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Department of Justice

U.S. Attorney's Office

District of Massachusetts

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Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy

**First successful prosecution of top pharmaceutical executives for crimes
related to the prescribing of opioids**

BOSTON – The founder and four former executives of Insys Therapeutics Inc. were convicted today by a federal jury in Boston in connection with bribing medical practitioners to prescribe Subsys, a highly-addictive sublingual fentanyl spray intended for cancer patients experiencing breakthrough pain, and for defrauding Medicare and private insurance carriers.

Insys founder and former Executive Chairman John N. Kapoor, 76, of Phoenix, Ariz.; Richard M. Simon, 48, of Seal Beach, Calif., the former National Director of Sales; Sunrise Lee, 38, of Bryant City, Mich., a former Regional Sales Director; Joseph A. Rowan, 45, of Panama City, Fla., a former Regional Sales Director; and Michael J. Gurry, 55, of Scottsdale, Ariz., the former Vice President of Managed Markets, were convicted by a federal jury of RICO conspiracy. Sentencing dates have not yet been set.

Prior to the start of the trial, two other high-level Insys executives pleaded guilty and testified during the trial: Michael Babich, of Scottsdale Ariz., the former CEO and President of the company, and Alec Burlakoff, of Charlotte, N.C., the former Vice President of Sales.

From May 2012 to December 2015, the defendants conspired to bribe practitioners, many of whom operated pain clinics, in order to induce them to prescribe Insys' fentanyl-based pain medication, Subsys, to patients often when medically unnecessary. Subsys is a powerful, rapid-onset opioid intended to treat cancer patients suffering intense breakthrough pain.

The defendants used pharmacy data to identify practitioners who either prescribed unusually high volumes of rapid-onset opioids, or had demonstrated a capacity to do so, and bribed and provided kickbacks to the practitioners to increase the number of new Subsys prescriptions, and

to increase the dosage and number of units of Subsys. The defendants also measured the success of their criminal enterprise by comparing the net revenue earned from targeted practitioners with the total value of bribes and kickbacks paid. The defendants used this information to reduce or eliminate bribes paid to practitioners who failed to meet satisfactory prescribing requirements, which they determined to be the net revenue equal to at least twice the amount of bribes paid to the practitioner.

The bribes and kickbacks took multiple forms. In March 2012, Insys began using “speaker programs” purportedly intended to increase brand awareness of Subsys through peer-to-peer educational lunches and dinners. However, the programs were used as a vehicle to pay bribes and kickbacks to targeted practitioners in exchange for increased Subsys prescriptions and increased dosage. In most instances, the programs were shams.

The defendants also conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. The defendants conspired to achieve this by setting up the “Insys Reimbursement Center,” (IRC) which was dedicated to obtaining prior authorization for payment directly from insurers and pharmacy benefit managers. Beginning in October 2012, employees of the IRC posed as employees of the practitioner and used “the spiel” – a script of false and misleading representations about patient diagnoses in order to secure approval for the drug by the insurance provider. For example, since insurers were more likely to authorize payment for Subsys if a patient was being treated for cancer-related pain, IRC employees were instructed to mislead insurers regarding the true diagnosis of the patient.

“Today’s convictions mark the first successful prosecution of top pharmaceutical executives for crimes related to the illicit marketing and prescribing of opioids,” said United States Attorney Andrew E. Lelling. “Just as we would street-level drug dealers, we will hold pharmaceutical executives responsible for fueling the opioid epidemic by recklessly and illegally distributing these drugs, especially while conspiring to commit racketeering along the way. I applaud the prosecutors and investigators who fought this case to the finish and won. This is a landmark prosecution that vindicated the public’s interest in staunching the flow of opioids into our homes and streets.”

“These executives exploited vulnerable patients and cashed in on dishonest doctors by bribing them to prescribe one of the most powerful, addictive opioid painkillers to patients who should never have received it. Motivated by sheer greed, they lied to insurance companies and are no better than street level drug dealers,” said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division. “Today’s verdict marks an important step in holding pharmaceutical company executives responsible for their role in fueling the opioid epidemic. Rest assured, the FBI will continue to identify and bring to justice corrupt individuals and companies whose business practices promote fraud with a total disregard for patient safety.”

“Combating the opioid epidemic remains a top priority for HHS OIG. For too long executives have not been held accountable for corporate wrongdoing. These verdicts underscore our continued commitment to holding individuals and corporations accountable for their fraudulent conduct,” said Phillip Coyne, Special Agent in Charge, U.S Department of Health and Human Services, Office of the Inspector General. “No matter what the scheme or how elaborately disguised, we

will follow the evidence where it takes us, including to the corporate ranks. HHS OIG and our law enforcement partners will continue to investigate and prosecute healthcare fraud to the fullest extent of the law.”

