

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	Criminal No.
v.	)	
	)	
INSYS THERAPEUTICS, INC.,	)	
	)	
	)	
Defendant	)	

DEFERRED PROSECUTION AGREEMENT

The United States Attorney's Office, by its attorney, Andrew E. Lelling, United States Attorney for the District of Massachusetts (the "United States") and Defendant, Insys Therapeutics, Inc., ("Insys"), a Delaware corporation with its principal place of business in Chandler, Arizona, hereby enter into the following Deferred Prosecution Agreement ("Agreement"):

1. **Charges:** Insys consents to the filing in the United States District Court for the District of Massachusetts of an Information charging it and its wholly-owned operating subsidiary, Insys Pharma, Inc. ("Insys Pharma"), with five counts of mail fraud, in violation of Title 18, United States Code, Section 1341. Specifically, the Information charges Insys with having devised and intending to devise a scheme and artifice to defraud, and for obtaining money and property by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing such scheme and artifice and attempting to do so, depositing and causing to be deposited matters and things, to wit, checks to practitioners, to be sent and delivered by the United States Postal Service and private and commercial interstate carriers as set forth below:

<u>Count</u>	<u>Check Issue Date</u>	<u>Description of Mailing</u>
1	11/21/2013	Check No. 801 for \$1,200 issued by Defendant
2	11/25/2013	Check No. 935 for \$2,000 issued by Defendant
3	01/23/2014	Check No. 1550 for \$1,000 issued by Defendant
4	03/20/2014	Check No. 2408 for \$2,000 issued by Defendant
5	08/04/2014	Check No. 25662 for \$1,000 issued by Defendant

Insys knowingly waives its right to indictment on these charges and agrees to venue of the case in the District of Massachusetts. Insys further knowingly waives any applicable statute of limitations and any legal or procedural defects in the Information.

2. **Acceptance of Responsibility:** Insys accepts and acknowledges responsibility for its conduct and that of its employees as set forth in the Statement of Facts attached hereto as Exhibit A and incorporated herein by reference (the "Statement of Facts"). If the United States, pursuant to Paragraph 8, initiates a prosecution that is deferred by this Agreement against Insys, Insys agrees that it will neither contest the admissibility of the Statement of Facts, nor contradict in any such proceeding the facts contained within the Statement of Facts. Insys waives and forgoes any right under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, or any other rule, that any statements made by or on behalf of Insys prior or subsequent to this Agreement, or any leads derived therefrom, shall be inadmissible, suppressed, or otherwise excluded from evidence at any judicial proceeding arising from this Agreement.

3. **Subsidiary Plea:** Insys's wholly-owned operating subsidiary, Insys Pharma, Inc. ("Insys Pharma"), will plead guilty in the United States District Court for the District of Massachusetts to all five counts of mail fraud set forth in the Information (the "Plea Agreement").

4. **Forfeiture Amount:** As a result of Insys's conduct, including the conduct set forth in the Statement of Facts, the parties agree that the United States could institute a civil and/or criminal forfeiture action against certain funds held by Insys and that such funds would be forfeitable pursuant to Title 18, United States Code, Section 981 and Title 28, United States Code, Section 2461(c). Insys hereby acknowledges that at least \$28,000,000 were proceeds of the mail fraud scheme described in the Statement of Facts, and that such conduct violated Title 18, United States Code, Section 1341. As part of the Plea Agreement, Insys Pharma agrees to pay to the United States the sum of \$30,000,000: \$28,000,000 in forfeiture (the "Forfeiture Amount") and a fine of \$2,000,000. Insys hereby agrees it shall be jointly and severally liable with Insys Pharma for the Forfeiture Amount. Insys further agrees that the Forfeiture Amount shall be considered substitute *res* for the purpose of forfeiture to the United States pursuant to Title 18, United States Code, Section 981, and Title 28, United States Code, Section 2461(c), and Insys releases any and all claims it may have to such funds.

