

**THE STATE OF NEW HAMPSHIRE  
MERRIMACK, SS SUPERIOR COURT**

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**IN THE MATTER OF:  
INSYS THERAPEUTICS, INC.**

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**ASSURANCE OF DISCONTINUANCE**

NOW COMES the State of New Hampshire, by and through the Office of the Attorney General, (“the State”) and Insys Therapeutics, Inc. (“Insys”) and enter into the following Assurance of Discontinuance (“the Assurance”) pursuant to NH RSA358-A:7.

**PARTIES**

1. Joseph A. Foster is the Attorney General for the State of New Hampshire and is authorized to investigate allegations of unfair or deceptive trade practices under New Hampshire’s Consumer Protection Act, NH RSA 358-A, and to enter into this Assurance of Discontinuance in accordance with NH RSA 358-A:7

2. Insys Therapeutics, Inc. (“Insys”) is a Delaware corporation headquartered in Chandler, Arizona. Insys is the manufacturer and provider of the opioid pain medication, Subsys®.

**INTRODUCTION**

3. On or about December 8, 2015, the State issued a subpoena to Insys in connection with an investigation into the commercial practices of Insys with respect to the marketing of Subsys in New Hampshire.

4. Insys produced documents in response to the subpoena and otherwise cooperated with the State’s investigation.

5. As a result of its investigation, the State has alleged, among other allegations, that Insys engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce in New Hampshire in violation of the New Hampshire Consumer Protection Act, NH RSA 358-A (the "Allegations"). The Allegations appear in the succeeding section of this Assurance.

6. Insys disputes and does not admit any of the alleged facts and conclusions of law set forth in the paragraphs below or any liability related thereto.

### **ATTORNEY GENERAL ALLEGATIONS**

7. Subsys® (fentanyl) sublingual spray is an opioid pain medication classified as a Schedule II controlled substance and is much more potent than morphine.

8. In January 2012, the FDA approved Subsys® for the management of breakthrough cancer pain in patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

9. Subsys® is subject to an FDA-required program (Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy or "TIRF REMS" program) that imposes rigorous controls on prescribing and dispensing and seeks to mitigate the risk of misuse, addiction, and overdose.

10. According to available data, New Hampshire patients received more than 800 Subsys® prescriptions and more than 100,000 units of Subsys® during 2013 and 2014. Based on this data, during this period, New Hampshire patients represented the second most prescriptions of Subsys® per capita in the country.

11. The majority of prescriptions to New Hampshire patients during 2013 and 2014 were written by Christopher Clough ("Clough"), a physician assistant working at PainCare, a pain clinic located in Somersworth, New Hampshire.

12. In 2013, a sales representative, who no longer works for Insys, began calling on Clough to encourage him to prescribe Subsys®.

13. On or about August 8, 2013, Clough signed a Speaker Agreement with Insys and joined the Insys Speaker Bureau. Programs conducted by speakers within the Insys Speaker Bureau were referred to as “ISPs.”

14. Clough became a frequent speaker within the Insys Speaker Bureau. A former Insys District Sales Manager, who was recently arrested on federal anti-kickback charges described Clough in an email as a “crucial part of [Insys’] speakers bureau.”

15. Clough spoke at 39 programs between August 8, 2013 and October 16, 2014. Based upon the investigation by the State of New Hampshire, the State alleges that some of the programs were attended by PainCare staff, and did not include anyone who could actually prescribe and despite that fact that many of the programs had repeat attendees, every program listed the same topic. The State also alleges that many of these speaker programs were sham events that were mere social gatherings at high-end restaurants also attended by Clough’s friends and members of the office staff of PainCare.

