

ORIGINAL

CHAD A. READLER
Acting Assistant Attorney General, Civil Division

NICOLA T. HANNA

United States Attorney

DOROTHY A. SCHOUTEN

Assistant United States Attorney

Chief, Civil Division

DAVID K. BARRETT

Assistant United States Attorney

Chief, Civil Fraud Section

DAVID M. HARRIS

Assistant United States Attorney

Deputy Chief, Civil Fraud Section

JOHN E. LEE (CBN 128696)

Assistant United States Attorney

300 N. Los Angeles Street, Room 7516

Los Angeles, California 90012

Tel: (213) 894-3995

Fax: (213) 894-7819

Email: john.lee2@usdoj.gov

MICHAEL D. GRANSTON

PATRICIA L. HANOWER

DAVID T. COHEN

Attorneys, Civil Division

United States Department of Justice

P.O. Box 261

Ben Franklin Station

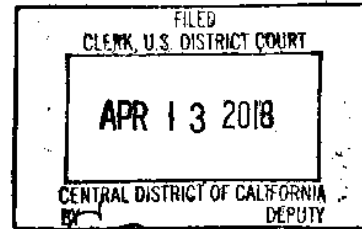
Washington, D.C. 20044

Telephone: (202) 307-0136

Facsimile: (202) 616-3085

E-mail: david.t.cohen@usdoj.gov

Attorneys for the United States of America



UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.*
[UNDER SEAL],

Plaintiff[s],

v.

[UNDER SEAL],

Defendant[s].

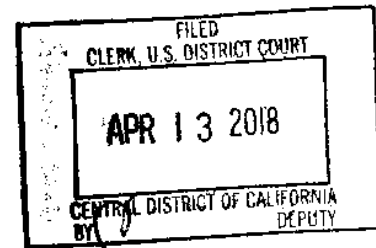
No. CV 13-5861 JLS (AJWx)

UNITED STATES' COMPLAINT IN
INTERVENTION

[FILED UNDER SEAL PURSUANT TO
THE FALSE CLAIMS ACT, 31 U.S.C.
§§ 3730(b)(2) AND (3)]

ORIGINAL

1 CHAD A. READLER
Acting Assistant Attorney General, Civil Division
2 NICOLA T. HANNA
United States Attorney
3 DOROTHY A. SCHOUTEN
Assistant United States Attorney
4 Chief, Civil Division
DAVID K. BARRETT
5 Assistant United States Attorney
Chief, Civil Fraud Section
6 DAVID M. HARRIS
Assistant United States Attorney
7 Deputy Chief, Civil Fraud Section
8 JOHN E. LEE (CBN 128696)
Assistant United States Attorney
9 300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
10 Tel: (213) 894-3995
Fax: (213) 894-7819
11 Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
12 PATRICIA L. HANOWER
DAVID T. COHEN
13 Attorneys, Civil Division
United States Department of Justice
14 P.O. Box 261
Ben Franklin Station
15 Washington, D.C. 20044
Telephone: (202) 307-0136
16 Facsimile: (202) 616-3085
E-mail: david.t.cohen@usdoj.gov
17 Attorneys for the United States of America



18 UNITED STATES DISTRICT COURT
19 FOR THE CENTRAL DISTRICT OF CALIFORNIA
20 WESTERN DIVISION

21 UNITED STATES OF AMERICA *ex rel.*
22 [UNDER SEAL],
23 Plaintiff[s],
24 v.
25 [UNDER SEAL],
26 Defendant[s].
27
28

No. CV 13-5861 JLS (AJWx)

UNITED STATES' COMPLAINT IN
INTERVENTION

[FILED UNDER SEAL PURSUANT TO
THE FALSE CLAIMS ACT, 31 U.S.C.
§§ 3730(b)(2) AND (3)]

1 CHAD A. READLER
Acting Assistant Attorney General, Civil Division

2 NICOLA T. HANNA
United States Attorney

3 DOROTHY A. SCHOUTEN
Assistant United States Attorney
Chief, Civil Division

4 DAVID K. BARRETT
Assistant United States Attorney
Chief, Civil Fraud Section

6 DAVID M. HARRIS
Assistant United States Attorney
Deputy Chief, Civil Fraud Section

7 JOHN E. LEE (CBN 128696)
Assistant United States Attorney
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012

9 Tel: (213) 894-3995

10 Fax: (213) 894-7819

Email: john.lee2@usdoj.gov

11 MICHAEL D. GRANSTON
PATRICIA L. HANOWER

12 DAVID T. COHEN
Attorneys, Civil Division

13 United States Department of Justice
P.O. Box 261

14 Ben Franklin Station

Washington, D.C. 20044

15 Telephone: (202) 307-0136

Facsimile: (202) 616-3085

16 E-mail: david.t.cohen@usdoj.gov

Attorneys for the United States of America

17 UNITED STATES DISTRICT COURT

18 FOR THE CENTRAL DISTRICT OF CALIFORNIA

19 WESTERN DIVISION

20 UNITED STATES OF AMERICA; the
21 STATES of CALIFORNIA, DELAWARE,
22 FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, LOUISIANA,
23 MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW HAMPSHIRE, NEW
24 JERSEY, NEW MEXICO, NEW YORK,
NORTH CAROLINA, OKLAHOMA,
RHODE ISLAND, TENNESSEE, TEXAS,
25 and WASHINGTON; COMONWEALTHS
of MASSACHUSETTS and VIRGINIA,
26 and the DISTRICT OF COLUMBIA *ex rel.*
MARIA GUZMAN,

27 Plaintiffs,
28

No. CV 13-5861 JLS (AJWx)

UNITED STATES' COMPLAINT IN
INTERVENTION

**[FILED UNDER SEAL PURSUANT
TO THE FALSE CLAIMS ACT, 31
U.S.C. §§ 3730(b)(2) AND (3)]**

1 v.

2 INSYS THERAPEUTICS, INC.;
3 MICHAEL BABICH, an individual; ALEC
4 BURLAKOFF, an individual; and DOES 1
5 through 15,

6 Defendants.

7 UNITED STATES OF AMERICA *ex rel.*
8 JOHN DOE and ABC, LLC,

9 Plaintiffs,

10 v.

11 INSYS THERAPEUTICS, INC.; ALEC
12 BURLAKOFF; and MICHAEL L.
13 BABICH,

14 Defendants.

No. CV 14-3488 JLS (AJWx)

15 UNITED STATES OF AMERICA *ex rel.*
16 TORGNY ANDERSSON,

17 Plaintiff,

18 v.

19 INSYS THERAPEUTICS, INC.,

20 Defendant.

No. CV 14-9179 JLS (AJWx)

21 UNITED STATES OF AMERICA *ex rel.*
22 ALLISON ERICKSON and SARA
23 LUEKEN,

24 Plaintiffs,

25 v.

