JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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U.S. DISTRICT COURT DISTRICT OF MASS.

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
United States of America, ex. rel. Torgny Andersson
[UNDER SEAL]

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jason W. Morgan (BBO #633802)
Drohan Tocchio & Morgan, PC
175 Derby Street, Suite 30, Hingham, MA 02043; 781-749-7200

DEFENDANTS
Insys Therapeutics, Inc.
[UNDER SEAL]

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☒ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 400 State Reapportionment
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 410 Antitrust
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 430 Banks and Banking
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 450 Commerce
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 840 Trademark	☐ 460 Deportation
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
☐ 196 Franchise				☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 895 Freedom of Information Act
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	☐ 871 IRS—Third Party 26 USC 7609	☐ 896 Arbitration
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence			☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 950 Constitutionality of State Statutes
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Federal False Claims Act, 31 U.S.C. Section 3729, et seq.
Brief description of cause:
Qui Tam case filed under Federal False Claims Act

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE _____ DOCKET NUMBER _____

DATE
10/15/2013

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA EX REL. [UNDER SEAL]	)	CA No. _____
Plaintiff,	)	ORIGINAL COMPLAINT
v.	)	
[UNDER SEAL]	)	
Defendant.	)	

FILED IN CAMERA AND UNDER SEAL

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA EX REL. TORGNY ANDERSSON Plaintiff, v. INSYS THERAPEUTICS, INC. Defendants.	)	C.A. No. _____ ORIGINAL COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 et seq.].

FILED IN CAMERA AND UNDER SEAL

JURY TRIAL DEMANDED

Qui tam plaintiff/relator Torgny Andersson, through his attorneys at Wagstaff & Cartmell LLP and Drohan Tocchio & Morgan, P.C., on behalf of the United State of America, for his Complaint against Defendant Insys Therapeutics, Inc. alleges based upon personal knowledge, communications with other Insys Therapeutics, Inc. employees, and relevant documents, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendant Insys Therapeutics, Inc. ("Insys") and/or its agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 et seq., as amended ("the FCA" or "the Act").

2. Since at least 2012, it has been Insys's practice to systematically and illegally promote its prescription drug Subsys for off-label indications. In addition to and in support of its off-label marketing efforts, Insys's sales force has offered and made unlawful financial inducements to providers to encourage them to prescribe Insys drugs. As alleged below, Insys disguises physician inducements as payments for "preceptorships" and speaking fees, among other things.

3. As a direct result of Insys's improper practices, federal and state health insurance programs including, but not limited to, Medicaid, CHAMPUS/TRICARE, CHAMPVA , Federal Employee Health Benefits Program, and other federal health care programs have been caused to pay false or fraudulent claims for reimbursement of off-label uses of the Insys prescription drugs that would not have been paid but for the defendant's illegal business practices.

4. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

5. The Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the

damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

6. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

7. Based on these provisions, qui tam plaintiff seeks through this action to recover on behalf of the United States damages and civil penalties arising from Insys's making or causing to be made false or fraudulent records, statements and/or claims in connection with its knowing off-label marketing of prescription drugs. Although Insys did not directly submit claims for prescription drugs to federal health insurance programs, it knew that its illegal off-label marketing practices and illegal inducements would cause the submission of thousands of claims to these health programs for prescriptions that were not eligible for program reimbursement.

II. PARTIES

8. Plaintiff/Relator Torgny Andersson is a resident of Jackson County, Missouri. Beginning in November 2012, Mr. Andersson was employed by Insys in a sales representative position in the Midwest.

9. Defendant Insys is a biopharmaceutical company, incorporated under the laws of the state of Delaware, and headquartered at a 444 South Ellis Street, Chandler, Arizona, 85224. Its primary business activity in the United States relates to the manufacture and/or sale of the drug at issue in this lawsuit: Subsys.

III. JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action based on 28 U.S.C. §1331, 28 U.S.C. §1367 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relator, moreover, would qualify under that section of False Claims Act as an "original source" of the allegations in this Complaint even had such a public disclosure occurred.

11. This Court has personal jurisdiction and venue over the defendant pursuant to 28 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the defendant can be found in, resides, or transacts or has transacted business in this District.

12. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the defendant can be found in and transacts or has transacted business in this District. At all times relevant to this Complaint, defendant regularly conducted substantial business within this District, maintained employees and offices in this District, and made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

IV. BACKGROUND

13. The only prescription drug manufactured and/or distributed by defendant Insys in the United States is Subsys, the drug at the center of this Complaint. Subsys is a formulation of fentanyl that is sublingually administered by using a spray delivery device for the treatment of breakthrough cancer pain. Breakthrough cancer pain is characterized by sudden intense episodes of severe pain which occur despite the presence of other pain medication in the body. Subsys

acts as a transmucosal immediate release fentanyl product and is absorbed through a mucous membrane such as the inside of the cheek.

14. Insys' activities relating to the manufacture, marketing, and sale of prescription pharmaceuticals such as Subsys are regulated by the United States Food and Drug Administration ("FDA") as alleged below. Subsys was first approved by the FDA on January 5, 2012. Subsys has been approved for breakthrough cancer pain in cancer patients who are 18 years of age or older who are already receiving and are tolerant of opioid therapy for their underlying persistent cancer pain.

15. At all times relevant to this Complaint, Insys had a sales and marketing staff dedicated to sales and promotion of Subsys. The Subsys narrow FDA-approved indication limits the potential sales growth of the drug. As alleged below, to grow drug sales in a constrained environment, Insys resorted to marketing strategies prohibited by federal and state laws.

V. APPLICABLE LAW

A. The FDA Regulatory Scheme

16. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§301—97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355(a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

17. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be

prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

18. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. 355(d).

19. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses – i.e., uses not listed on the approved label – the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

20. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different from those approved by the FDA.

21. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not

approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

22. An off-label use of a drug can cease to be off label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b) & (c).

23. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses.

24. With regard to the first practice – disseminating written information – the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

25. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,070, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

26. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

27. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid and other federal health care programs.

1. The Medicaid Program

28. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

29. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(1), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id. §1396r-8(k)(3).

30. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or use of which is supported by one of the drug compendia identified in the Medicaid statute. Id. §1396r-8(k)(6). During the time period relevant to this Complaint, many of the off-label uses of the drug promoted by Insys were not eligible for reimbursement from Medicaid because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute. Upon information and belief, use of Subsys, for example, on an outpatient basis for breakthrough pain other than cancer pain is not supported by the compendia as medically safe and effective, although Insys has promoted the drug for that use in the ways set forth below.

31. Additionally, because Insys's unlawful off-label marketing efforts were designed to generate overutilization of their drugs in situations in which the drugs either were not proven

safe and effective or were not medically necessary for treatment of patients' specific medical conditions, Insys caused physicians to submit claims for reimbursement to Medicaid that were unwarranted and therefore false.

2. Other Federal Health Care Programs

32. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

33. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (b) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

34. During the time period relevant to this Complaint, the off-label uses of Subsys promoted by Insys did not qualify for reimbursement under any of the various federal health care programs because there was inadequate approval or support for such drugs to be eligible for reimbursement and/or because Insys's unlawful marketing activity created overutilization of such drug in situations where they were not medically necessary for treatment of patients' specific medical conditions.

3. The Anti-Kickback Statute

35. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, or poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

36. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend drugs that may be paid for by Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, or other federal health care program.

37. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company to a physician which has as one of its purposes inducement of the physician to write additional prescriptions for the company's pharmaceutical products.

38. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the improper practices cited by the Inspector General

are drug companies' payments to physicians where the physician had offered no particular services of benefit to the drug company but the payment appeared to have been based on the volume of business the doctor could generate for the drug company. Id.