5. **Forfeiture Payments:** Insys agrees that the Forfeiture Amount plus any associated transfer fees will be paid by Insys according to the following schedule:

- \$3 million, plus interest, shall be due within ten days of the Insys Pharma sentencing.
- \$5 million, plus interest, shall be due one year after the Insys Pharma sentencing date.

- \$5 million, plus interest, shall be due two years after the Insys Pharma sentencing date.
- \$5 million, plus interest, shall be due three years after the Insys Pharma sentencing date.
- \$5 million, plus interest, shall be due four years after the Insys Pharma sentencing date.
- \$5 million, plus interest, shall be due five years after the Insys Pharma sentencing date.

If Insys fails to make any payments due in connection with the Forfeiture amount for any reason, the Forfeiture Amount shall become immediately due and payable.

6. **Deferral of Prosecution:** In consideration of Insys's remedial actions to date and its willingness to: (a) acknowledge and accept responsibility for its actions; (b) have its subsidiary Insys Pharma plead guilty to the crimes charged in the Information; (c) cooperate in the criminal investigation in the District of Massachusetts; (d) terminate the conduct set forth in the Statement of Facts; (e) continue its cooperation with the United States as stated in Paragraph 7; (f) demonstrate its future good conduct and full compliance with federal law; and (g) comply with the obligations set forth herein, including in Paragraphs 4 through 5:

a. *Deferred Prosecution:* The United States agrees that it will recommend to the Court that prosecution of Insys on the Information be deferred for the duration of this Agreement and shall not seek to prosecute Insys, its subsidiaries, affiliates, successors, or assigns for any act within the scope of, or related to, the Statement of Facts, the Information, the subject of the criminal investigation in the District of Massachusetts, or facts currently known to the United States regarding sales, promotion and marketing practices of Insys during the term of the Agreement, with the exception of the Plea Agreement outlined in Paragraph 3.



b. *The Term:* This Agreement is effective for a period beginning on the date on which the Information is filed, and ending 60 months from that date (the "Term"). Insys expressly waives any and all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution for the Term of this Agreement. Moreover, Insys agrees: (1) to join the Government in seeking to exclude, pursuant to Title 18, United States Code, Section 3161(h)(2), the Term of this Agreement from the time within which trial of the offense charged in the Information must commence, for the purpose of allowing Insys to demonstrate its good conduct; and (2) to waive any rights to a speedy trial under Federal Rule of Criminal Procedure 48(b).

c. *Extension of the Term:* Insys agrees that, in the event the United States determines in its sole discretion that Insys has knowingly and materially violated any provision of this Agreement, an extension of the Term of the Agreement may be imposed by the United States, in its sole discretion, for up to an additional 12-month period, without prejudice to the right of the United States to proceed as provided in Paragraph 8 below. Any extension of the Agreement extends all terms of the Agreement.

d. *Completion of the Term:* The United States shall, if Insys is in full compliance with all of its obligations under this Agreement, within thirty (30) days of the expiration of the Term of this Agreement set forth above in Paragraphs 6(b) and (c), or earlier at the discretion of the United States, seek dismissal with prejudice of the Information filed against Insys pursuant to Paragraph 1, and this Agreement shall expire and be of no further force or effect. The United States further agrees not to file charges in the future against Insys relating to the Statement of Facts, the Information, the subject of

the criminal investigation in the District of Massachusetts, or facts currently known to the United States regarding sales, promotion and marketing practices of Insys.

7. **Cooperation and Compliance:** As part of this Agreement, Insys agrees that it shall comply with the following terms:

a. *Cooperation:* Insys agrees to cooperate fully with the United States, and any agency thereof, regarding any matter of which Insys has knowledge or information in any federal investigation, trial, or other proceeding of its current and former officers, agents, and employees, on the subject matter arising from conduct: (1) covered by the Information and Statement of Facts; (2) that was the subject of the criminal investigation; or (3) currently known to the United States regarding sales, promotion, and marketing practices in connection with its drug Subsys. As part of its cooperation, Insys will provide documents, records, and/or other tangible evidence not protected by any applicable privilege or protection regarding matters about which the United States may inquire and identify knowledgeable directors, officers, employees, agents, and/or representatives to provide information, materials, and testimony. Insys will maintain and expeditiously produce any non-privileged documents, records, and/or other tangible evidence requested by the United States in connection with any federal investigation, trial, or other proceeding of its current and former owners, officers, agents, and employees.

