

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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August 2, 2018

Saeed Motahari
President and Chief Executive Officer
Insys Therapeutics, Inc.
1333 S. Spectrum Blvd. Suite 100
Chandler, AZ 85286

Dear Mr. Motahari:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is continuing to investigate the opioid epidemic in the United States. According to the Centers for Disease Control and Prevention, 115 Americans die from an opioid overdose every day and that more than 351,000 lives have been lost since 1999.¹

For more than a year, the Committee has been investigating potential breakdowns in the controlled substances supply chain which may have contributed to the nation's opioid epidemic. Pharmaceutical manufacturers play a unique and critical role in this supply chain by both researching and developing products for the consumer market as well as marketing such products after approval from the Food and Drug Administration (FDA).

While numerous companies are engaged in the manufacture and marketing of prescription opioids in the United States, Insys Therapeutics' practices have come under intense scrutiny in recent years. In 2016, a federal grand jury indicted former Insys executives, including the company's former President and CEO, on charges related to an alleged kickback scheme meant to boost sales of Subsys, a sublingual fentanyl spray.² Fentanyl is a synthetic opioid that is

¹ Centers for Disease Control and Prevention, *Understanding the Epidemic, Opioid Overdose* (last updated Aug. 30, 2017) available at <https://www.cdc.gov/drugoverdose/epidemic/index.html> and Centers for Disease Control and Prevention, *Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016*, available at https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4.

² See *United States v. Babich et al.*, Indictment, No. 16-cr-10343-ADB (D. Mass Dec 6, 2016) available at <https://www.justice.gov/usao-ma/press-release/file/916681/download>. In 2017, the grand jury issued a superseding indictment which also charged Insys' founder, and former CEO and Executive Chairman of the Board with violating federal law in relation to his involvement with the alleged kickback scheme related to Subsys prescribing. See

approximately 50 times more potent than heroin and 100 times more potent than morphine.³ Insys began marketing Subsys in 2012 after the drug was approved by FDA to treat breakthrough cancer pain in adults.⁴ However, prosecutors allege that Insys officials bribed doctors and pharmacies to prescribe and dispense Subsys to patients who were not diagnosed with cancer while simultaneously engaging in conduct to subvert Drug Enforcement Administration (DEA) reporting requirements found at 21 C.F.R. § 1301.74.⁵ Prosecutors also alleged that Insys personnel conspired to defraud health insurance companies by misleading them so the insurers would authorize coverage of the drug.⁶ At least four doctors have been convicted of crimes related to the kickback scheme⁷ while charges are pending against others.⁸ In addition, several former Insys sales representatives have pleaded guilty to charges including conspiracy to commit bribery.⁹

Subsys was introduced into the market at a time when pharmaceutical manufacturers were already facing criticism over the aggressive marketing of opioid painkillers.¹⁰ Years earlier, Purdue Pharma, along with three company executives, pleaded guilty and were forced to pay more than \$634 million in criminal and civil penalties for misbranding the extended-release opioid OxyContin and misleading doctors and patients about the drug's risk of addiction and its potential to be abused.¹¹ Another pharmaceutical manufacturer, Cephalon, agreed to pay \$425 million in 2008 to settle criminal and civil allegations that it illegally marketed three brand drugs

United States v. Babich et al., Indictment, No. 16-cr-10343-ADB (D. Mass. Oct. 24, 2017) available at <https://www.justice.gov/usao-ma/page/file/1010246/download>.

³ Centers for Disease Control & Prevention, *Injury Prevention & Control: Opioid Overdose, Synthetic Opioid Overdose Data* (last updated Dec. 16, 2016) available at <https://www.cdc.gov/drugoverdose/data/fentanyl.html>.

⁴ See Letter from Bob A. Rappaport, M.D., Dir., Division of Anesthesia, Analgesia, and Addiction Products, Office of Drug Evaluation II, Center for Drug Evaluation and Research, U.S. Food and Drug Admin. to Insys Therapeutics, Inc., Jan. 4, 2012 available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202788s000ltr.pdf.

⁵ *United States v. Babich et al.*, *supra* note 2.

⁶ *Id.*

⁷ Janelle Lawrence and Jef Feeley, *Ivy League doctor gets 4 years in prison for Insys opioid kickbacks*, Bloomberg, Mar. 9, 2018, <https://www.bloomberg.com/news/articles/2018-03-09/ivy-league-doctor-gets-4-years-prison-for-insys-opioid-kickbacks>.