26 INSYS THERAPEUTICS, INC.,

27 Defendant.

No. CV 16-2956 JLS (AJWx)

1 UNITED STATES OF AMERICA *ex rel.*
2 JANE DOE and the States of
3 CALIFORNIA, COLORADO,
4 CONNECTICUT, DELAWARE,
5 FLORIDA, GEORGIA, HAWAII,
6 ILLINOIS, INDIANA, IOWA,
7 LOUISIANA, MARYLAND,
8 MASSACHUSETTS, MICHIGAN,
9 MINNESOTA, MONTANA, NEVADA,
10 NEW JERSEY, NEW MEXICO, NEW
11 YORK, NORTH CAROLINA,
12 OKLAHOMA, RHODE ISLAND,
13 TENNESSEE, TEXAS, VERMONT,
14 VIRGINIA, WASHINGTON, the CITY
15 OF CHICAGO, and the DISTRICT OF
16 COLUMBIA,

17 Plaintiffs,

18 v.

19 INSYS THERAPEUTICS, INC. and
20 LINDEN CARE LLC,

21 Defendants.

No. CV 16-7937 JLS (AJWx)

22 **COMPLAINT IN INTERVENTION OF THE UNITED STATES**

23 **I. INTRODUCTION**

24 1. This is an action brought by the United States of America (United States) to
25 recover treble damages and civil penalties under the False Claims Act, 31 U.S.C.
26 §§ 3729-3733, and to recover damages under the common law theory of payment by
27 mistake and unjust enrichment.

28 2. Fentanyl is a powerful, but highly addictive, opioid painkiller. Defendant
Insys Therapeutics, Inc. (Insys) is the manufacturer of Subsys, a sublingual spray form
of fentanyl. In 2012, Subsys was approved by the Food and Drug Administration (FDA)
for the treatment of persistent breakthrough pain in adult cancer patients who are already
receiving, and tolerant to, around-the-clock opioid therapy.

3. Since 2012, Insys has knowingly offered and paid kickbacks to induce
physicians and nurse practitioners to prescribe Subsys for their patients. Many of these

1 kickbacks have taken the form of speaker program payments for speeches to physicians
2 that were, in fact, shams. Insys has also hired prescribers' relatives and friends in order
3 to induce prescriptions of Subsys. Insys has also provided prescribers with lavish meals
4 and entertainment to induce them to prescribe Subsys.

5 4. Insys has knowingly caused Medicare and other federal health care
6 programs to pay for Subsys for uses for which it was not covered. Insys has done this by
7 (1) encouraging physicians to prescribe Subsys in situations where it was not medically
8 reasonable and necessary based on patients' medical conditions (i.e., because a patient
9 did not have cancer), and (2) by misrepresenting patients' medical diagnoses to Medicare
10 Part D Plan Sponsors or Pharmacy Benefits Managers in order to obtain reimbursement
11 for Subsys.

12 5. Insys' conduct has violated the Anti-Kickback Statute, 42 U.C.S. § 1320(a)-
13 7b(b)(1)(A), and the False Claims Act, 31 U.S.C. §§ 3729-3733. Federal health
14 programs have suffered tens of millions of dollars in damages due to Insys' misconduct.

15 II. JURISDICTION AND VENUE

16 6. This Court has jurisdiction over the subject matter of this action pursuant to
17 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a
18 plaintiff pursuant to the False Claims Act.

19 7. This Court may exercise personal jurisdiction over the Defendant pursuant
20 to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and
21 because the Defendant has transacted business in the Central District of California.

22 8. Venue is proper in the Central District of California pursuant to 31 U.S.C.
23 § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because the Defendant has transacted
24 business within this district, maintained employees within the district, made sales within
25 the district, and/or committed violations of 31 U.S.C. § 3729 within this district.

26 III. PARTIES

27 9. The United States brings this action on behalf of the Department of Health
28 and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS),

1 on behalf of the Medicare program; and the Defense Health Agency, on behalf of the
2 TRICARE program.

3 10. Defendant Insys Therapeutics, Inc., is a pharmaceutical manufacturer that is
4 incorporated in Delaware, with headquarters in Chandler, Arizona.

5 11. In August 2013, Relator Mia Guzman filed the first of these consolidated
6 actions, United States, et al., ex rel. Guzman v. Insys Therapeutics, Inc., et al., 13-cv-
7 5861 JLS (AJWx) (C.D. Cal.), pursuant to the *qui tam* provisions of the False Claims
8 Act, 31 U.S.C. § 3730(b). At the time, she was a resident of Virginia and a former Insys
9 employee.

10 12. In October 2013, Relator Torgny Andersson filed the second of these
11 consolidated actions, United States ex rel. Andersson v. Insys Therapeutics, Inc., 14-cv-
12 9179 JLS (AJWx) (C.D. Cal.), pursuant to the *qui tam* provisions of the False Claims
13 Act, 31 U.S.C. § 3730(b). The case was filed in the District of Massachusetts and
14 subsequently transferred to this district. At the time, he was a resident of Missouri and a
15 current employee of Insys.

16 13. In May 2014, Relators Christopher Connors and PRAPOMA, LLC
17 (PRAPOMA) filed the third of these consolidated actions, United States ex rel. John Doe
18 and ABC, LLC v. Insys Therapeutics, Inc., et al., 14-cv-3488 JLS (AJWx) (C.D. Cal.),
19 pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). At the
20 time, Mr. Connors was a resident of New Jersey and a former employee of Insys.
21 PRAPOMA was a limited liability corporation based in Delaware that was formed for
22 the purpose of bringing this *qui tam* action. PRAPOMA's managing member was the
23 NHCA Group, LLC, whose principal was John Mininno.

24 14. In March 2015, Relators Allison Erickson and Sara Lueken filed the fourth
25 of these consolidated actions, United States ex rel. Erickson and Lueken v. Insys
26 Therapeutics, Inc., 16-cv-2956 JLS (AJWx) (C.D. Cal.), pursuant to the *qui tam*
27 provisions of the False Claims Act, 31 U.S.C. § 3730(b). At the time, they were both
28 residents of Minnesota and employees of Prime Therapeutics, a Pharmacy Benefits

1 Manager that processed Medicare Part D claims for the Medicare program. The case
2 was filed in the Eastern District of Pennsylvania and subsequently transferred to this
3 district.

4 15. In October 2016, Relator Melina Spalter filed the fifth of these consolidated
5 actions, United States ex rel. Jane Doe, et al. v. Insys Therapeutics, Inc. and Linden Care
6 LLC, 16-cv-7937 JLS (AJWx) (C.D. Cal.), pursuant to the *qui tam* provisions of the
7 False Claims Act, 31 U.S.C. § 3730(b). At the time, she was a resident of New Jersey
8 and a former Insys employee.

