, federal agents followed the package to the residence of Frances D. Halpern, David Halpern's mother and co-defendant in the case. Drugs and records seized in the search of the residence suggested the detained shipment was only the tip of an iceberg of a large and complex organization involved in international smuggling of "Fountain of Youth" drugs.

With this, the U.S. attorney called on FDA to participate in a joint investigation with Customs. FDA assigned Degan, Jon Hunt from the Division of Field Investigations, and Vincent Iacono, an investigator with the Los Angeles district, to the case. Under the direction of Assistant U.S. Attorney Phillip L.B. Halpern (not related to the defendants), the agencies began pursuing leads stemming from the search. Over the next two years, the agents executed search warrants at numerous mail drops and residences, conducted interviews with customers and employees of the organization in the United States, and analyzed thousands of records.

The path also led overseas, where Degan and Philip Halpern interviewed individuals with knowledge of the illegal activities. The British Customs Service agreed to help obtain evidence and information on the roles of various co-conspirators in England, and the Customs Service in Germany executed search warrants and conducted interviews to obtain evidence against participants in that country.

Copies of all the evidence gathered from England, Germany, and the United States were sent to Degan's Detroit office, where he and his staff organized and analyzed the material to unravel the nature, scope and size of the organization.

“We spent countless hours reviewing the information to organize the case,” says Degan. “We had some 20,000-plus pages of documents we used to create computerized records that defined the roles of the conspirators and crystallized the evidence needed to assemble the case.”

FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research also aided the investigation by examining product labels and providing crucial information on the potential dangers of the products.

According to the indictment, David Halpern set up a number of corporations in England to cover his illegal purchases of procaine hydrochloride and other “Fountain of Youth” products. He then arranged for a British citizen to run the overseas operation. He directed that orders be divided, falsely declared, and sent to mail drops throughout Southern California to avoid detection. Similarly, Halpern arranged with German executive Maximillian Schmidt to use his firm, Zumba GmbH, to illegally ship “Fountain of Youth” drugs from Germany. Both Schmidt and Zumba GmbH are also co-defendants in the case.

The indictment also details how Halpern's mother, his sister, Frances H. Wellgood, and his brother-in-law, Edward Sollisch (also co-defendants), assisted him in collecting more than 13 tons of smuggled drugs at various mail drops throughout Southern California. The co-conspirators had opened these mail drops under fictitious names, such as “Susie Smothers,” “Mary Bell & Associates,” and “Tudor Trading Company.” To further conceal the illegal activity, the drug packages were mislabeled as salt and pepper shakers, glass animals, buttons, plastic screws, guitar picks, Chinese checkers, gift boxes, and other items.

The investigators also learned that Sollisch instructed employees not to worry about FDA notices they occasionally found in the mail drops stating that these were unapproved products that could not legally be imported. (FDA never received responses to notices put in any of the mail drops.)

According to Assistant U.S. Attorney Halpern, the drugs were repackaged and sold to black-market wholesale distributors, health food stores, chiropractors, gyms, natural food stores, nutrition centers, and individual consumers in 43 states, Canada, Guam, and the Virgin Islands.

During the investigation, the agents learned of numerous other acts intended to conceal the defendants' illegal activities, including:

- shredding business records, including orders, price lists, and computer printouts

- refusing to accept new customers without a referral
- directing customers not to store the products on the shelves for open sale
- instructing employees to say they sold only vitamins and cosmetics
- destroying records and other evidence in the case.

Halpern's alleged activities are part of a \$2 billion anti-aging black market in the United States, described by Congress as the fastest growing and perhaps most profitable segment of the \$10 billion “quackery scandal.”

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