⁸ Brendan Pierson, *Five New York doctors charged with taking kickbacks from Insys*, Reuters, Mar. 14, 2018, <https://www.reuters.com/article/us-insys-opioids/five-new-york-doctors-charged-with-taking-kickbacks-from-insys-idUSKCN1GS2G3>.

⁹ See Ed Silverman, Stat, *Another Insys sales rep pleads guilty to bribing docs for writing Subsys prescriptions*, STAT, May 31, 2018, <https://www.statnews.com/pharmalot/2018/05/31/insys-sales-rep-bribes-subsys/>; See also Nate Raymond, *Ex-Insys saleswomen plead guilty in U.S. to drug kickback schemes*, Reuters, July 11, 2017, <https://www.reuters.com/article/us-insys-court/ex-insys-saleswomen-plead-guilty-in-u-s-to-drug-kickback-schemes-idUSKBN19W219> and Dina Gusovsky, *Former sales rep for painkiller company pleads guilty*, CNBC, Feb. 19, 2016, <https://www.cnn.com/2016/02/19/sales-rep-for-insys-painkiller-company-pleads-guilty.html>.

¹⁰ See, e.g., Peter Whoriskey, *Rising painkiller addiction shows damage from drugmakers' role in shaping medical opinion*, Wash. Post., Dec. 31, 2012, https://www.washingtonpost.com/business/economy/2012/12/30/014205a6-4bc3-11e2-b709-667035ff9029_story.html?utm_term=.735f8a6ec8c4 and John Fauber, *Networking fuels painkiller boom*, Milwaukee Journal Sentinel, Feb. 19, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2m-139609053.html/>.

¹¹ *United States v. The Purdue Frederick Company*, Opinion and Order, Case No. 1:07CR00029 (W.D. Va. 2007) available at <http://www.vawd.uscourts.gov/OPINIONS/JONES/107CR00029.PDF>.

it manufactured.¹² One of the drugs included in the settlement was the berry-flavored fentanyl lollipop Actiq—sometimes called “perc-o-pops” on the street—which was approved for cancer patients but allegedly was also promoted to treat migraines and backaches.¹³

Despite the well-publicized settlements and serious concerns raised by federal investigators about pharmaceutical manufacturers’ marketing tactics involving opioid medications and off-label marketing, Insys allegedly went forward with an aggressive marketing campaign for Subsys that promoted off-label use.¹⁴ According to public filings, Subsys sales took off in 2013, and Insys reported a net revenue of \$95.7 million from Subsys sales that year.¹⁵ The same year, the company spent \$29.2 million on sales and marketing of the drug.¹⁶ Sales of Subsys reached \$329 million in 2015.¹⁷ The company spent \$80.7 million in 2015 on sales and marketing expenses, and noted in Securities and Exchange Commission filings that the increase was “due primarily to sales compensation expense and incremental product marketing expense associated with the increase in sales of Subsys.”¹⁸

According to media reports, Insys paid doctors thousands of dollars to participate in a speaker’s program meant to promote Subsys—some of whom had a history of legal or disciplinary trouble.¹⁹ Prosecutors allege the speaker’s program events were nothing more than a “sham” and often served as “social gatherings at high-priced restaurants that involved no education and no presentation.”²⁰ The goal of the program was not for the speaker to provide information about the drug, but to reward the doctor for writing more Subsys prescriptions, a former sales representative told the *New York Times*.²¹

To encourage doctors to write more prescriptions for Subsys, Insys executives also allegedly regularly entertained certain doctors. According to media reports, the company employed many “extremely attractive women” as sales representatives, including a former exotic dancer as a regional sales representative, who according to company officials, “doctors really

¹² Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008) available at <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

¹³ Linda Loyd, *Cephalon settles charges for \$425 million*, Phila. Inquirer, Sept. 30, 2008, http://www.philly.com/philly/business/20080930_Cephalon_settles_charges_for_425_million.html.

¹⁴ Katie Thomas, *Doubts raised about off-label use of Subsys, a strong painkiller*, N.Y. TIMES, May 13, 2014, <https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html>.

¹⁵ Insys Therapeutics, Inc., Form 10-K, Mar. 4, 2014, available at https://www.sec.gov/Archives/edgar/data/1516479/000143774914003376/insy20131231_10k.htm.

¹⁶ *Id.*

¹⁷ CBS News, *Former drugmaker executives accused of bribing doctors to push pain medication*, Dec. 22, 2016, <https://www.cbsnews.com/news/insys-therapeutics-conspiracy-charges-bribing-doctors-fentanyl-subsys-opioid-addiction-painkillers/>.