b. *Employees:* Insys will use its good faith efforts to make available its current and former directors, officers, employees, consultants, representatives, and agents when requested by the United States to provide additional information and materials concerning this investigation or related inquiries, to testify (including sworn testimony before a grand jury or in a judicial proceeding), and to be interviewed by law enforcement

authorities provided that the testimony sought is not protected by any applicable privilege or protection.

c. *Government Use of Information:* The United States will not use, in any criminal or civil case, any self-incriminating information provided by Insys pursuant to its cooperation that was not previously known to the United States, or any information directly or indirectly derived therefrom, except in (i) a prosecution or other proceeding for perjury, making a false statement, or obstruction of justice; (ii) a prosecution or other proceeding for any act of violence or act of terrorism; (iii) a prosecution or other proceeding relating to any violation of the Internal Revenue Code; (iv) any prosecution or other proceeding permitted herein as a result of failure by Insys to comply with the terms of this Agreement.

d. *Evidence Sharing:* With respect to any information, testimony, documents, records, or other tangible evidence provided to the United States pursuant to this Agreement, Insys consents to any and all disclosures, subject to applicable law and regulations, to other governmental authorities of such materials that the United States, in its sole discretion, shall deem appropriate.

e. *Legal Compliance:* Insys agrees to fully comply with federal law with respect to the marketing, selling, and distribution of its drug products, including the Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 331, *et seq.*; acts involving federal health care programs, Title 42, United States Code, Sections 1320a-7(a) and 1320a-7(b); and, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Title 42, United States Code, Sections 1320d-6(a) and 6(b).



f. *Compliance Program:* Insys agrees it will continue to implement compliance procedures and training designed to ensure that all of Insys's directors, officers, employees, agents, or representatives fully comply with federal laws and regulations related to the marketing, selling, and distribution of its drug products.

g. *Corporate Integrity Agreement:* Insys agrees to abide by any and all requirements of any Corporate Integrity Agreement and Conditional Exclusion Release by and between Insys and the Office of Inspector General of the United States Department of Health and Human Services regarding remedial measures or other required actions related to the conduct outlined in the Statement of Facts.

h. *Civil Settlement:* Insys agrees to abide by any and all requirements of any civil settlement reached with the United States Department of Justice of certain civil claims related to the conduct outlined in the Statement of Facts regarding remedial measures or other required actions related to the conduct outlined in the Statement of Facts.

i. *Notification:* Insys agrees to notify the United States of any governmental criminal, civil, administrative, or regulatory investigation of or action against Insys or its current directors, officers, employees, agents, or representatives related to Insys's compliance with federal laws and regulations related to the marketing, selling, and distribution of its drug products.

8. **Breach of the Agreement:** If the United States determines that Insys has committed a willful and material breach of any provision of this Agreement, the United States shall provide written notice to Insys's counsel of the alleged breach and provide Insys with a two-week period from the date of receipt of said notice, or longer at the discretion of the United States, in which to make a presentation to the United States to



demonstrate that no breach has occurred or, to the extent applicable, that the breach is not willful or material, or has been cured. The United States agrees to consider such explanation in determining whether to institute a prosecution of Insys. The parties expressly understand and agree that if Insys fails to make the above-noted presentation within such time period, it shall be presumed that Insys is in willful and material breach of this Agreement. The parties further understand and agree that the United States' exercise of discretion under this paragraph is not subject to review in any court or tribunal outside the Department of Justice and the United States Attorney's Office for the District of Massachusetts. In the event of a breach of this Agreement that results in a prosecution, such prosecution may be premised upon any information provided by or on behalf of Insys to the United States or any investigative agencies, whether prior to or subsequent to this Agreement, and/or any leads derived from such information, including the attached Statement of Facts, unless otherwise agreed to by the United States and Insys in writing at the time the information was provided to the United States.