9 IV. THE MEDICARE PROGRAM

10 16. The Medicare program was established in 1965 pursuant to amendments to
11 Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.* The Medicare program
12 is a health care benefit program that provides basic health insurance coverage to certain
13 disabled persons as well as to individuals 65 years or older. Medicare is a "federal
14 health care program" under Title 42, United States Code, Section 1320a-7b(f) and a
15 "health care benefit program" under Title 18, United States Code, Section 1347.

16 17. Medicare is funded by the federal government and administered by CMS,
17 which is part of HHS. Persons enrolled in the Medicare program are hereinafter referred
18 to as "beneficiaries."

19 18. In 2003, Congress passed the Medicare Prescription Drug, Improvement,
20 and Modernization Act (MMA), Pub. L. 108-173, 117 Stat. 2066, which established a
21 voluntary prescription drug benefit program for Medicare enrollees known as Medicare
22 Part D. An individual is eligible to enroll in Part D if the individual lives in the service
23 area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under
24 Part B. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

25 19. Medicare Part D coverage is not provided within the traditional Medicare
26 program model. Medicare Part D is based on a private market model. Medicare
27 contracts with private entities known as Part D Plan "Sponsors" to administer
28 prescription drug plans. A Part D Sponsor may be a prescription drug plan, a Medicare

1 Advantage organization that offers a Medicare Advantage prescription drug plan (MA-
 2 PD plan), a Program of All-inclusive Care for the Elderly (PACE) organization offering
 3 a PACE plan including qualified prescription drug coverage, or a cost plan offering
 4 qualified prescription drug coverage. 42 C.F.R. § 423.4.

5 20. Medicare beneficiaries who wish to receive Part D benefits must enroll in a
 6 Part D Plan offered by a Part D Plan Sponsor.

7 21. Many Part D Plan Sponsors contract with other companies, including
 8 companies known as Pharmacy Benefits Managers (PBMs), to assist with the
 9 administration of Part D Plans. Many Part D Plans require prior authorization for
 10 specified drugs in order for the drug to be reimbursable. To grant prior authorization, the
 11 Plan Sponsor or PBM often communicates with the prescriber to confirm the
 12 beneficiary's diagnosis and need for the drug.

13 22. Once a prescription has been approved and filled, the Plan Sponsor or PBM
 14 transmits claims data to CMS through a Prescription Drug Event (PDE) record.

15 23. The Medicare Part D Program only covers drugs that are used for a
 16 medically accepted indication, which means a use that is approved under the Food, Drug,
 17 and Cosmetic Act, or a use which is supported by one or more citations included or
 18 approved for inclusion in one of the specified compendia: American Hospital Formulary
 19 Service Drug Information, United States Pharmacopoeia-Drug Information (or its
 20 successor publication), or DrugDex (hereinafter referred to collectively as the
 21 Compendia). 42 U.S.C. § 1395w-102(e)(1) & (e)(4); 42 U.S.C. §1396r-8(g)(1)(B)(i) &
 22 (k)(6); 42 C.F.R. § 423.100.

23 24. Part D Plan Sponsors are only authorized to approve payment for Subsys
 24 for Medicare Part D beneficiaries if Subsys is prescribed for a medically accepted
 25 indication, as defined above.

26 V. THE TRICARE PROGRAM

27 25. TRICARE (formerly CHAMPUS) is a managed health care program
 28 established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE

1 provides health care benefits to eligible beneficiaries, including active duty service
2 members, retired service members, and their dependents.

3 26. TRICARE regulations define off-label use of FDA-approved drugs as “[a]
4 use other than an intended use for which the prescription drug. . . is legally marketed
5 under the Federal Food, Drug, and Cosmetic Act or the Public Health Services Act,”
6 including “any use that is not included in the approved labeling” of the drug. 32 C.F.R.
7 § 199.2.

8 27. The TRICARE program does not cover off-label uses of drugs unless such
9 off-label use is proven medically necessary and safe and effective by medical literature,
10 national organizations, or technology assessment bodies. *See* C.F.R.
11 § 199.4(g)(15)(i)(A)(Note).

12 VI. THE LAW

13 A. The False Claims Act

14 28. The False Claims Act provides for the award of treble damages and civil
15 penalties for, *inter alia*, knowingly presenting or causing to be presented false or
16 fraudulent claims for payment to the United States and for knowingly making or using
17 false records or statements material to false or fraudulent claims paid by the United
18 States. 31 U.S.C. § 3729(a)(1).

19 29. The False Claims Act provides, in pertinent part, that a person who:

20 (a)(1)(A) knowingly presents, or causes to be presented, a false or
21 fraudulent claim for payment or approval; [or]

22 (a)(1)(B) knowingly makes, uses, or causes to be made or used, a
23 false record or statement material to a false or fraudulent claim; . . .

24 is liable to the United States Government for a civil penalty of not
25 less than \$5,500 and not more than \$11,000, as adjusted by the Federal
26 Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note;
27 Public Law 104-410), plus 3 times the amount of damages which the
28 Government sustains. . . .

1 31 U.S.C. § 3729.

2 30. For purposes of the False Claims Act,

3 (1) the terms “knowing” and “knowingly”—

4 (A) mean that a person, with respect to information—

5 (i) has actual knowledge of the information;

6 (ii) acts in deliberate ignorance of the truth or falsity of the
7 information; or

8 (iii) acts in reckless disregard of the truth or falsity of the
9 information; and

10 (B) require no proof of specific intent to defraud[.]

11 31 U.S.C. § 3729(b)(1).

12 31. The standard of proof under the False Claims Act is preponderance of the
13 evidence. 31 U.S.C. § 3731(d).

14 B. The Anti-Kickback Statute

15 32. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of
16 Congressional concern that payoffs to those who can influence health care decisions
17 would result in goods and services being provided that are medically unnecessary, of
18 poor quality, or potentially harmful to a vulnerable patient population. To protect the
19 integrity of federal health care programs from these difficult-to-detect harms, Congress
20 enacted a per se prohibition against the payment of kickbacks in any form, regardless of
21 whether the particular kickback gave rise to overutilization or poor quality of care. The
22 statute was first enacted in 1972, and was strengthened in 1977, 1987, and 2010 to
23 ensure that kickbacks masquerading as legitimate transactions did not evade its reach.
24 *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42
25 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No.
26 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L.
27 No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat.
28 119.

1 33. The Anti-Kickback Statute prohibits any person or entity from offering,
2 making or accepting payment to induce or reward any person for referring,
3 recommending or arranging for federally-funded medical services, including services
4 provided under the Medicare program. In pertinent part, the statute provides:

5 (b) Illegal remuneration . . .