16. Between August 8, 2013 and November 2014, Insys paid Clough a total of \$44,000 for speaking at nearly 40 programs on behalf of the company as he quickly became the highest prescriber of Subsys® in New Hampshire and one of the top Subsys® prescribers in the country. In a two year span, Clough wrote more than 760 Subsys® prescriptions. During 2013 and 2014, Clough was responsible for 84% of the Subsys® prescriptions written in New Hampshire. On August 11, 2014, Clough received a notice of hearing from the New Hampshire Board of Medicine alleging inappropriate prescribing practices. Within days of that notice, Clough was in communication with Insys and by September of that year, Clough informed Insys

that he was unwilling to participate further in the Speaker Bureau. In November 2014, Clough was removed from the Insys Speaker Bureau.

17. In 2015, the New Hampshire Board of Medicine (“Board”) banned Clough from managing chronic pain, prescribing schedule II-IV drugs, and performing pain procedures. On December 8, 2016, the Board revoked his license to work as a physician assistant in the State of New Hampshire.

18. The State alleges that the speaker programs conducted by Clough as a member of the Insys Speaker Bureau were a scheme by Insys to provide payments to induce, and in exchange for, prescribers to prescribe Subsys®.

19. At times relevant to the Allegations, Insys maintained the Insys Reimbursement Center (“IRC”) to assist patients with the prior authorization process required by many insurance companies. Generally, a prior authorization is a requirement that pre-approval be obtained from a patient’s health insurance plan before the plan will pay the cost of the prescription.

20. The State alleges that, on certain occasions, members of the IRC made misrepresentations to insurance companies about the condition of New Hampshire patients in order to obtain insurance coverage for Subsys®.

21. By purportedly engaging in the conduct alleged above related to the marketing and sale of Subsys®, the Attorney General alleges that Insys engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce in New Hampshire in violation of the New Hampshire Consumer Protection Act, NH RSA 358-A.

## RECITALS

WHEREAS, the State has concluded its investigation into certain sales and marketing practices of Insys with respect to its product Subsys®;

WHEREAS, the Attorney General is authorized to enter into this Assurance, by and through the Consumer Protection and Antitrust Bureau (" Bureau") of the New Hampshire Department of Justice, pursuant to NH RSA 358-A:4, III;

WHEREAS, the State is willing to accept the terms of this Assurance and settle all claims arising as a result of its investigation;

WHEREAS, the Parties wish to avoid the expense, uncertainty and inconvenience of potential litigation; and

WHEREAS, the Parties agree there is no just reason for delay and consent to the entry of this Assurance without a trial or adjudication of any issue of fact or law;

**NOW, THEREFORE, IT IS STIPULATED AND AGREED AS FOLLOWS:**

## COMPLIANCE OBLIGATIONS

1. In the promotion, marketing, sale and/or distribution of Subsys® in New Hampshire, Insys shall not make any written or oral claim that is false, misleading, or deceptive.

2. In the promotion, marketing, sale and/or distribution of Subsys® in New Hampshire, Insys shall not represent that Subsys® has approval, characteristics, uses, benefits or qualities that it does not have.

3. In the promotion, marketing, sale and/or distribution of Subsys® in New Hampshire, Insys agrees to adhere to each of the following requirements:

- A. Insys shall not make any written or oral promotional claim for Subsys® that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. or any regulation promulgated thereunder;
- B. Insys shall not make any written or oral promotional claim for Subsys® that violates any final written guidance documents issued by the FDA Office of Prescription Drug Promotion.
- C. Insys shall not distribute any Subsys® that is adulterated or misbranded;
- D. Insys shall comply with all other applicable federal and state laws relating to the promotion, marketing, sale and/or distribution of Subsys®, including but not limited to New Hampshire Consumer Protection Act (NH RSA 358-A) and the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and all accompanying regulations.