9. **Waiver of Rights:** Insys hereby further expressly agrees that within six (6) months of a willful and material breach of this Agreement by Insys, any violations of federal law that were not time-barred by the applicable statute of limitations as of the date of this Agreement, including any claims covered by the tolling agreement signed by the parties, and that: (a) relate to the Statement of Facts; or (b) were hereinafter discovered by the United States, may in the sole discretion of the United States be charged against Insys, notwithstanding the provisions or expiration of any applicable statute of limitations. In the event of a willful and material breach, Insys expressly waives: any challenges to the venue or jurisdiction of the United States District Court for the District of Massachusetts; any

right to be charged by an Indictment returned by a grand jury; and agrees to be prosecuted on the Information filed in this matter or a superseding Information arising from the facts presented in the Statement of Facts.

10. **Requirement to Obey the Law:** If the United States determines during the term of this Agreement that Insys has committed any federal crime after the date of the signing of this Agreement, Insys shall, in the sole discretion of the United States, thereafter be subject to prosecution for any federal crimes of which the United States has knowledge, including but not limited to the conduct described in the Statement of Facts. The discovery by the United States of any purely historical criminal conduct that did not take place during the term of the Agreement will not constitute a breach of this provision.

11. **Parties Bound by the Agreement:** This Agreement and all provisions set forth herein bind Insys, which agrees to ensure that its wholly-owned subsidiaries comply with the requirements and obligations set forth in this Agreement. It is further understood that this Agreement and all provisions set forth herein are binding on the United States. It is further understood that this Agreement does not bind any federal agencies, or any state or local authorities, although the United States will bring the cooperation of Insys and its compliance with its other obligations under this Agreement to the attention of federal, state, or local prosecuting offices or regulatory agencies, if requested by Insys or its attorneys. Nothing in this Agreement restricts in any way the ability of the United States, any other federal department or agency, or any state or local government from proceeding criminally, civilly, or administratively, against any current or former directors, officers, employees, agents, or representatives of Insys or against any other entities or individuals. The parties to this Agreement intend that the Agreement does not confer or provide any benefits,

privileges, immunities, or rights to any other individual or entity other than the parties hereto.

12. **Severability:** With the exception of Paragraph 17 of the Agreement titled “Bankruptcy and No Successor Liability,” any provision of this Agreement which is prohibited or unenforceable shall be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof.

13. **Public Statements:** Insys expressly agrees that it shall not cause to be made, through its attorneys, board of directors, agents, officers, employees, consultants or authorized agents (including, contractors, subcontractors, or representatives), including any person or entity controlled by any of them, any public statement contradicting the acceptance of responsibility by Insys set forth above or the facts described in the Statement of Facts. Any such public statement by Insys, its attorneys, board of directors, agents, officers, employees, consultants, contractors, subcontractors, or representatives, including any person or entity controlled by any of them, shall, subject to the cure rights of Insys set forth below, constitute a willful and material breach of this Agreement as governed by Paragraph 8 of this Agreement, and Insys would thereafter be subject to prosecution pursuant to the terms of this Agreement. The decision of whether any public statement by any such person contradicting the acceptance of responsibility by Insys set forth above or the facts described in the Statement of Facts will be imputed to Insys, for the purpose of determining whether Insys has breached this Agreement, shall be in the sole discretion of the United States. If the United States determines that Insys has made a public statement contradicting its acceptance of responsibility or any fact contained in the Statement of Facts, the USAO shall so notify Insys. Upon the United States’ notification to Insys of a



public statement by any such person that in whole or in part contradicts the acceptance of responsibility by Insys set forth above or the facts described in the Statement of Facts, Insys may avoid breach of this Agreement by publicly repudiating such statement within 5 business days after notification by the United States. Insys shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of Insys in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of Insys. Subject to this paragraph, Insys retains the ability to provide information or take legal positions in litigation or other regulatory proceedings in which the United States is not a party.