6 (2) whoever knowingly and willfully offers or pays any
7 remuneration (including any kickback, bribe, or rebate) directly or
8 indirectly, overtly or covertly, in cash or in kind to any person to
9 induce such person—

10 * * *

11 (B) to purchase, lease, order or arrange for or
12 recommend purchasing, leasing or ordering any good,
13 facility, service, or item for which payment may be made in
14 whole or in part under a Federal health care program,
15 shall be guilty of a felony and upon conviction thereof, shall be fined
16 not more than \$25,000 or imprisoned for not more than five years, or
17 both.

18 42 U.S.C. § 1320a-7b(b).

19 34. The *scienter* element of the Anti-Kickback Statute is established by
20 showing that “one purpose” of the remuneration at issue was to induce referrals, even if
21 the remuneration also had other purposes that were legitimate. See United States v. Kats,
22 871 F.2d 105, 108 (9th Cir. 1989); see also United States v. Borrasi, 639 F.3d 774, 782
23 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000);
24 United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); United States v. Greber,
25 760 F.2d 68 (3d Cir. 1985). In 2010, Congress clarified the *scienter* standard under the
26 Anti-Kickback Statute by adding the following language to the statute: “With respect to
27 violations of this section, a person need not have actual knowledge of this section or
28 specific intent to commit a violation of this section.” 42 U.S.C. § 1320a-7b(h).

1 35. Compliance with the Anti-Kickback Statute is a material condition of
2 payment by the Medicare program.

3 36. In 2010, Congress amended the Anti-Kickback Statute through the Patient
4 Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), to
5 clarify that any claim “that includes items or services resulting from a violation” of the
6 Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act.
7 42 U.S.C. § 1320a-7b(g); *see also*, United States ex rel. Hutcheson v. Blackstone
8 Medical, Inc., 647 F.3d 377 (1st Cir. 2011); United States v. Rogan, 517 F.3d 449 (7th
9 Cir. 2008).

10 37. Violation of the Anti-Kickback Statute can also subject the perpetrator to
11 exclusion from participation in federal health care programs and civil monetary
12 penalties. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

13 VII. SUBSYS

14 38. Fentanyl is a powerful, but highly addictive, opioid painkiller. Subsys is a
15 liquid formulation of fentanyl that is applied under the tongue as a sublingual spray.

16 39. In early 2012, Subsys was approved by the FDA for the management of
17 breakthrough pain in cancer patients 18 years of age and older who are already receiving,
18 and tolerant to, around-the-clock opioid therapy, for their underlying persistent cancer
19 pain. In other words, the FDA determined that Subsys could be marketed and distributed
20 legally for the purpose of treating adult cancer patients who are already taking opioids to
21 treat their cancer pain, but have found the other opioids to be insufficient to treat
22 instances of breakthrough pain. The FDA has never approved the use of sublingual
23 spray fentanyl by patients who are not suffering from cancer. Also, the Compendia do
24 not support the use of Subsys by patients who are not suffering from cancer. The FDA-
25 approved label for Subsys states that it is contraindicated for opioid non-tolerant patients
26 and for the management of acute or postoperative pain. The label warns that the drug
27 poses risks of misuse, abuse, addiction, overdose, and serious complications, including
28 fatal respiratory depression, due to medical errors. The label carries a “boxed warning,”

1 which is the strictest warning the FDA uses on drug labels, and is designed to call
2 attention to serious or life-threatening risks.

3 40. Because Subsys has not been approved for uses other than the treatment of
4 breakthrough cancer pain in opioid-tolerant patients, and because such uses are not
5 supported by the Compendia, Subsys is not reimbursable by Medicare or TRICARE
6 unless a patient has cancer and is opioid-tolerant.

7 41. Subsys falls within a category of drugs known as Transmucosal Immediate
8 Release Fentanyl (TIRF) products. As a condition of approval, the FDA requires that all
9 TIRF drugs be subject to a class-wide Risk Evaluation and Mitigation Strategy (REMS).
10 The TIRF-REMS Access Program was designed to mitigate the risks of misuse, abuse,
11 addiction, overdose, and serious complications due to medication errors, associated with
12 the use of TIRF medications. The program imposes a number of restrictions and training
13 and reporting obligations on prescribers, pharmacists, and others involved in the
14 prescription and distribution of TIRF products.

15 42. Subsys has also been designated as a “Schedule II” controlled substance
16 under the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended,
17 21 U.S.C. §§ 801-971, otherwise known as the Controlled Substances Act. Drugs are
18 designated as Schedule II drugs based on a determination that they have a high potential
19 for abuse. Schedule II drugs, including Subsys, are subject to a number of legal
20 restrictions.

21 VIII. THE DEFENDANT’S MISCONDUCT

22 A. Insys Has Paid Kickbacks to Potential Prescribers 23 to Induce Them to Prescribe Subsys

24 43. Since 2012, Insys has operated a “speaker program” through which it has
25 paid Subsys prescribers to give speeches about Subsys to physicians and other healthcare
26 professionals. Insys has pretended that these presentations were intended to provide
27 potential Subsys prescribers with substantive medical information about the drug. In
28 reality, many of these events have been mere pretexts for paying thousands of dollars in

1 sham speaking fees to prescribers for the purpose of inducing them to prescribe Subsys.
 2 Many of these speeches have been attended only by the prescriber's own office staff, by
 3 close friends who attended multiple presentations, or by people who were not medical
 4 professionals and had no legitimate reason for attending. Many of the "speeches" have
 5 not involved any actual substantive presentation by the purported "speaker." The events
 6 have often been held in expensive restaurants.

7 44. Insys has also provided kickbacks to prescribers in other forms. These
 8 include jobs for the prescribers' relatives and friends, visits to strip clubs, and lavish
 9 meals and entertainment.

10 45. Insys provided these kickbacks to prescribers knowingly and willfully, in
 11 violation of the Anti-Kickback Statute. These kickbacks rendered false, within the
 12 meaning of the False Claims Act, the claims for payment that were submitted to federal
 13 health care programs for Subsys prescriptions that were written by kickback recipients
 14 subsequent to their receipt of the kickbacks. As such, Insys caused the submission of
 15 false claims to federal health care programs.

16 46. The following paragraphs describe illustrative examples of the kickbacks
 17 that Insys has provided. This is not intended as a complete or comprehensive list of the
 18 kickbacks that Insys has paid.

19 1. Drs. John Patrick Couch and Xiulu Ruan

20 47. Drs. John Patrick Couch and Xiulu Ruan operated a physician practice in
 21 Mobile, Alabama called Physician's Pain Specialists of Alabama (PPSA).

22 48. Between 2012 and 2015, Insys paid Dr. Ruan at least \$170,000 in speaking
 23 fees, and it paid Dr. Couch at least \$100,000 in speaking fees. Upon information and
 24 belief, many of the events for which Insys paid Dr. Ruan and Dr. Couch were in fact
 25 shams.