4. Insys agrees to maintain and comply with written policies and procedures designed to ensure that ISPs the speaker program with respect to Subsys® conforms to appropriate standards. With respect to ISPs for Subsys® conducted in New Hampshire, Insys agrees to the following limitations:

- A. A quarterly cap of two (2) and an annual cap of eight (8) ISPs that can be conducted by any one speaker;
- B. An annual cap of \$32,000 of aggregate honoraria payments that can be made to a local speaker who practices medicine in New Hampshire in connection with ISPs. An annual cap of \$45,000 of aggregate honoraria payments that can be made to a national speaker for ISPs conducted in New Hampshire;

- C. A requirement that at least 75% of all proposed program attendees be licensed physicians, nurse practitioners or physicians assistants from practice groups not affiliated with the employer of the speaker;
- D. Objective criteria used to evaluate each speaker candidate's qualifications;
- E. A cap of two (2) programs an attendee can attend each year;
- F. Routine monitoring of speaker programs;
- G. An annual third-party fair market value analysis of payment ranges for compensating health care providers in a consultant or speaking capacity;
- H. A requirement that Insys make reasonable efforts to search readily accessible public information and to reject a speaker nominee or terminate an existing speaker relationship if such searches reveal that the speaker or nominee has been sanctioned by a state medical board or has been convicted of or pleaded guilty to violating any state or federal law.

If Insys intends to make changes to any of the foregoing policies and procedures in connection with its New Hampshire speaker program, Insys must provide written notification to the Bureau of the proposed changes 30 calendar days in advance of the proposed change. If Insys does not receive a written objection within 30 calendar days of providing such notice, Insys may implement the changes outlined in the notice. On an annual basis and beginning on the effective date of this Assurance, Insys will provide the Bureau with the name of all New Hampshire speakers for the past year, the number of programs conducted by that speaker and payments made to the speaker for the programs, and the names of the individuals who attended each program. The requirements contained in this paragraph shall expire on January 1, 2020.

5. In the promotion and marketing of Subsys® in New Hampshire, Insys' sales representatives in New Hampshire shall not be assigned to detail family members about Subsys®.

6. In the promotion and marketing of Subsys® in New Hampshire, Insys shall develop and comply with a written call plan for targeting New Hampshire physicians and other New Hampshire health care providers which shall be provided to the Bureau no later May 1, 2017. Insys' written policies and procedures shall require the call plan to be reviewed at least annually by a cross-functional team consisting of representatives from at least the Business Intelligence, Medical Affairs, Marketing, Regulatory, Legal and Compliance departments. This review will evaluate the bases upon which physician specialties or other health care providers are included or excluded from the call plans with the goal of assuring that Insys' marketing and promotion at all times remains consistent with paragraph 3 of this Assurance. If Insys intends to make changes to the foregoing requirements in connection with its New Hampshire call plan, Insys will provide written notification to the Bureau of the proposed changes at least 30 calendar days in advance of the changes taking effect. If Insys does not receive a written objection within 30 calendar days of such notice, Insys may implement the changes outlined in the notice. The requirements contained in this paragraph shall expire on January 1, 2020.

7. On an annual basis and beginning on the effective date of this Assurance, Insys will provide the Bureau with the name of all New Hampshire prescribers for the immediate past year, the number of patients for whom each prescriber wrote prescriptions for Subsys®, the number of prescriptions for each patient, the dose and number of units of each prescription. Insys shall also provide the Bureau the names of all Insys sales representatives, employees and



agents operating within New Hampshire. The requirements contained in this paragraph shall expire on January 1, 2022.

### **SETTLEMENT PAYMENT**

8. Within three (3) business days of the acceptance of this Assurance by the Attorney General, Insys shall pay the sum of \$2,900,000 to the State of New Hampshire to be deposited by New Hampshire in the Consumer Protection Escrow Account in accordance with NH RSA 7:6-f as funds received by the Attorney General on behalf of the State as a result of a settlement or a claim, suit, petition or other action under NH RSA 358-A or related consumer protection statutes.

9. Within ten (10) business days of the acceptance of this Assurance by the Attorney General, Insys shall make a charitable contribution of \$500,000 directly to the New Hampshire Charitable Foundation, 37 Pleasant Street, Concord, NH 03301 (603-225-6641). All of those funds shall be used for the purpose of preventing or remediating problems related to abuse, misuse, or misprescribing of opioid drugs in New Hampshire.