¹⁸ Insys Therapeutics, Inc., Form 10-K, Feb. 26, 2016, available at https://www.sec.gov/Archives/edgar/data/1516479/000143774916026220/insy20151231_10k.htm.

¹⁹ Katie Thomas, *Using doctors with troubled pasts to market a painkiller*, N.Y. TIMES, Nov. 27, 2014, <https://www.nytimes.com/2014/11/28/business/drug-maker-gave-large-payments-to-doctors-with-troubled-track-records.html>.

²⁰ *United States v. Babich et al.*, *supra* note 2.

²¹ Evan Hughes, *The Pain Hustlers*, N.Y. TIMES, May 2, 2018, <https://www.nytimes.com/interactive/2018/05/02/magazine/money-issue-insys-opioids-kickbacks.html>.

enjoyed spending time with.”²² In one instance, Insys sales representatives reportedly invited a doctor to visit the company’s headquarters and took him out for the night to a club where, according to a company sales representative, “[h]e had to have had one of the best nights of his life.”²³ The doctor, who wrote an average of three Subsys prescriptions a week before the trip, wrote 17 prescriptions in less than a week after the trip.²⁴ In addition, this doctor allegedly received over \$260,000 in payments under Insys’s speaker’s program.²⁵

Beyond the kickback allegations, media reports have also raised a series of concerns regarding patients’ use of Subsys for conditions other than cancer. According to the *Palm Beach Post*, Subsys is considered a primary suspect in at least 908 deaths reported to FDA over a five-year period.²⁶ Media reports have also raised accusations that Insys sales representatives may have directly marketed Subsys to non-cancer patients as well as contacting patients’ insurance companies in order to secure prior authorization for the drug’s coverage.²⁷ For example, a former Insys sales representative told *NBC News* that it was company practice for sales representatives to contact insurance companies, posing as employees from doctors’ offices and providing false medical information for non-cancer patients, in order to obtain the authorization that was necessary to ensure insurance coverage for the Subsys prescription.²⁸ NBC and other media outlets reported that Subsys use potentially played a role in the death of a 32-year-old fibromyalgia patient who died of an “adverse effect of drugs.”²⁹ A toxicology report later showed that at the time of her death, the patient’s blood contained a lethal level of fentanyl.³⁰ The patient reportedly began using Subsys a year earlier, after an Insys sales representative sat in on a meeting with her and her doctor and recommended she begin using the drug.³¹ In a recording of a subsequent phone call between an Insys sales representative and the patient’s pharmacy benefit manager, the sales representative represented that she was employed by the patient’s doctor and attempted to mislead the benefit manager regarding the nature of the patient’s condition.³²

²² Roddy Boyd, *Insys Therapeutics and the new ‘Killing It,’* Southern Investigative Reporting Foundation, Apr. 24, 2015, <http://sirf-online.org/2015/04/24/the-new-killing-it/>.

²³ David Armstrong, *Company gave doctor ‘one of the best nights of his life’ to boost fentanyl sales*, STAT, Dec. 8, 2016, <https://www.statnews.com/2016/12/08/fentanyl-insys-indictment-doctors/>.

²⁴ *Id.*

²⁵ *Id.*

²⁶ John Pacenti and Holly Baltz, *Ex-Boca school counselor used exotic dancer, models to push fentanyl*, Palm Beach Post, Apr. 4, 2018, <https://www.mypalmbeachpost.com/news/boca-school-counselor-used-exotic-dancer-models-push-fentanyl/4pKKuVALfpjNZPx48VB0EO/>.

²⁷ Corky Siemaszko, *Dangerously Addictive Painkiller Prescribed for Patients Who Shouldn’t Have Received It, Says Whistleblower*, NBC News, June 4, 2017, <https://www.nbcnews.com/storyline/americas-heroin-epidemic/dangerously-addictive-painkiller-prescribed-patients-who-shouldn-t-have-received-n767311>.

²⁸ *Id.*

²⁹ David Armstrong, *A potent painkiller, and the drug maker’s marketing, are faulted in a woman’s death*, STAT, Sept. 30, 2016, available at <https://www.statnews.com/2016/09/30/fentanyl-opioid-insys-subsy/>.

