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CHICAGO PSYCHIATRIST ALLEGEDLY SUBMITTED AT LEAST 190,000 FALSE CLAIMS TO MEDICARE AND MEDICAID; LAWSUIT ALLEGES KICKBACKS TO PRESCRIBE ANTIPSYCHOTIC MEDICATION FOR NURSING HOME PATIENTS

CHICAGO — A Chicago psychiatrist received illegal kickbacks from pharmaceutical companies and submitted at least 140,000 false claims to Medicare and Medicaid for antipsychotic medications he prescribed for thousands of mentally ill patients in area nursing homes, according to a civil health care fraud lawsuit filed today by the United States. The defendant, **Dr. Michael J. Reinstein**, also submitted at least 50,000 claims to Medicare and Medicaid, falsely stating that he provided “pharmacologic management” for his patients at more than 30 area nursing homes and long-term care facilities, the lawsuit alleges.

The lawsuit seeks triple damages under the False Claims Act, plus a civil penalty of \$5,500 to \$11,000 for each alleged false claim.

“This is the largest civil case alleging prescription medication fraud against an individual ever brought in Chicago,” said Gary S. Shapiro, Acting United States Attorney for the Northern District of Illinois. He announced the lawsuit with William C. Monroe, Acting Special Agent-in-Charge of the Chicago Office of the Federal Bureau of Investigation, and Lamont Pugh III, Special Agent-in-Charge of the Chicago Regional Office of the HHS-OIG. The investigation is continuing, they said.

Reinstein, 69, of Skokie, has provided psychiatric medical services in the Chicago area since 1973. Since at least 1999, he has maintained an office in Chicago's Uptown neighborhood, which has the densest concentration of mentally ill nursing home residents in Illinois.

According to the lawsuit, Reinstein routinely prescribed antipsychotic and other psychiatric medications knowing that, because most of his patients are indigent nursing home residents, pharmacies dispensing the medications submitted claims to Medicaid, and beginning in 2006, to Medicare Part D. Reinstein also submitted Medicare and Medicaid claims for pharmacologic management of his patients, knowing that he did not engage in substantive evaluations of his patients' medical and psychiatric conditions to properly manage their medications. Instead, he allegedly prescribed medications to his patients based on his receipt of kickbacks from pharmaceutical companies.

The lawsuit involves Reinstein's use of clozapine, a rarely-used medication that has serious potential side effects and is generally considered a drug of last resort, particularly for elderly patients. While clozapine has been shown to be effective for treatment-resistant forms of schizophrenia, it is also known to cause numerous side effects, including a potentially deadly decrease in white blood cells, seizures, inflammation of the heart muscle, and increased mortality in elderly patients.

Prior to August 2003, Reinstein prescribed Clozaril, the trade name for clozapine manufactured by Novartis, and he often had more than 1,000 patients using the medication at any given time. For many years, Novartis paid Reinstein to promote Clozaril, the complaint alleges. After Novartis' patent for Clozaril expired in 1998, Reinstein resisted pharmacy and drug company efforts to switch his patients to generic clozapine and he continued to be the largest prescriber of

Clozaril to Medicaid recipients in the United States. In July 2003, Novartis notified Reinstein that it would be withdrawing its support for Clozaril, and ended the regular payments that it had been making to Reinstein.

In August 2003, Reinstein finally agreed to switch his patients to generic clozapine manufactured by Miami-based IVAX Pharmaceuticals, Inc., the suit alleges, if IVAX agreed to pay Reinstein \$50,000 under a one-year “consulting agreement;” pay his nurse to speak on behalf of clozapine; and fund a clozapine research study by a Reinstein-affiliated entity known as Uptown Research Institute. IVAX agreed and Reinstein immediately began switching his patients from Clozaril to IVAX’s clozapine. He quickly became the largest prescriber of generic clozapine in the country.

“Reinstein’s inordinate prescribing of clozapine stands in stark contrast to its extremely limited use by other physicians,” the lawsuit states. While generally only four percent of schizophrenia patients who were prescribed antipsychotics received clozapine, during the time Reinstein was allegedly accepting kickbacks from IVAX, more than 50 percent of his patients were prescribed IVAX’s clozapine. At one nursing home, Reinstein had 75 percent of the 400 residents on IVAX’s clozapine.

Between 2003 and 2006, Reinstein allegedly requested, and IVAX provided, additional direct and indirect benefits to Reinstein and his associates, including:

- ▶ paying airfare, lodging, meals, and entertainment expenses for a pharmacy owner and spouse, Reinstein’s nurse, his accountant and spouse, his administrative assistant and spouse, and Reinstein and his wife to travel to IVAX’s headquarters in Miami. IVAX also paid for Reinstein and his entourage to go on a fishing trip, a boat cruise, and a golf outing;
- ▶ annual renewal of Reinstein’s \$50,000 “consulting agreement;” and

- ▶ tickets to sporting events and free IVAX-manufactured medication for Reinstein's personal use.

In January 2006, IVAX became a subsidiary of Teva Pharmaceuticals Industries, Ltd., an Israeli company. About seven months before the merger, Reinstein began moving large numbers of his patients to a form of clozapine manufactured by a competitor of IVAX/Teva. In April 2006, Teva paid all expenses for Reinstein and his entourage to travel to Miami, including a \$2,300 boat cruise, and at least two dinners costing more than \$1,700 each. During this trip Teva employees asked Reinstein what the company could do to induce Reinstein to prescribe more clozapine, and Reinstein suggested that Teva hire an associate of his from Chicago, the lawsuit alleges. Teva agreed and in the months after the hiring Reinstein put several hundred patients back on Teva's clozapine.

From 2007 to 2009, the suit alleges, Teva and Reinstein entered into annual "speaker agreements" that resulted in Teva paying Reinstein more than \$100,000.

The suit alleges that Medicaid received and paid more than 100,000 false claims from various pharmacies for IVAX/Teva clozapine prescriptions written by Reinstein between August 2003 and July 2011 as a result of illegal kickbacks he solicited and received from IVAX and Teva. Between 2006 and July 2011, Medicare Part D received and paid more than 40,000 false claims involving similar kickback-induced prescriptions.

Likewise, between August 2003 and July 2011, Reinstein allegedly submitted more than 40,000 false claims and received payment from Medicaid for purported pharmacologic management, as well as more than 10,000 similar false claims to Medicare.

The government is being represented by Assistant U.S. Attorney Eric S. Pruitt.

A civil lawsuit contains merely allegations of unlawful conduct. In civil cases, the government has the burden of proving the allegations by a preponderance of the evidence.

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