26 49. Natalie Perhacs was an Insys Sales Representative who worked with Drs.
 27 Couch and Ruan. In February 2016, Ms. Perhacs pleaded guilty to criminal charges that
 28 included the payment of illegal kickbacks to Drs. Couch and Ruan on behalf of Insys. In

1 the Factual Resume submitted in support of her plea, Ms. Perhacs admitted that she
2 scheduled approximately one speaker program per week for Drs. Couch and Ruan, but
3 that “for a majority of the speaker programs, Dr. Ruan and Dr. Couch either (1)
4 repeatedly spoke to the same prescribers about Subsys, (2) spoke to just the PPSA staff
5 about Subsys, or (3) did not speak about Subsys at all.”

6 50. In February 2017, following a seven-week federal criminal trial, a jury in
7 Alabama found Drs. Couch and Ruan guilty of several federal criminal offenses,
8 including (1) illegally prescribing fentanyl and other opioid drugs outside the usual
9 course of professional practice and not for a legitimate medical purpose, and (2)
10 accepting kickbacks from Insys. In May 2017, they were sentenced to 20 and 21 years
11 in prison, respectively.

12 51. Since 2012, Medicare has paid over \$3 million for Subsys that was
13 prescribed by Dr. Couch. For example, between July 1, 2013 and May 18, 2015, Dr.
14 Couch wrote 26 Subsys prescriptions for Patient # M1, a Medicare beneficiary.¹
15 Medicare ultimately paid more than \$369,000 for these 26 prescriptions.

16 52. Since 2012, TRICARE has paid over \$2.2 million for Subsys that was
17 prescribed by Dr. Couch. For example, between October 2012 and May 2015, Dr.
18 Couch wrote 30 Subsys prescriptions for Patient #T1, a TRICARE beneficiary.
19 TRICARE ultimately paid over \$250,000 for these 31 prescriptions.

20 53. Since 2012, Medicare has paid over \$1.4 million for Subsys that was
21 prescribed by Dr. Ruan. For example, between July 31, 2012 and March 24, 2015, Dr.
22 Ruan wrote 33 Subsys prescriptions for Patient # M2, a Medicare beneficiary. Medicare
23 ultimately paid more than \$124,000 for these 33 prescriptions.

24 54. Since 2012, TRICARE has paid over \$2.6 million for Subsys that was
25 prescribed by Dr. Ruan. For example, between April 2013 and May 2015, Dr. Ruan
26

27 ¹ Patient identities are not provided here to protect patient privacy. Upon entry of
28 an appropriate protective order, the United States will provide the Defendant with a list
identifying the names of the patients described in this Complaint.

1 wrote 38 Subsys prescriptions for Patient #T2, a TRICARE beneficiary. TRICARE
2 ultimately paid more than \$279,000 for these 39 prescriptions.

3 2. Heather Alfonso

4 55. Heather Alfonso is an Advanced Practice Registered Nurse who practiced
5 in Derby, Connecticut. Between January 2013 and March 2015, Insys paid Ms. Alfonso
6 approximately \$83,000 in speaking fees for more than 70 dinner programs.

7 56. Upon information and belief, many of the events for which Insys paid Ms.
8 Alfonso were in fact shams, attended only by Insys representatives and/or Ms. Alfonso's
9 friends and office staff, and involving little or no substantive presentation by Ms.
10 Alfonso.

11 57. In June 2015, Ms. Alfonso entered a criminal guilty plea, admitting that she
12 accepted kickbacks from Insys in violation of the Anti-Kickback Statute, 42 U.S.C.
13 § 1320a-7b(b).

14 58. Natalie Levine was an Insys Sales Representative who worked with Ms.
15 Alfonso. In July 2017, Ms. Levine entered a criminal guilty plea, admitting that she
16 conspired to violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), in connection
17 with her work at Insys.

18 59. Between 2013 and 2015, Medicare paid over \$1.2 million for Subsys that
19 was prescribed by Ms. Alfonso. For example, between March 17, 2014 and January 6,
20 2015, she wrote 9 Subsys prescriptions for Patient # M3, a Medicare beneficiary.
21 Medicare ultimately paid more than \$102,000 for these 9 prescriptions.

22 60. Between October 2013 and May 2014, Ms. Alfonso wrote 7 Subsys
23 prescriptions for Patient #T3, a TRICARE beneficiary. TRICARE ultimately paid more
24 than \$111,000 for these prescriptions.

25 3. Dr. Gavin Awerbuch

26 61. Dr. Gavin Awerbuch was a neurologist who practiced at various locations
27 in Michigan.
28

1 62. Insys paid Dr. Awerbuch over \$89,000 to give over 70 speeches on behalf
2 of the company. He was generally paid \$1,600 per event. Many of these events were
3 duplicative and pretextual. At least five individuals went to three or more of his
4 presentations.

5 63. Dr. Awerbuch made his first speech for Insys in October 2012. In the six
6 months preceding this speech, he wrote an average of less than 13 Subsys prescriptions
7 per month. In the six months after this speech, he averaged approximately 118 Subsys
8 prescriptions per month.

9 64. In November 2016, Dr. Awerbuch pleaded guilty to felony charges of
10 healthcare fraud and unlawful distribution of Subsys. On February 26, 2017, he was
11 sentenced to 32 months in prison and ordered to pay \$4.1 million in restitution and fines.

12 65. Between 2012 and his arrest in 2014, Medicare paid over \$6 million for
13 Subsys that was prescribed by Dr. Awerbuch. At that time, he was the most prolific
14 prescriber of Subsys for Medicare beneficiaries in the country. For example, between
15 March 22, 2013 and May 5, 2014, he wrote 23 Subsys prescriptions for Patient # M4, a
16 Medicare beneficiary. Medicare ultimately paid more than \$129,000 for these 23
17 prescriptions.

18 66. Since 2012, TRICARE has paid over \$84,000 for Subsys that was
19 prescribed by Dr. Awerbuch. For example, between February 2013 and April 2014, he
20 wrote 10 Subsys prescriptions for Patient #T4, a TRICARE beneficiary. TRICARE
21 ultimately paid more than \$54,000 for these 10 prescriptions.

22 4. Dr. Jerrold Rosenberg

23 67. Dr. Jerrold Rosenberg is a physiatrist who practiced in Providence, Rhode
24 Island. Between 2013 and 2015, Insys paid Dr. Rosenberg more than \$167,000 in
25 speaking fees.