39. Compliance with the Anti-Kickback law is a precondition to participating as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her State. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In Massachusetts and a number of other states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

VI. ALLEGATIONS

40. To grow sales of Subsys, a drug with limited approval and a limited consumer base, Insys has engaged in an extensive fraudulent marketing scheme. Insys' fraudulent scheme grossly disregards Food and Drug laws prohibiting pharmaceutical manufacturer promotion of drugs off-label.

41. Although Insys did not directly provide Subsys to federal and state health insurance programs or issue prescriptions for the drug, it embarked on a course of unlawful

conduct that it knew would lead to the submission by physicians and pharmacists of thousands of claims for Subsys when such prescriptions were not eligible for federal or state health care program reimbursement. Insys knew their actions would inevitably cause these providers to submit false claims to the federal and state governments. Accordingly, Relator Andersson, on behalf of the United States, seeks to hold defendants liable for knowingly causing these false claims to be presented to the United States for payment in violation of 31 U.S.C. § 3729.

42. As set forth more fully below, Insys pursued aggressive marketing goals for Subsys by promoting it for uses that the FDA had not found were safe or effective, and for uses that were not approved for reimbursement by Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefits Program, and other federal health care programs.

43. As stated, Subsys' sole FDA-approved use is for treating breakthrough cancer pain in opioid tolerant patients. "Breakthrough" cancer pain is a flare of moderate to severe spike of pain that "breaks through" medication cancer patients use to control their persistent pain. Subsys' side effects are typical of opioids, and can range from somnolence, nausea, vomiting and dizziness to respiratory depression, which can be life threatening.

44. Further, like all opioid medications, Subsys is susceptible to misuse and addiction. In fact, because of the risk of misuse, abuse, addiction and overdose, Subsys is available only through a restricted program called the TIRF REMS Access program. Although the general effectiveness of opioids like Subsys in treating various forms of pain is well known, opioids raise safety concerns as a primary danger raised by off-label use of this drug. For that reason, among others, serious concern should be raised about the inherent risks of Insys' marketing decision to promote off-label use of Subsys to doctors who might not have the

experience with opioids necessary to fully appreciate the dangers of the drug even with a restricted access program in place.

45. Insys began marketing Subsys through a group of sales representatives and managers who specialized in the product and who made sales calls primarily to pain specialists and oncologists. Within four months of launch, new sales leadership who had previously been with a company called Cephalon, Inc. sought to maximize sales and thus began focusing efforts on expanding sales for off-label uses of its sole marketed product - Subsys.

46. As a result of efforts by those sales leaders to expand the market to off-label pain applications in pain management, the sales of Subsys increased from $2.5 million in 2012 to $23.4 million by June 30, 2013.

47. Specifically with a view toward expanding the market to off-label pain applications even further, by fall of 2012, Insys expanded its sales force so that now its sales representatives and managers market Subsys to a broader group of physicians that includes internists, general practitioners, family practitioners, rheumatologists and neurologists who are likely to prescribe the medication for non-cancer pain and/or chronic pain.

48. Despite concerns about Subsys' serious risks and propensity for misuse and addiction, and despite the lack of scientific studies or compendia discussion that support the safety and efficacy of Subsy for any of the wide variety of off-label pain treatments it promotes, Insys has elected to change its marketing model so that more sales representatives with less expertise about the drug are now marketing the product to a larger pool of physicians (also with less expertise in cancer pain management and opioids) in an effort to further accelerate the growth of off-label use of the product.

49. Insys continues to pay lip service in its written materials to FDA's prohibitions against off-label marketing of prescription drugs, so as to give the false appearance of compliance. However, through oral and written directives and by altering its marketing program design, Insys increasingly pressured its sales force to target inappropriate medical specialists and to engage in kickbacks and other illegal remunerations in order to reach demanded levels of sales of Subsys.