“The opioid epidemic is one of the largest public health tragedies our country has faced, and as the FDA continues to forcefully confront the opioid crisis, ensuring safe and appropriate use of these powerful medications remains a cornerstone of our efforts,” said Melinda K. Plaisier, FDA Associate Commissioner for Regulatory Affairs. “In this case, we’ve seen unacceptable behavior from the defendants who influenced health care providers to prescribe the most powerful type of opioid – an immediate release form of fentanyl – to patients who did not need it, putting them at serious risk of overdose and in some cases, death. The FDA has taken recent steps to strengthen our risk mitigation program for this specific class of products to better ensure the safe use of these products, and we will continue to work with our law enforcement partners to pursue and bring to justice those who place profits before the public health.”

“The reckless actions by these executives whose products included controlled medications increased the potential for diversion and addiction, which jeopardizes the public health and safety,” said DEA Special Agent in Charge Brian D. Boyle. “DEA pledges to work with our law enforcement and regulatory partners to ensure that rules and regulations are followed.”

“The integrity of TRICARE, the U.S. Defense Department’s health care program for military members and their dependents, is a top priority for the Defense Criminal Investigative Service (DCIS),” stated Special Agent-in-Charge Leigh-Alistair Barzey, DCIS Northeast Field Office. “Today’s verdicts are the direct result of a joint effort by several agencies and is demonstrative of their commitment to investigate and prosecute individuals and companies that commit health care fraud. The DCIS will continue to work with its law enforcement partners and the U.S. Attorney’s Office to protect the TRICARE program and ensure that TRICARE patients receive the excellent health care that they deserve.”

“This case shows that healthcare fraud will not be tolerated. The Employee Benefits Security Administration will work together with our law enforcement partners in these important investigations to protect participants in private sector health plans, detect and deter health care fraud, and contribute to fighting the opioid epidemic,” said Carol S. Hamilton, Acting Regional Director of the U.S. Department of Labor, Employee Benefits Security Administration, Boston Regional Office.

“Today’s verdict highlights our commitment to defending our mail system from illegal misuse and ensuring public trust in the mail,” said Inspector in Charge Joseph W. Cronin of the U.S. Postal Inspection Service’s Boston Division. “We are committed to investigating and bringing to justice those who contribute to the opioid abuse epidemic. We would not be successful in doing so without our fellow law enforcement partners and the U.S. Attorney’s Office.”

“The verdict in this case sends a clear message to pharmaceutical companies that tactics like these will not be tolerated,” said Matthew Modafferi, Special Agent in Charge of the United States Postal Service Office of Inspector General in the Northeast Area Field Office. “This is a win for the public in the war against opioids. The Special Agents of the U.S. Postal Service Office of Inspector General will continue to work closely with the U.S. Attorney’s Office and our law enforcement partners to bring those to justice who commit these kind of offenses.”

“Bribing doctors and misrepresenting patient’s medical conditions in order to boost profits by overprescribing a highly addictive opioid is reprehensible criminal conduct,” said Sean J. Smith, Special Agent in Charge of the Department of Veterans Affairs, Office of Inspector General, Criminal Investigations Division. “Today’s verdict is an important step in holding those in the industry that commit crimes accountable. Targeting veterans’ dependents in the CHAMPVA program with these corrupt practices is unacceptable and we are pleased to have contributed to this outstanding multi-agency criminal investigation.”

“Every day, millions of Americans struggle with opioid addiction,” said Thomas W. South, OPM Deputy Assistant Inspector General for Investigations. “These executives put the health and wellbeing of Federal employees, annuitants, and their families at risk in order to make a profit. I would like to recognize the incredible work done by the United States Attorney’s Office, OPM OIG agents, and our law enforcement partners to hold these executives accountable. The OPM OIG remains committed in working to stop such unscrupulous behavior.”

The charge of RICO conspiracy provides for a sentence of no greater than 20 years in prison, three years of supervised release and a fine of \$250,000, or twice the amount of pecuniary gain or loss. Sentences are imposed by a federal district court judge based upon the U.S. Sentencing Guidelines and other statutory factors.

The U.S. Attorney’s Office would like to acknowledge the cooperation and assistance of the U.S. Attorney’s Offices around the country engaged in parallel investigations, including the District of Connecticut, Eastern District of Michigan, Southern District of Alabama, Southern District of New York, District of Rhode Island and the District of New Hampshire. The efforts of the Central District of California and the Justice Department’s Civil Fraud Section of the Department of Justice are also greatly appreciated.

Assistant U.S. Attorneys K. Nathaniel Yeager, Chief of Lelling’s Health Care Fraud Unit, David Lazarus, Chief of Lelling’s Asset Recovery Unit, and Fred M. Wyshak, Chief of Lelling’s Public Corruption & Special Prosecutions Unit, are prosecuting the case.

Topic(s):

Health Care Fraud

Component(s):

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