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TEN INDIVIDUALS, INCLUDING 4 DOCTORS, INDICTED IN ALLEGED SCHEME TO DEFRAUD PATIENTS AND INSURANCE COMPANIES IN CONNECTION WITH ALLERGY TESTING AND SHOTS

CHICAGO – Six individuals associated with a group of companies offering allergy testing and shots, together with 4 doctors who acted as Medical Directors for the companies, were indicted yesterday on federal charges for allegedly defrauding hundreds of individual victims and insurance companies from 2000 to early 2007, federal officials announced today.

A federal grand jury returned a 34-count indictment late yesterday against the ten defendants, all of whom were associated with a group of businesses that operated in Chicago, Northwest Indiana, and Phoenix, Arizona, principally under the name of American Institute of Allergy (AIA). The indictment alleges that AIA patients were recruited with promises of free blood tests for allergies. In fact, according to the indictment, doctors never saw patients to determine that the testing was medically necessary, and patients' blood samples often were not sent for testing until their insurance companies agreed to pay for the tests, even though this delay sometimes caused the blood to deteriorate and rendered the allergy tests unreliable. The indictment also alleges that patients whose blood tests showed positive reactions to allergens were advised to receive allergy shots. According to the indictment, these allergy shots were ordered without a doctor's evaluation of the risks to patients, were prepared by unqualified personnel in unsanitary conditions, and were dispensed

without the equipment and trained personnel necessary to ensure patients' safety. The indictment does not allege that any patients were injured as a result of the defendants' conduct.

John Froelich, 49, of Harwood Heights, a nurse licensed by the State of Illinois, is alleged to have controlled and operated the companies. The indictment alleges that during the course of the scheme, Froelich's companies defrauded insurance companies out of a total of more than \$1.5 million, and that more than 500 AIA patients were victims of the fraudulent conduct. Diane Smoot, 39, of Gary, Indiana, who had no medical training, allegedly worked closely with Froelich in soliciting patients to undergo allergy testing and receive shots. The indictment alleges that Smoot and other AIA personnel recruited patients for AIA at private gyms, firehouses, and other public and private locations, by promising that the allergy tests would be performed at no cost to the patients and that the patients would be informed of the results.

Defendants **Paul Kocourek**, 53, of Chicago, and his brother **Frank Kocourek**, 41, of Chicago, allegedly worked for AIA and submitted fraudulent bills to insurers. **Joey Reyes**, 36, of Okemos, Michigan, and **Theodore Zegarski**, 50, of Chicago, allegedly were pharmacy technicians employed by AIA, who prepared allergy shots even though they were not licensed or qualified to prepare the allergy shots without the direct supervision of a pharmacist or doctor. Defendants **Dr. Robert Tully**, 50, of Mesa, Arizona, **Dr. Edgar Vargas**, 70, of Arlington Heights, and **Dr. Oranu Ibekie**, 43, of Merrillville, Indiana, allegedly ordered allergy shots, which are prescription drugs, without examining the individual victims, and without knowing whether the individuals actually needed the tests or shots. Those doctors, as well as defendant **Dr. Hartley Thomas**, 54, of Valparaiso, Indiana, allegedly ordered allergy tests without first examining the patients, and without knowing whether the patients had any symptoms or complaints relating to allergies. According to

the indictment, fraudulent insurance claims were submitted under the names of those doctors, with their knowledge.

Froelich and Paul Kocourek were arrested this morning by federal agents and will appear at 1:30 p.m. today before Magistrate Judge Martin C. Ashman. The other defendants will receive summonses to appear for arraignment before U.S. District Court Judge Mark Filip in Chicago on a date yet to be determined. Through their attorneys, Smoot and Vargas have authorized the government to disclose that they are cooperating in the investigation.

The indictment identifies the defendants, with the charges against each, as follows:

John Froelich – 24 counts of wire fraud, 6 counts of mail fraud, 2 counts of misbranding drugs, and 1 count of conspiracy to misbrand drugs. Froelich was a nurse who allegedly controlled and operated American Institute of Allergy, Inc.; American Institute of Allergy of Indiana, Inc.; American Institute of Allergy of Illinois, Inc.; American Institute of Allergy of Arizona, Inc.; Support Services of Illinois, Inc.; New Horizons, Inc.; and Progressive Care of Illinois, Inc. (collectively referred to as "AIA"). AIA operated in the areas of Chicago, Northwest Indiana, and Phoenix, Arizona.

Diana Smoot – 1 count of wire fraud. Smoot allegedly worked for AIA recruiting individuals to have blood tests and allergy shots, and also supervised and trained AIA personnel to recruit patients, draw blood, and give allergy shots. Smoot held herself out as the Director of Services for AIA, and a National Account Representative for AIA. Smoot had no medical background or education. Smoot worked with AIA from approximately early 2002 through October 2005.

Paul Kocourek – 24 counts of wire fraud and 6 counts of mail fraud. Paul Kocourek allegedly handled billing and administrative work for AIA, and at times held himself out as the owner or manager of AIA. Paul Kocourek worked with AIA from approximately early 2000 through early 2007.

Frank Kocourek – 24 counts of wire fraud and 6 counts of mail fraud. Frank Kocourek, the brother of Paul Kocourek, allegedly handled billing for AIA, and worked for AIA from approximately early 2000 through July 2004.

Joey Reyes – 8 counts of wire fraud, 3 counts of mail fraud, and one count of conspiracy to misbrand drugs. Reyes, a licensed pharmacy technician, allegedly prepared allergy shots for AIA. Reyes worked for AIA from approximately early 2000 through the summer of 2006.