14. Insys agrees that if it or any of its direct or indirect subsidiaries or affiliates issues a press release or holds any press conference in connection with this Agreement, Insys shall first consult the United States to determine: (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the United States and Insys; and (b) whether the United States has any objection to the release.

15. **Conduct Covered by Agreement:** It is further understood that this Agreement does not relate to or cover any conduct by Insys other than for any act within the scope of the Statement of Facts, the Information, the subject of the criminal investigation in the District of Massachusetts, or facts currently known to the United States regarding sales, promotion and marketing practices of Insys.



16. **Public Filing:** Insys and the United States agree that this Agreement (and its attachments) and an Order deferring prosecution shall be publicly filed in the United States District Court for the District of Massachusetts.

17. **Bankruptcy and No Successor Liability:** Notwithstanding anything to the contrary in the Agreement, (i) the filing of a petition under the Bankruptcy Code by Insys or Insys Pharma shall not constitute a breach, default, failure to perform, or violation of the Agreement, (ii) the failure of Insys or Insys Pharma to make any payments or perform any other obligation hereunder after becoming a debtor under the Bankruptcy Code shall not constitute a breach, default, failure to perform, or violation of the Agreement, (iii) nothing in the Agreement shall be binding on, or shall be deemed to apply in any matter whatsoever to, any successor to Insys or Insys Pharma or any of their respective affiliates, including, but not limited to, any reorganized debtor under a chapter 11 plan under the Bankruptcy Code or a purchaser of any of Defendant's or Insys's or their affiliates' assets whether under the Bankruptcy Code or otherwise (a "Successor"), and (iv) the United States agrees that it shall not take any action against a Successor based on acts or omissions committed by Insys or Insys Pharma or any of their affiliates prior to the date hereof. Notwithstanding anything contained in this paragraph, the filing of a petition under the Bankruptcy Code does not relieve Insys of its obligation to pay the Forfeiture Amount under this Agreement. If Insys fails to make any payments due in connection with the Forfeiture Amount for any reason, the Forfeiture Amount shall become immediately due and payable as stated in Paragraph 5. Nothing contained in this paragraph shall be construed to prohibit the operation of the basic tenet of the Bankruptcy Code that a bankruptcy filing operates as the

automatic acceleration of the principal amount of all claims against a debtor. This paragraph shall survive termination of this Agreement.

18. **Complete Agreement and Notice:** This Agreement sets forth all the terms of the Agreement between Insys and the United States. There are no promises, agreements, or conditions that have been entered into other than those expressly set forth in this Agreement, and none shall be entered into and/or be binding upon Insys or the United States unless signed by the United States, Insys's attorneys, and a duly authorized representative of Insys. This Agreement supersedes any prior promises, agreements, or conditions between Insys and the United States. Insys agrees that it has the full legal right, power, and authority to enter into and perform all of its obligations under this Agreement and it agrees to abide by all terms and obligations of this Agreement as described herein.

19. Any notice, certification, resolution, or report to the United States under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, to:

Chief, Health Care Fraud Unit  
U.S. Attorney's Office for the District of Massachusetts  
John Joseph Moakley Federal Courthouse  
One Courthouse Way, Suite 9200  
Boston, MA 02210

20. Any notice to Insys under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Insys Therapeutics, Inc.

Attention: General Counsel  
1333 South Spectrum Blvd  
Suite 100  
Chandler, AZ 85286

Geoffrey E. Hobart  
Covington & Burling LLP

[REDACTED]  
[REDACTED]  
[REDACTED]

21. Notice shall be effective upon actual receipt by the United States or Insys.
22. This Agreement, to become effective, must be signed by all of the parties listed below. No promises, agreements, terms, or conditions other than those set forth in this Agreement will be effective unless memorialized in writing and signed by all parties or confirmed on the record before the Court.