50. Insys has also developed strategies to lure potentially-large off-label prescribers through financial inducements. Among these is the payment by Insys sales representatives of potentially high-prescribing physicians to speak at breakfast, lunch or dinner presentations to other physicians.

51. Insys often pays these speakers between $1200 and $2400 for talking even if the event is as short as fifteen minutes long. Sometimes the speakers are paid although they never speak to any other physicians. They are paid to speak to no one although attendance forms may be falsified to give the appearance that other physicians attended the engagement.

52. The more Subsys prescriptions a physician writes, particularly for off-label uses, the more likely Insys is to continue to pay the physician to hold speaking engagements.

53. Insys sales representatives are also encouraged to dine with physicians who may have a high propensity to prescribe off label. In fact, sales managers instruct their sales representatives to take the manager's company credit card information and use it to dine with these physicians.

54. Insys' sales model with respect to Subsys is eerily similar to the off-label marketing scheme of Cephalon, Inc. of its promotions of Actiq - another oral transmucosal fentanyl delivery system via a lollipop with FDA approval for use in treating breakthrough

cancer pain in opioid tolerant patients. In 2008 Cephalon Inc. settled with federal prosecutors over charges that it illegal off-label marketed Actiq, as well as two other drugs, for $425 million.

55. In fact, a number of Insys sales managers were formerly with Cephalon, and appear to have brought Actiq's marketing scheme to Insys for the promotion of Subsys.

Count I
Federal False Claims Act
31 U.S.C. §§3729(a)(1) and (a)(2)

56. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 55 of this complaint.

57. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

58. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

59. By virtue of the acts described above, Insys knowingly made, used or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

60. Each prescription that was written as a result of defendant's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label or illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

61. Relator cannot at this time identify all of the false claims for payment that were caused by Insys's conduct. The false claims were presented by thousands of separate entities,

across the United States, and over many months. Relator has no control over or dealings with such entities and has no access to the records in their possession.

62. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the defendant, paid and continues to pay the claims that would not be paid but for Insys's illegal off-label marketing practices and illegal inducements.

63. By reason of the defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid many claims, amounting to many hundreds of thousands of dollars, for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by Insys.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against the defendants as follows:

1. That defendant cease and desist from violating 31 U.S.C. §3729 et seq., and the equivalent provisions of the state statutes set forth above;

2. That this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of defendant's actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the federal False Claims Act, and the equivalent provisions of any applicable state statutes;

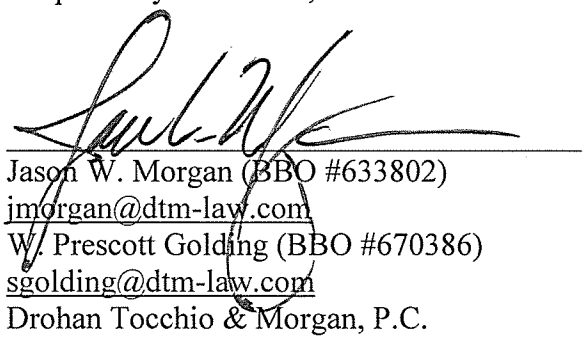
4. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Relator recover such other relief as the Court deems just and proper, or that is necessary to make Relator whole.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Respectfully Submitted,



Dated: October 15, 2013

Jason W. Morgan (BBO #633802)
jmorgan@dtm-law.com
W. Prescott Golding (BBO #670386)
sgolding@dtm-law.com
Drohan Tocchio & Morgan, P.C.
175 Derby Street, Suite 30
Hingham MA 02043
(781) 749-7200
FAX: (781) 740-4335

OF COUNSEL:

Brian J. Madden (to be admitted *pro hac vice*)
Thomas J. Preuss (to be admitted *pro hac vice*)
Wagstaff & Cartmell, LLP
4740 Grand Ave., Suite 300
Kansas City MO 64112
(816) 701-1100
FAX: (816) 531-2372
bmadden@wcllp.com
tjpreuss@wcllp.com

ATTORNEYS FOR RELATOR