Theodore Zegarski – 1 count of wire fraud. Zegarski, a licensed pharmacy technician, allegedly prepared allergy shots for AIA. Zegarski worked for AIA from approximately March 2002 through August 2004.

Dr. Robert Tully – 5 counts of wire fraud. Tully, a doctor licensed in Arizona, and the medical director for AIA in Arizona from approximately August 2000 through March 2002, allegedly authorized allergy shots for patients.

Dr. Edgar Vargas – 1 count of conspiracy to misbrand drugs. Vargas, a doctor licensed in Illinois, was the medical director for AIA in Illinois from approximately October 2001 through April 2002, and allegedly authorized allergy shots for patients.

Dr. Oranu Ibekie – 5 counts of wire fraud. Ibekie, a doctor licensed in Indiana, was the medical director for AIA in Indiana from approximately April 2003 through October 2003, and allegedly authorized allergy tests and shots for patients.

Dr. Hartley Thomas – 10 counts of wire fraud. Thomas, a doctor licensed in Indiana, was the medical director for AIA in Indiana from approximately June 2005 through the end of 2006, and allegedly authorized allergy tests for patients.

According to the indictment, the defendants' criminal conduct included the following:

- Defendants obtained blood samples and medical insurance policy information from patients, for the stated purpose of conducting allergy testing and treatment, by making false representations concerning the cost of the program, the involvement of doctors, and the benefits to be gained by the patients, and by falsely promising that allergy test results would be promptly sent to patients, even though many patients never received any test results.
- Defendants convinced patients to agree to have a series of allergy shots by falsely representing that the shots were medically necessary when, in fact, defendants knew that they were acting without regard to the patients' actual medical need for allergy shots, and knowing that no doctor had determined that allergy shots would be beneficial for the patients.
- Defendants attempted to reassure patients who agreed to shots by falsely representing that the shots were safe, and failing to warn patients of potential life threatening risks associated with the shots.
- Defendants attempted to persuade patients and insurance companies that the blood tests and allergy shots were medically necessary by creating the appearance that doctors were writing valid prescriptions referred to as "Doctor's Order Forms" when, in fact, the doctors wrote those prescriptions without knowing whether the patients needed the blood tests or allergy shots.

Moreover, the prescriptions did not meet state statutory requirements and failed to identify what allergy shots were to be given or the strength of the shots, leaving the selection of the contents and strength of the shots to Zegarsky and Reyes, who were unqualified to make such decisions.

- Defendants attempted to make patients and insurance companies believe that the allergy shots were legitimately and appropriately prepared by professionals when, in fact, the allergy shots were mixed and prepared in unsanitary conditions and without proper ventilation by AIA personnel lacking proper training and certification for such work. In addition, certain antigens used in the shots had passed the expiration date set for those antigens.
- Defendants attempted to obtain payment from the insurance companies by causing the submission of fraudulent insurance claims relating to allergy tests and allergy shots, including claims for medically unnecessary blood tests and allergy shots, claims for services that were not provided, and claims that included false information concerning the name of the physician, the location of the services, the existence of a diagnosis, and the work that AIA performed.
- Defendants submitted false and fraudulent documents to insurance companies, including fraudulent Doctor's Order Forms and progress notes, to convince insurance companies to pay claims submitted by AIA.
- Defendants tried to mislead the insurance companies by submitting claims falsely representing that AIA had conducted blood testing, even though all blood testing was performed by a laboratory that was not operated or owned by AIA, and by submitting claims for certain blood tests even though those blood tests had not been performed.

The United States Attorney's Office announced the charges with Michael Cleary, Special Agent in Charge of the U.S. Food and Drug Administration, Office of Criminal Investigations; James Vanderberg, Special Agent-in-Charge of the U.S. Department of Labor Office of Inspector General in Chicago; Kenneth T. Laag, Inspector-in-Charge of the U.S. Postal Inspection Service; and Steve Haguen, Acting Regional Director of the U.S. Department of Labor Employment Benefit Service Administration in Chicago.

"The FDA takes seriously situations where individuals motivated by monetary gain place the public at risk," said Michael Cleary, Special Agent in Charge for the FDA's Office of Criminal Investigation, Chicago Field Office. Gordon S. Heddell, Inspector General, United States Department of Labor, stated: "This indictment demonstrates that we will continue to collaborate with other law enforcement agencies in investigating those who abuse their professional training and status for personal gain."

If individuals who received allergy shots or any other treatment from AIA have medical concerns, they should contact their doctors. The United States Attorney's Office in the Northern District of Illinois has established a toll free number. Persons who believe they have been victims of the conduct charged in the indictment may call the toll free number, 1-866-364-2621. Identified victims will receive a letter concerning this matter with additional contact information within approximately 2 weeks.

The government is being represented by Assistant U.S. Attorney Jacqueline Stern.

Upon conviction, the charges alleged in the indictment carry the following maximum penalties on each count: mail fraud and wire fraud – 20 years in prison and a \$250,000 fine, or as an alternative maximum fine, the Court could impose a fine of twice the gross profit to any defendant or twice the loss to any victim. The felony charge of conspiracy to misbrand drugs in Count 31 carries a maximum sentence of five years in prison and a \$250,000 fine. The charges of misbranding drugs in Counts 32 and 33 carry a sentence of 3 years in prison and a \$250,000 fine, and the conspiracy to misbrand drugs charged in Count 34 carries a sentence of 1 year in prison and a \$100,000 fine. The Court, however, would determine the appropriate sentence to be imposed.

The public is reminded that an indictment contains only charges and is not evidence of guilt.

The defendants are presumed innocent and are entitled to a fair trial at which the government has the burden of proving guilt beyond a reasonable doubt.

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