**ACKNOWLEDGMENT ON BEHALF OF INSYS THERAPEUTICS, INC.**

I, Andrece Housley, Chief Financial Officer, the duly authorized representative of Insys Therapeutics, Inc., hereby expressly acknowledge the following: (1) that I have read this entire Agreement as well as the other documents filed herewith in conjunction with this Agreement, including the Information and Statement of Facts; (2) that I have had an opportunity to discuss this Agreement fully and freely with Insys's counsel, Covington & Burling LLP; (3) that Insys fully and completely understands each and every one of the terms of this Agreement; (4) that Insys is fully satisfied with the advice and representation provided to it by its counsel, Covington & Burling LLP; (5) that I am authorized, on behalf of Insys, to enter into this Agreement; and (6) that Insys has signed this Agreement knowingly and voluntarily.

Insys Therapeutics, Inc.

DATE

6/5/19


Andrece Housley  
Chief Financial Officer  
Insys Therapeutics, Inc.



**ACKNOWLEDGMENT BY COUNSEL OF INSYS THERAPEUTICS, INC.**

I, Geoffrey E. Hobart, the attorney representing Insys Therapeutics, Inc., hereby expressly acknowledge the following: (1) that I have reviewed and discussed this Agreement with my client; (2) that I have explained fully each one of the terms of the Agreement to my client; (3) that I have answered fully each and every question put to me by my client regarding the Agreement; and (4) that I believe my client fully and completely understands all of the Agreement's terms.


6/4/2019  
DATE

  
Geoffrey E. Hobart  
Covington & Burling LLP

**ON BEHALF OF THE GOVERNMENT**

ANDREW E. LELLING  
UNITED STATES ATTORNEY

6/4/19  
DATE

  
Amanda P.M. Strachan  
Assistant U.S. Attorney

**STATEMENT OF FACTS FOR INSYS THERAPEUTICS, INC. DEFERRED  
PROSECUTION AGREEMENT AND INSYS PHARMA, INC. PLEA AGREEMENT**

Defendant, Insys Therapeutics, Inc., its agents and subsidiaries, (collectively “Insys”) hereby agrees and stipulates that at all times relevant to the Information pending against it in the United States District Court for the District of Massachusetts, in *United States v. Insys Therapeutics, Inc.*, et al., Criminal No. 19-cr-10191-RWZ, the following is true and accurate:

1. Insys is a Delaware corporation that maintains a principal place of business in Chandler, Arizona. At all times relevant to the Information, Insys Pharma, Inc. was a wholly owned subsidiary of Insys Therapeutics, Inc. and was its main operating subsidiary.

2. Insys developed and owns a drug called SUBSYS® (hereinafter “Subsys”), a spray formulation of fentanyl to be applied under a patient’s tongue (also called a sublingual spray). The United States Food and Drug Administration (“FDA”) approved Subsys in or about January 2012 for the management of breakthrough pain in patients 18 years of age or older with cancer who are already receiving and who are already tolerant to opioid therapy for their underlying persistent cancer pain. Subsys is in a category of drugs called Transmucosal Immediate Release Fentanyl (“TIRF”) products, which includes other fentanyl-based rapid onset opioids that competed with Subsys.

3. From in or about March 2012 to the present, Insys marketed and sold Subsys in interstate commerce, including in the District of Massachusetts.

4. Subsys could only be prescribed by a licensed medical practitioner who was registered with the DEA and able to prescribe opioids in the usual course of professional practice for a legitimate medical purpose.

5. Market demand for Subsys was driven in large part by the practitioners who wrote prescriptions for their patients. Practitioners willing to write prescriptions for Subsys had a number of competing medications from which to choose. In addition to other brand name TIRF drugs, practitioners could also prescribe a generic TIRF medicine.

6. Depending on the dosage and number of units prescribed, a prescription for Subsys often cost thousands of dollars each month. Most patients relied on commercial insurance and/or publicly funded insurance, including Medicare and Medicaid, to subsidize the cost of taking Subsys.