³⁰ *Id.*

³¹ *Id.*

³² Press Release, Sen. Claire McCaskill, BREAKING: McCaskill Opioid Investigation Releases First Report Detailing Systemic Manipulation of Prior Authorization Process by Insys Therapeutics (Sept. 6, 2017), <https://www.mccaskill.senate.gov/media-center/news-releases/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics->; Aaron M. Kessler, *Report: Drug company faked cancer patients to sell drug*, CNN, Sept. 6, 2017,

The Committee has serious concern regarding Insys Therapeutics' marketing and sales practices as well as possible deaths related to the company's fentanyl spray, Subsys. To assist the Committee's understanding of Insys' role in the opioid epidemic in the United States, please provide the following information as well as scheduling a briefing on these matters by August 16, 2018:


1. How were doctors chosen for the company's speaker's program?
 - a. Were doctors required to meet any Subsys prescription quotas in order to maintain participation in the program? If so, what were the requisite quota levels for participation?
2. Does Insys Therapeutics still operate a speaker's program or any other similarly situated program?
 - a. If so, what, if any, changes have been implemented to the speaker's program, or any successor program since bribery allegations were first raised?
 - b. Please provide all policies and procedures referring or relating to Insys Therapeutics' speaker's program, any successor program, or any other similar programs since January 1, 2012.
 - c. Please provide all training materials regarding Subsys provided to doctors in the speaker's program, any successor program, or any other similar programs since January 1, 2012.
3. Please provide all minutes from any meeting since January 1, 2012, of Insys Therapeutics' Board of Directors or Committees where the abuse, potential for abuse, or marketing of Subsys was discussed.
4. Has Insys ever commissioned an internal or independent investigation related to the company's marketing of Subsys? If so, please provide a copy of any report, memorandum, or other document that details the findings of any such investigation. If not, why not?
5. Please provide all documents since January 1, 2012, relating to training and sales materials for Subsys that Insys provided to its marketing and sales staff.
6. Is it currently, or has it ever been, Insys' policy to allow company personnel to communicate directly with patients or with representatives for patients' insurance companies? Does Insys have any knowledge or records of Insys personnel engaging in

such conduct, irrespective of whether such conduct was sanctioned by the company? If so, please provide all documents referring or relating to any such engagement.


7. Please provide a chart, broken down by year from 2012 to the present, documenting the total amount paid to each of the top 50 doctors who were part of the company's speaker's program, or any successor program, as well as the total number of Subsys prescriptions written each year by each doctor so identified.
8. With respect to Subsys, did Insys ever make use of sales quotas, base employee remuneration on sales, or utilize any other sales-based incentive program for its employees?
 - a. If so, please provide the year(s) any such policies were in effect, along with copies of such policies and the amount Insys paid its employees, broken down by year, under any such policies or programs.
 - b. Does Insys currently have any such program or policy in effect?
9. What is Insys' current practice for determining to which practitioners it markets Subsys? Has this always been the company's practice? If not, when and how did the company's practice change?
10. Does Insys plan to continue to provide funding to outside organizations and finance grants related to pain management? If so, what steps will Insys take to ensure that no conflicts of interest arise from such awards?
 - a. Please provide all policies and procedures referring or relating to monetary support to outside organizations or grants since January 1, 2012.
11. Please provide all copies of the suspicious order reports, if any, Insys submitted to the DEA regarding orders placed for Subsys between January 1, 2012, and August 2, 2018.
12. Please provide a list of all wholesale distributors, physicians, or pharmacies that Insys terminated as customers since January 1, 2012.
13. Please provide all memoranda of meetings since January 1, 2012, between Insys and DEA related to Subsys abuse.
14. Please provide all memoranda of meetings since January 1, 2012, between Insys and FDA related to Subsys abuse.
15. Please provide copies of all adverse event reports, if any, since January 1, 2012, related to Subsys that Insys submitted to FDA.
16. Please provide all documents since January 1, 2012, related to any analysis prepared for Insys of adverse event reports related to Subsys.

An attachment to this letter provides additional information about responding to the Committee's request. If you have any questions, please contact Alan Slobodin, Christopher Santini or Andrea Noble of the Majority staff at (202) 225-2927 or Kevin McAloon of the Minority staff at (202) 225-3641. Thank you for your prompt attention to this matter.


Sincerely,



Greg Walden
Chairman



Frank Pallone, Jr.
Ranking Member



Gregg Harper
Chairman
Subcommittee on Oversight
and Investigations



Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations



Morgan H. Griffin
Vice Chairman
Subcommittee on Oversight
and Investigations



Kathy Castor
Vice Ranking Member

Attachment