26 68. Between June 2012 and September 2013, Insys employed Dr. Rosenberg's
27 son as a sales representative.
28

1 69. In October 2017, Dr. Rosenberg pleaded guilty to health care fraud and
2 conspiracy to receive kickbacks in violation of the Anti-Kickback Statute. Dr.
3 Rosenberg admitted that he took unlawful kickbacks from Insys. In March 2018, he was
4 sentenced to 51 months in federal prison. Dr. Rosenberg has also agreed to pay more
5 than \$750,000 in restitution to health insurers, including the Medicare Part D Program.

6 70. Since 2012, Medicare paid over \$666,000 for Subsys that was prescribed by
7 Dr. Rosenberg. For example, between February 19, 2013 and August 28, 2014, he wrote
8 15 Subsys prescriptions for Patient # M5, a Medicare beneficiary. Medicare ultimately
9 paid more than \$55,000 for these 15 prescriptions.

10 5. Dr. Parveen Khanna

11 71. Dr. Parveen Khanna was a pain management specialist who practiced in
12 Jacksonville, Florida. Between 2012 and 2015, Insys paid Dr. Khanna between \$1,000
13 and \$2,000 per event to give speeches on behalf of the company. In all, Insys paid her
14 over \$68,000 in speaking fees.

15 72. Many of the events for which Insys paid Dr. Khanna were shams, with no
16 physicians or other potential Subsys prescribers present. Many of these events were
17 attended only by Insys representatives and/or Dr. Khanna's office staff. Many were held
18 at expensive restaurants. Other events for which Dr. Khanna was paid were actually
19 short visits to pharmacies, during which Dr. Khanna did little more than determine
20 whether the pharmacy stocked Subsys.

21 73. Karen Hill was the Insys Sales Representative that worked with Dr.
22 Khanna. In July 2017, Ms. Hill pleaded guilty to one count of Conspiracy to Violate the
23 Anti-Kickback Statute in connection with her work at Insys.

24 74. Between 2013 and 2016, Medicare paid over \$700,000 for Subsys that was
25 prescribed by Dr. Khanna. For example, between February 4, 2014 and January 15,
26 2016, she wrote 23 Subsys prescriptions for Patient #M6, a Medicare beneficiary.
27 Medicare ultimately paid \$331,865.50 for these 23 prescriptions.

28 75. Since 2012, TRICARE has paid over \$938,000 for Subsys that was

1 prescribed by Dr. Khanna. For example, between August 2012 and April 2014, she
2 wrote 20 Subsys prescriptions for Patient #T5, a TRICARE beneficiary. TRICARE
3 ultimately paid more than \$133,000 for these 20 prescriptions.

4 6. Dr. Judson Somerville

5 76. Dr. Judson Somerville is an anesthesiologist who practiced in Laredo,
6 Texas. In 2013 alone, Insys paid Dr. Somerville over \$67,000 in speaker fees. These
7 fees ranged from \$1,600 to \$2,400 per event.

8 77. Most of the speeches for which Insys paid Dr. Somerville were attended by
9 a small group of repeat attendees. Medical Assistant R.F. attended at least sixteen of his
10 speeches, and Medical Assistant E.G. attended at least fourteen of his speeches. Medical
11 Assistants D.L., D.S., and R.M., and Drs. M.M., R.P., J.S., J. A-B., and E.N., each
12 attended at least five of his speeches.

13 78. In December 2013, the Texas Medical Board ordered Dr. Somerville to stop
14 prescribing painkillers after it found that he had authorized employees to hand out pre-
15 signed prescriptions to patients, and that three of his patients had died in 2012 of drug
16 overdoses.

17 79. In 2013, Medicare paid over \$600,000 for Subsys that was prescribed by
18 Dr. Somerville. For example, between May 21, 2013 and November 8, 2013, Dr.
19 Somerville wrote 4 Subsys prescriptions for Patient # M7, a Medicare beneficiary.
20 Medicare ultimately paid more than \$64,000 for these 4 prescriptions.

21 80. Since 2012, TRICARE has paid more than \$353,000 for Subsys that was
22 prescribed by Dr. Somerville. For example, between February and December 2013, Dr.
23 Somerville wrote 12 Subsys prescriptions for a Patient #T6, a TRICARE beneficiary.
24 TRICARE ultimately paid more than \$222,000 for these 12 prescriptions.

25 7. Dr. Alexander Weingarten

26 81. Dr. Alexander Weingarten is a physician who specializes in anesthesiology
27 and pain management. He is also a co-Medical Director of Comprehensive Pain
28 Management Associates, a two-physician group that operates at several locations in New

1 York City and Long Island.

2 82. Between 2012 and 2015, Insys paid Dr. Weingarten over \$200,000 in
3 speaking fees. Dr. Weingarten was paid between \$1,600 and \$3,000 per speech for
4 approximately 80 speeches. Many of these events were held at restaurants. At least
5 seven were held in Comprehensive Pain Management Associates' own offices.

6 83. Many of the speeches for which Insys paid Dr. Weingarten were shams,
7 attended by only Dr. Weingarten's own office staff or a small circle of frequent guests.
8 One Doctor of Osteopathy, with initials J.B., attended at least 16 of Dr. Weingarten's
9 speeches. L.M., who was identified in different documents as a Medical Assistant, Legal
10 Secretary, and Office Manager, attended at least 15 speeches; Dr. H.F. and Physician
11 Assistant L.M. each attended at least 10 speeches; Dr. A.K. attended at least 8 speeches;
12 and Medical Assistant/Office Managers D.R. and J.U. each attended at least 6 speeches.

13 84. Since 2012, Medicare has paid over \$3.5 million for Subsys that was
14 prescribed by Dr. Weingarten. For example, between June 21, 2013 and December 7,
15 2015, he wrote 26 Subsys prescriptions for Patient # M8, a Medicare beneficiary.
16 Medicare ultimately paid more than \$221,000 for these 26 prescriptions.

17 85. In May 2012, Dr. Weingarten wrote two Subsys prescriptions for Patient
18 #T7, a TRICARE beneficiary. TRICARE paid more than \$1,600 for these two
19 prescriptions.

20 8. Dr. Thomas Whitten

21 86. Dr. Thomas Whitten is a pain management specialist practicing in
22 Greensburg, Pennsylvania. Between 2013 and 2015, Insys paid Dr. Whitten over
23 \$100,000 to give approximately 40 speeches.

24 87. Many of the speeches for which Insys paid Dr. Whitten were in fact shams.
25 At least four of his speeches were attended only by members of his own office staff. For
26 at least nine of Dr. Whitten's speeches, Dr. R.M. was the only attendee who was not on
27 Dr. Whitten's office staff. Dr. M.G., along with two members of his own office staff,
28 attended at least 9 of Dr. Whitten's speeches. At least five of Dr. Whitten's speeches

1 were attended by an Esthetician/Cosmetologist and a Physician's Assistant who worked
2 for a plastic surgery practice.