7. Insys knew that insurers would not authorize payment for Subsys if the prescription was written in exchange for a bribe, or kickback, and was not medically necessary. In general, patients had to have a specific medical diagnosis before the insurer, including Medicare, would authorize payment for Subsys. Many insurers would not pay for Subsys until the patient had tried and failed certain other preferred medications.

8. Beginning in August 2012 and continuing until June 2015, Insys paid bribes to certain practitioners as part of a scheme to defraud patients and insurers, including Medicare. Insys paid the bribes in order to induce certain practitioners to write unnecessary Subsys prescriptions.

9. Specifically, Insys used pharmacy data acquired from third parties to identify practitioners who either prescribed high volumes of rapid-onset opioids or who had demonstrated a capacity to prescribe large volumes of rapid-onset opioids.

10. Insys paid bribes to certain practitioners to prescribe Subsys through its Speaker Program. The Speaker Program was a marketing program that purported to increase brand awareness of Subsys by sponsoring peer-to-peer educational lunches and dinners. Purportedly in



exchange for a practitioner educating other prescribers about Subsys, Insys agreed to pay the speaker a fee, also referred to as an "honoraria," for each speaking event.

11. The Speaker Program included certain speaker practitioners who had the potential to prescribe Subsys, and was used to induce them to write more, medically unnecessary prescriptions in exchange for payment of money by Insys in the form of honoraria. Insys fashioned the payments to these certain practitioners as speaker fees, or honoraria, in order to hide the fact that they were in fact bribes paid to induce certain practitioners to write Subsys prescriptions.

12. Rather than educational gatherings, Speaker Program events often did not involve any education or presentations about the drug. Frequently, Speaker Program events did not have attendees who were licensed to prescribe Subsys, but rather included support staff employed by the speaker. Many speaker events had no attendees at all. When this occurred, Insys's sales representatives were directed by management to falsify the names of attendees and their signatures on sign-in sheets. Sham Speaker Program events occurred at restaurants within the District of Massachusetts and elsewhere, and functioned as bribes in the form of free dinners for speakers, friends, and, at times, family, and served as a vehicle to pay a bribe to the speaker in the disguised form of an honoraria.

13. In a number of instances, high-level officers, directors, executives, managers, and the executive chairman of Insys's Board of Directors expressly required a practitioner to write a minimum number of Subsys prescriptions, write prescriptions at a minimum dosage, and write prescriptions for a minimum number of units of Subsys, in order for the speaker to continue receiving the bribe, that is, the so-called honoraria, for sham events. For all speakers during certain periods, Insys tracked its so-called return on investment: it measured the effect of the payments, which functioned as bribes to certain practitioners, on the speaker's prescribing habits, and,

correspondingly, the effect of the bribes on the revenue that each bribed speaker generated for it. If a speaker failed to meet the minimum prescription and return on investment requirements, Insys took Speaker Program payments away from practitioners, or reduced the total amount of Speaker Program payments paid to practitioners, unless and until the practitioner wrote a satisfactory number of new prescriptions, or raised the dosage and volume of existing Subsys prescriptions. Each new prescription, refill, or existing prescription written for a higher dose of Subsys generated greater income to Insys.

14. Insys agreed with certain practitioners, including but not limited to certain practitioners in New Hampshire and Illinois, to conduct Speaker Programs, which were solely a mechanism to pay bribes to these practitioners for prescribing Subsys.

15. One such practitioner targeted by Insys and to whom Insys, through certain employees, offered bribes was a physician's assistant ("P.A.") who practiced with a pain clinic based in Somersworth, New Hampshire.

16. During the first year that Subsys was on the market, the P.A. did not write any Subsys prescriptions. In or about April 2013, a sales representative working on behalf of Insys catered a lunch at the P.A.'s pain clinic. In or about June 2013, the P.A. wrote his first prescription for Subsys. The sales representative encouraged the P.A. to submit his resume for consideration in the Insys Speaker Program, which the P.A. did on the same day.

