# Former officials at US fentanyl maker charged with bribing doctors

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Earlier this month, federal agents arrested six former employees of small pharmaceutical company Insys Therapeutics, including the company's former CEO, for allegedly bribing doctors to inappropriately prescribe the company's highly addictive fentanyl product, Subsys.

The charges included conspiracy to commit racketeering, conspiracy to commit wire and mail fraud, and conspiracy to violate the Anti-Kickback Statute. Subsys is Insys Therapeutics' only product.

"As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to abuse and life threatening respiratory depression," said Harold H. Shaw, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division.

The indictment takes place in the midst of a heroin epidemic in the United States, with opioid deaths surpassing 30,000 for the first time in recent history.

The chilling details of the case are a further indictment of the for profit medical system in the United States, where the health and safety of the public is held hostage to for profit drug companies, insurers and hospital chains seeking only to pad their bottom lines.

However, the filing of charges against pharmaceutical companies is exceedingly rare, with the big pharmaceuticals, like the big banks, seemingly immune from federal scrutiny.

Founded in 2002 and based in Scottsdale, Arizona, Insys Therapeutics launched Subsys in 2012. Due to the company's aggressive marketing practices, and alleged bribing of doctors, Subsys soon captured half of the market for rapid-acting fentanyl products. Since 2013, the company's revenue has tripled and its profits have grown 45 percent to $58.5 million.

Fentanyl is a synthetic opioid that is fast acting and 50-100 times as powerful as morphine. The company's Subsys product is a sublingual fentanyl spray that is applied under the tongue. In January 2012 the FDA approved the drug for the management of breakthrough pain (severe pain that is no longer responsive to other pain medications) in cancer patients.

The company officials arrested were Michael Babich, the former CEO of Insys, Michael Gurry, former VP of Managed Markets, Richard Simon, former director of sales, and former regional sales directors Sunrise Lee and Joseph Rowan. Their co-conspirators were physicians licensed in states in the Midwest, Northeast, and Southern regions.

According to the 60-page indictment filed in the United States District Court for the District of Massachusetts, from around June 2012 to December 2015, the indicted and their co-conspirators operated a kickback scheme that encouraged doctors to write Fentanyl Spray prescriptions.

As part of the scheme between March and August 2012, Insys set up a speaker program intended to increase brand awareness. Participating physicians would be compensated through the payment of a speaker fee or "honoraria."

Communication skills were not a prerequisite for a physician to be a speaker. For the company, enthusiasm, real or feigned, by doctors for their fentanyl spray was the chief consideration for enrolling them in the speaker program.

The company defendants then identified physicians who wrote prescriptions for TIRF products, ranked them into deciles according to the number of prescriptions they wrote, and had the company's sales force target the doctors in the highest deciles.

The company collected data on the prescribing habits of the speakers, "and for a time, explicitly calculated the ratio of return on investment for each speaker." The company would reduce or increase the number of paid speaking engagements depending upon the number of prescriptions written by the doctor.

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When Babich received a list of medical practitioners in November 2013 who had written prescriptions for competitor drugs, including those receiving speaking fees, he e-mailed Burlakoff: “I thought we owned the high decile folks? Lot’s of big names on there.”

Since physicians treating cancer were not high-prescribers of Subsys, the company began targeting practitioners that were prescribing TIRF products for all types of pain.

At the start of 2013, the company set up a reimbursement unit, which was dedicated to getting prior authorization from pharmacy benefit managers (PBMs) and insurance providers. Company officials set up financial bonuses to reward employees for obtaining prior authorizations and set a weekly minimum threshold for the unit known as a “gate.”

Babich and Gurry trained employees of the reimbursement unit in the best practices for obtaining prior authorization. They instructed members of the reimbursement unit to lie to insurers and pharmacy benefit managers, telling them that they were calling “from” the doctor’s office, and later “on behalf” of a specific doctor or “with” a specific doctor’s office. They masked their incoming phone number to ensure that it did not conflict with the doctor’s area code. If employees of the reimbursement unit were pressed on their identity, they were instructed to hang up and call back later in hopes of connecting to a different (and hopefully less inquisitive) PBM or insurance agent.

Since the label for Subsys stated it was for the management of breakthrough cancer pain—and few of the patients had cancer, and none of the co-conspirator practitioners were oncologists—the company put together different versions of “the spiel” that members of the reimbursement unit were to give insurers:

If “the spiel” wasn’t enough, members of the reimbursement unit were told to provide insurers and PBM’s with false diagnoses that would have the best shot at being covered, or falsely claim that the patient had tried and failed the list of medications required for prior authorization.

By the end of 2013, the reimbursement unit had succeeded in getting 85 percent of all prior authorizations approved.

In addition to speaker fees, Insys also allegedly used other forms of bribes and kickbacks, including finding employment for the practitioners’ friends and family, or purchasing food from and scheduling program events at establishments owned by their friends or family.

Expensive meals and drinks were furnished at speaker programs. Sometimes speaker events were only attended by the physician’s support staff. Many events had no attendees at all, requiring sales representatives to falsify names on the attendee list for the “sham” events.

The fees from speaker programs and other alleged kickbacks and bribes were effective tools for encouraging doctor’s to write more prescriptions. One physician, listed as Practitioner #1 in the indictment, began prescribing Subsys shortly after its launch, writing an average of 2.2 prescriptions per week in June 2012. By September, after the physician had participated in his first two speaker program events, he was writing an average of 11 fentanyl spray prescriptions per week.

On December 20, Burlakoff wrote the salesperson working with the doctor, Joseph A. Rowan: “Joe…Congrats, you are officially #1 in the company (with only one doctor). I am pretty sure your formula worked, you may want to pass it along to your team.” By this time the company had paid Practitioner #1 $24,000 in alleged bribes and kickbacks. By May 2015, approximately 2,148 Subsys prescriptions written by Practioner #1 had been approved, and he had received $229,640 in speaker fees.

Other physicians named as co-conspirators in the indictment had similar stories.

Insys Therapeutics would also wine and dine the doctors when necessary. In January 2013, Practitioner #4 was invited to corporate headquarters in Arizona where Burlakoff and Rowan took him out to a club, where he had a “fantastic night.” In exchange for 2,030 authorized prescriptions for Subsys between August 2012 and November 2015, Practitioner #4 received $260,050 in speaker fees.

The company focused on not only increasing the number of prescriptions written by doctors, but also their dosage, which brought in more money.

Insys officials had no qualms dealing with physicians who were clearly running “pill mills.” A sales representative in the Chicago e-mailed Babich on September 17, 2012 to update him on her efforts to work with a doctor, Practitioner #6, who “runs a very shady pill mill and only accepts cash.”

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