3 88. Upon information and belief, Insys hired Dr. Whitten's daughter to work as
4 an Insys Sales Representative in 2014, shortly after she graduated college.

5 89. Since 2013, Medicare has paid over \$4 million for Subsys that was
6 prescribed by Dr. Whitten. For example, between March 25, 2014 and December 27,
7 2017, he wrote 51 Subsys prescriptions for Patient # M9, a Medicare beneficiary.
8 Medicare ultimately paid more than \$1.1 million for these 51 prescriptions.

9 9. Dr. Steven Chun

10 90. Dr. Steven Chun is a physician who practices in association with Sarasota
11 Pain Associates in Bradenton, Florida. Between 2012 and 2015, Insys paid Dr. Chun
12 over \$270,000 in speaking fees. Insys paid Dr. Chun between \$2,400 and \$3,000 per
13 speech for more than 60 speeches.

14 91. Many of the speeches for which Insys paid Dr. Chun were in fact shams
15 attended by a small group of repeat attendees. For example, Pharmacist V.D. attended at
16 least 16 of his speeches, Dr. M.G. attended at least 11, Pharmacy Assistant A.N. attended
17 at least 9, Advanced Practice Registered Nurse S.P. attended at least 8, and a number of
18 other individuals attended multiple speeches. Many of Dr. Chun's speeches did not
19 include any physician attendees. Many of his speaking events were held in expensive
20 restaurants.

21 92. Since 2013, Medicare has paid over \$9 million for Subsys that was
22 prescribed by Dr. Chun. For example, between June 4, 2013 and December 18, 2017, he
23 wrote 59 Subsys prescriptions for Patient # M10, a Medicare beneficiary. Medicare
24 ultimately paid more than \$1.4 million for these 59 prescriptions.

25 93. Between November 2013 and May 2016, Dr. Chun wrote Subsys
26 prescriptions for three TRICARE beneficiaries. TRICARE paid over \$19,000 for these
27 prescriptions. One of these, dispensed in December 2013, was for Patient #T8.
28 TRICARE paid over \$4,000 for this prescription.

1 10. Dr. Gordon Freedman

2 94. Dr. Gordon Freedman is a physician certified in pain management and
3 anesthesiology who practices in New York City. Between 2012 and 2015, Insys paid
4 Dr. Freedman over \$280,000 to give more than 60 speeches regarding Subsys.

5 95. Many of Dr. Freedman's speaking events were duplicative and pretextual.
6 For example, a Nurse Practitioner with initials M.R. attended at least three of Dr.
7 Freedman's speaking events, and was the only attendee who was not an Insys employee
8 at two of them. Pharmacists L.P. and B.C., and physicians J.N. and S.B., each attended
9 at least three of Dr. Freedman's speaking events.

10 96. Jonathan Roper and Fernando Serrano were two of the Insys employees
11 who worked with Dr. Freedman. In May 2017, Mr. Serrano pleaded guilty to multiple
12 federal crimes, including violation of the Anti-Kickback Statute, in connection with his
13 work at Insys. In August 2017, Mr. Roper pleaded guilty to multiple federal crimes,
14 including violation of the Anti-Kickback Statute, in connection with his work at Insys.

15 97. In March 2018, Dr. Freedman was one of five physicians indicted by a
16 federal grand jury in the Southern District of New York on charges that included
17 violation of the Anti-Kickback Statute and conspiracy to violate the Anti-Kickback
18 Statute, in connection with their participation in the Insys speaker program.

19 98. Since 2013, Medicare has paid over \$2.9 million for Subsys that was
20 prescribed by Dr. Freedman. For example, between June 11, 2014 and November 22,
21 2017, Dr. Freedman wrote 45 Subsys prescriptions for Patient # M11, a Medicare
22 beneficiary. Medicare ultimately paid more than \$864,000 for these 45 prescriptions.

23 11. Dr. Jeffrey Goldstein

24 99. Dr. Jeffrey Goldstein is doctor of osteopathic medicine who practices in
25 New York City. Since 2013, Insys has paid Dr. Freedman over \$180,000 in speaking
26 fees to give more than 30 speeches.

27 100. Many of Dr. Goldstein's speaking events were duplicative and pretextual.
28 For example, at least four of the speeches that he gave on behalf of Insys were attended

1 solely by members of his own office staff. Dr. J.B., who was on Dr. Goldstein's staff,
2 attended three of Dr. Goldstein's speaking events. Dr. R.J attended at least three of his
3 speaking events.

4 101. Jonathan Roper and Fernando Serrano, discussed above, were two of the
5 Insys employees who worked with Dr. Goldstein.

6 102. In March 2018, Dr. Goldstein was one of five physicians indicted by a
7 federal grand jury in the Southern District of New York, on charges that included
8 violation of the Anti-Kickback Statute and conspiracy to violate the Anti-Kickback
9 Statute, in connection with their participation in the Insys speaker program.

10 103. Since 2013, Medicare has paid over \$2.6 million for Subsys that was
11 prescribed by Dr. Goldstein. For example, between May 13, 2013 and July 7, 2016, Dr.
12 Goldstein wrote 34 Subsys prescriptions for Patient # M12, a Medicare beneficiary.
13 Medicare ultimately paid more than \$620,000 for these 34 prescriptions.

14 12. Dr. Bart Gatz

15 104. Dr. Bart Gatz is an anesthesiologist who practices in Greenacres, Boynton
16 Beach, and other locations in Florida. Between 2012 and 2015, Insys paid Dr. Gatz over
17 \$229,000 in speaking fees. Upon information and belief, many of the speeches for
18 which Dr. Gatz was paid were actually shams.

19 105. On or about January 18, 2013, Dr. Gatz was taken to a strip club in
20 Scottsdale, Arizona by two Insys executives, Alec Burlakoff and Joe Rowan. The next
21 day, Mr. Burlakoff texted a colleague, saying "Went fantastic last night. Bart and I got
22 back around 4 am. He had to have had one of the best nights of his life." Several days
23 later, Dr. Gatz sent a text to Mr. Rowan stating, "Thank you for the best weekend in
24 years!!!"

25 106. Upon information and belief, Insys also provided Dr. Gatz with lavish
26 meals and at least one trip to a shooting range. Upon information and belief, in 2012,
27 Insys provided Thanksgiving dinners for Dr. Gatz' entire office staff.

28 107. Since 2012, Medicare has paid over \$3.3 million for Subsys that was

1 prescribed by Dr. Gatz. For example, between December 30, 2013 and April 20, 2015,
2 he wrote 22 Subsys prescriptions for Patient # M13, a Medicare beneficiary. Medicare
3 ultimately paid more than \$421,000 for these 22 prescriptions.

4 108. On February 14, 2013, Dr. Gatz dispensed a Subsys prescription for Patient
5 #T9, a TRICARE beneficiary. TRICARE paid more than \$6,200 for this prescription.