17. Approximately one month later, Insys approved the P.A. as a speaker on the recommendation of Insys's then Vice President of Sales.

18. The P.A. and Insys's sales representative frequently discussed new patients for whom the P.A. could prescribe Subsys.

19. On or about November 14, 2013, the sales representative arranged a Speaker Program event at a restaurant in Portsmouth, New Hampshire at which the P.A. was the purported Subsys speaker. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signature of physician's assistant S.T. was forged on a sign-in sheet to make it appear S.T. was present at the dinner when he was not.

20. On or about November 21, 2013, Insys issued check number 801 to the P.A. in the amount of \$1,200 as payment in part for the November 14, 2013 Speaker Program event.

21. On or about November 19, 2013, the sales representative arranged a Speaker Program event at a second restaurant in Portsmouth, New Hampshire at which the P.A. was the purported Subsys speaker. No other practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signature of nurse practitioner K.T. was forged on a sign-in sheet to make it appear K.T. was present at the dinner when she was not.

22. On or about November 25, 2013, Insys issued check number 935 to the P.A. in the amount of \$2,000 as payment in part for the November 19, 2013 Speaker Program event.

23. On or about January 13, 2014, the sales representative arranged a Speaker Program event at a restaurant in Boston, Massachusetts at which the P.A. purportedly spoke about Subsys. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signatures of physician's assistant L.C. and medical assistant P.M. were forged on a sign-in sheet to make it appear they were present at the dinner when they were not.



24. Insys issued check number 1550 to the P.A. in the amount of \$1,000 as payment in part for the January 13, 2014 Speaker Program event.

25. On March 11, 2014, Insys arranged a Speaker Program event at a second restaurant in Boston, Massachusetts at which the P.A. was the purported speaker. No other medical professionals who could prescribe Subsys were present, and the P.A. did not make a presentation about the drug. The only attendees at the dinner were the P.A., a relative of the P.A., and Insys's sales representative. The signature of physician's assistant L.C. was forged on a sign-in sheet to make it appear she was present at the dinner when she was not.

26. On or about March 20, 2014, Insys issued check number 2408 to the P.A. in the amount of \$2,000 as payment in part for the March 11, 2014 Speaker Program event.

27. On July 28, 2014, Insys arranged a Speaker Program event at a third restaurant in Portsmouth, New Hampshire at which the P.A. was the purported speaker. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signatures of S.M. and T.C. were forged on a sign-in-sheet to make it appear they were present at the dinner when they were not.

28. On or about August 4, 2014, Insys's agent, on behalf of Insys, issued check number 25662 to the P.A. in the amount of \$1,000 as payment in part for the July 28, 2014 Speaker Program event.

29. Between August 2013 and October 2014, Insys's employees invited the P.A. to approximately 44 Speaker Program events at various restaurants and other locations. For each of the events, the P.A. was paid a fee of between \$500 and \$2,000. Insys paid the P.A. approximately \$44,000 for purportedly speaking about Subsys at Speaker Program events when, in fact, he had



not. Instead, they were bribes paid by Insys to the P.A. for the purpose of inducing the P.A. to write medically unnecessary Subsys prescriptions.

30. Had the insurers known that Insys paid bribes to the P.A. that caused the P.A. to write medically unnecessary Subsys prescriptions, the insurers would not have authorized payment for those prescriptions.

31. Insys caused each of the bribes in the form of the above-described honoraria checks to be sent and delivered in interstate commerce by the United States Postal Service and by private and commercial interstate carriers.

32. The payments made by Insys to the P.A. for sham Speaker Program events, as described in this Statement of Facts, violated Title 18, United States Code, Section 1341.

33. Insys agreed with and paid certain other practitioners, including a practitioner in Illinois, to conduct sham Speaker Program events that were solely to induce this practitioner and certain others to prescribe Subsys, in violation of Title 18, United States Code, Section 1341.

34. Insys's net revenues were approximately \$95.8 million in 2013 due to sales of Subsys. That amount rose to approximately \$219.5 million in 2014.