10. Nothing in this Assurance shall prevent Insys from classifying and characterizing the settlement payments specified in this Assurance as Insys deems appropriate under applicable tax laws and regulations.

### **RELEASE**

11. This Assurance is a settlement of a disputed matter. It shall not be considered an admission of any violation of law, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Insys expressly denies. This Assurance does not constitute an admission or concession by Insys for any purpose, of any fact or of a violation of any law, rule, or regulation, nor does this Assurance constitute evidence of any liability, fault, or wrongdoing,

all of which Insys expressly denies. Insys enters into this Assurance for the sole purpose of resolving any claims the State may have relating to the Allegations. Insys does not admit any violation of any laws, including but not limited to the New Hampshire Consumer Protection Act, and does not admit any wrongdoing that is or could have been alleged by the State. Insys and the State agree that no provision of this Assurance operates as a penalty, forfeiture, or punishment under the Constitution of the United States, under the Constitution of the State of New Hampshire, or under any other provision of law.

12. This Assurance does not create a waiver or limit Insys' legal rights, remedies, or defenses in any other action, and does not waive or limit Insys' right to defend itself from, or make any argument in, any other matter, claim, or suit, including but not limited to any investigation or litigation relating to the subject matter or terms of this Assurance. This Assurance is made without trial or adjudication of any issue of fact or law or any finding of liability of any kind.

13. This Assurance shall be inadmissible in any case against Insys, and shall not otherwise be used to support any claim, cause of action, right asserted or request for relief of any kind in any action against Insys, except an action to enforce this Assurance. This Assurance shall not create a private cause of action or confer any right to any third party for violation of any federal or state statute or law except that the Bureau may file an action to enforce the terms of this Assurance.

14. This Assurance settles and resolves the State's investigation into the marketing, promotion and sale of Subsys®, a sublingual fentanyl spray indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. For purposes of

this Assurance, the subject matter of the State's investigation of Insys' business practices shall be referred to as the "Matters Investigated."

15. In consideration of the remedies, payments and undertakings provided for in this Assurance, and on Insys making full payment of the amounts specified in this Assurance, the State of New Hampshire releases and forever discharges, to the fullest extent permitted by law, Insys and its past and present officers, directors, shareholders, employees, representatives, agents, affiliates, parents, direct and indirect subsidiaries, joint ventures, joint venturers, and the predecessors, attorneys, assigns, successors and transferees of any of the foregoing (collectively, the "Releasees"), from the following: all civil claims, causes of action, *parens patriae* claims, damages, restitution, civil fines, costs, fees, and/or civil penalties ("Released Claims") of any kind known or unknown, that were or could have been asserted against the Releasees through the date of this Release that arise from or relate to in any way the Allegations and the Matters Investigated and which are not expressly reserved or excluded.

16. Notwithstanding any term of this Assurance, specifically reserved and excluded from the Released Claims as to any entity or person, including Releasees, are any and all of the following:

- A. Any claims arising under state tax laws;
- B. Any claims for violations of securities laws;
- C. Any criminal liability;
- D. Any civil claims unrelated to the Matters Investigated; and
- E. Any action to enforce this Assurance and subsequent, related orders or judgments.

**BREACH OF THIS ASSURANCE**

17. If the Bureau believes that Insys has failed to comply with any of the terms of this Assurance, the Bureau shall notify Respondent in writing via electronic mail to [fdelfosse@insysrx.com](mailto:fdelfosse@insysrx.com) and overnight mail addressed to INSYS, 1333 S. Spectrum Blvd., Suite 100, Chandler, AZ 852868435, Attention: General Counsel, with a copy to Respondent's attorneys by electronic mail to [ghobart@cov.com](mailto:ghobart@cov.com) and overnight mail addressed to Geoffrey E. Hobart, Covington & Burling LLP, One CityCenter, 850 Tenth Street, N.W., Washington, D.C. 20001 and any person subsequently designated by Insys to receive such notice of failure to comply. The notice shall advise Insys of the manner in which it is believed that this Assurance has been violated. Insys shall then have fifteen (15) business days from the receipt of such written notice to provide a good faith written response to the Bureau's notice of noncompliance (the "Cure Period"). The response shall include an affidavit containing, at a minimum, either:

- A. a statement explaining why Insys believes it is in compliance with the Assurance; or
- B. an explanation of how the alleged violation occurred and
  - (1) a statement that the alleged breach has been cured and how; or
  - (2) a statement that the alleged breach cannot be reasonably cured within fifteen (15) business days from receipt of the notice, but:
- C. Insys has begun to take corrective action to cure the alleged breach;

- D. Insys is pursuing such corrective action with reasonableness and due diligence; and
- E. Insys has provided the Bureau with a reasonable timetable for curing the alleged breach.

18. Nothing herein shall prevent the Bureau from agreeing in writing to provide Insys with additional time beyond the fifteen (15) business day period to respond to the notice of failure to comply.

19. This Assurance shall be filed in the Merrimack County Superior Court. This matter may be reopened by the Attorney General at any time it is in the public interest. Consistent with NH RSA 358-A:7, evidence of a violation of this Assurance shall constitute prima facie evidence of an act or practice declared to be unlawful by NH RSA 358-A in any action thereafter commenced by the Attorney General.

#### MISCELLANEOUS

20. The parties acknowledge that no other promises, representations, or agreements of any nature have been made or entered into by the parties. The parties further acknowledge that this Assurance constitutes a single and entire agreement that is not severable or divisible, except that if any provision herein is found to be legally insufficient or unenforceable, the remaining provisions shall continue in full force and effect.

21. This Assurance may not be changed, altered or modified except by written agreement of the Parties.

22. This Assurance becomes effective upon being accepted by the Attorney General.

**INSYS THERAPEUTICS, INC.**

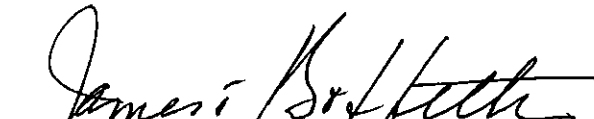


Franc Del Fosse  
General Counsel  
Insys Therapeutics, Inc.  
1333 South Spectrum Blvd, Suite 100  
Chandler, AZ 85286  
Tel.: (480) 500-3163  
E-mail: fdelfosse@insysrx.com

Dated: 01/17/2017

This Assurance is accepted on 1/18/2017 by the Attorney General.

**THE STATE OF NEW HAMPSHIRE,  
JOSEPH A. FOSTER, ATTORNEY GENERAL**



James T. Boffetti, N.H. Bar #0948  
Senior Assistant Attorney General  
Chief Consumer Protection & Antitrust Bureau  
63 Capitol Street  
Concord, NH 03301-6397  
(603) 271-3643  
james.boffetti@doj.nh.gov

**ATTORNEY GENERAL  
DEPARTMENT OF JUSTICE**

33 CAPITOL STREET  
CONCORD, NEW HAMPSHIRE 03301-6397

JOSEPH A. FOSTER  
ATTORNEY GENERAL



ANN M. RICE  
DEPUTY ATTORNEY GENERAL

January 18, 2017

Tracy A. Uhrin, Esquire  
Merrimack County Superior Court  
PO Box 2880  
Concord, NH 03302-2880

RE: In The Matter Of: Insys Therapeutics, Inc.

Dear Clerk Uhrin:

Enclosed please find the Assurance of Discontinuance signed by all parties for filing in the above-referenced case.

Thank you for your assistance in this matter.

Sincerely,

A handwritten signature in black ink that reads "James T. Boffetti".

James T. Boffetti  
Senior Assistant Attorney General  
Consumer Protection & Antitrust Bureau  
(603) 271-0302

JTB/mjt  
Enclosure

cc: Franc Del Fosse, Esquire, Insys  
Geoffrey Hobart, Esquire, Covington & Burling, LLP  
Michael D. Ramsdell, Esquire, Ramsdell Law Firm, PLLC