6 13. Dr. Jeffrey Kesten

7 109. Dr. Jeffrey Kesten is a physician who practiced at the Red Rocks Center for
8 Rehabilitation in Golden, Colorado. Between 2012 and 2015, Insys paid Dr. Kesten
9 over \$290,000 to give over 100 speeches. Insys paid Dr. Kesten between \$2,400 and
10 \$4,700 per speech.

11 110. Many of the speeches for which Insys paid Dr. Kesten were, in fact, shams.
12 A significant number of them were attended only by members of his own office staff at
13 the Red Rocks Center for Rehabilitation. Most of the individuals who attended Dr.
14 Kesten's speeches were office staff and other individuals who were not authorized to
15 prescribe Subsys.

16 111. Since 2013, Medicare has paid over \$3.8 million for Subsys that was
17 prescribed by Dr. Kesten. For example, between January 13, 2014 and March 30, 2016,
18 he wrote 31 Subsys prescriptions for Patient # M14, a Medicare beneficiary. Medicare
19 ultimately paid more than \$400,000 for these 31 prescriptions.

20 14. Dr. Paul Wand

21 112. Dr. Paul Wand is a neurologist who practices in association with the Brain
22 Healing Center of America in Coral Springs, Florida (the Brain Healing Center).
23 Between 2013 and 2015, Insys paid Dr. Wand over \$84,000 to give more than 50
24 speeches. Many of these speeches were given at restaurants.

25 113. Many of the speeches for which Insys paid Dr. Wand were shams. At least
26 two of his speeches were attended solely by members of the staff at the Brain Healing
27 Center, including a marriage therapist, a medical assistant, and an office manager. At
28 least seven of his speeches were attended only by pharmacy staff. A number of

1 individuals attended more than one of his speeches.

2 114. Since 2013, Medicare has paid over \$2 million for Subsys that was
3 prescribed by Dr. Wand. For example, between April 28, 2015 and April 8, 2016, he
4 wrote 14 Subsys prescriptions for Patient # M15, a Medicare beneficiary. Medicare
5 ultimately paid more than \$162,000 for these 15 prescriptions.

6 115. Between May 2013 and August 2015, Dr. Wand dispensed 70 separate
7 Subsys prescriptions for two TRICARE beneficiaries. One of them, Patient #T10,
8 received 57 Subsys prescriptions from Dr. Wand, for which TRICARE paid \$392,000.

9 15. Christopher Clough

10 116. Christopher Clough was a Physician Assistant who practiced in
11 Somersworth, New Hampshire. Between 2013 and 2014, Insys paid Mr. Clough more
12 than \$40,000 to give more than 30 speeches.

13 117. Many of the speeches for which Insys paid Mr. Clough were actually
14 shams. Many, if not most, of them were attended solely by members of his own office
15 staff.

16 118. In 2015, the New Hampshire Board of Medicine reprimanded Mr. Clough
17 for overprescribing opioid drugs and permanently barred him from prescribing opioid
18 drugs in the future.

19 119. In March 2017, Mr. Clough was indicted based on federal charges that he
20 accepted illegal kickbacks from Insys. Those charges are currently pending.

21 120. In 2013-14, Medicare paid almost \$2 million for Subsys that was prescribed
22 by Mr. Clough. For example, between July 30, 2013 and August 29, 2014, he wrote 17
23 Subsys prescriptions for Patient # M16, a Medicare beneficiary. Medicare ultimately
24 paid more than \$223,000 for these 17 prescriptions.

25 121. Between July 2013 and February 2015, Mr. Clough wrote 26 separate
26 prescriptions for Patient #T11, a TRICARE beneficiary. TRICARE has paid more than
27 \$595,000 for these prescriptions.

1 16. Dr. Steve Fanto

2 122. Dr. Steve Fanto was a physician who practiced in Scottsdale, Arizona. In
3 July 2017, Dr. Fanto signed an interim consent agreement with the Arizona Medical
4 Board suspending his ability to engage in the practice of medicine in the State of
5 Arizona. The suspension was based on interim findings of fact that Dr. Fanto had
6 improperly prescribed opioid drugs, including Subsys, for several of his patients.

7 123. Between 2012 and 2015, Insys paid Dr. Fanto more than \$230,000 to give
8 more than 70 speeches. Insys paid Dr. Fanto between \$2,400 and \$4,700 per speech.
9 Many of the speeches for which Insys paid Dr. Fanto were actually pretextual or
10 duplicative.

11 124. A number of individuals attended more than one of Dr. Fanto's speaking
12 events. In addition, attendance at his speaking events was often padded with individuals
13 who had no ability to prescribe Subsys, including medical assistants, office managers,
14 receptionists, clerks, students, a phlebotomist, a massage therapist, a lab collector, a
15 hearing instrument specialist, a radiation therapist, a dentist, and a "sanitation" specialist.

16 125. For example, on June 12, 2015, Dr. Fanto met with eleven medical
17 assistants and office staff personnel at the Sedona office of Arizona Oncology. No
18 physicians were in attendance. On July 17, 2015, he held a second event at the same
19 office. Only one physician was present, and eight of the attendees from the first
20 presentation also attended the second presentation. Insys paid Dr. Fanto \$4,700 per
21 event for these two meetings.

22 126. Since 2012, Medicare has paid almost \$2.7 million for Subsys that was
23 prescribed by Dr. Fanto. For example, between April 16, 2014 and March 16, 2016, he
24 wrote 27 Subsys prescriptions for Patient # M17, a Medicare beneficiary. Medicare
25 ultimately paid more than \$534,000 for these 27 prescriptions.

26 127. Since 2012, TRICARE has paid over \$4.5 million for Subsys that was
27 prescribed by Dr. Fanto. Over \$4 million of this was for just three patients, each of
28 whom received more than 40 Subsys prescriptions, worth between \$1.2 million and \$1.5

1 million, from Dr. Fanto. For example, between February 2014 and May 2017, Dr. Fanto
2 wrote 44 Subsys prescriptions for Patient #T12, a TRICARE beneficiary. TRICARE has
3 paid \$1.5 million for these 44 prescriptions.

4 17. Dr. Edward Lubin

5 128. Dr. Edward Lubin is a physician who practices at several locations in
6 Florida. Between 2013 and 2015, Insys paid Dr. Lubin over \$120,000 to give more than
7 20 speeches.

8 129. Many of the speeches for which Insys paid Dr. Lubin were actually shams.
9 Most of his speaking events were conducted at pharmacies, even though pharmacists
10 cannot prescribe Subsys. At least one of his speeches was attended only by a colleague
11 from his own office. One physician attended at least three of his speeches.

12 130. Since 2013, Medicare has paid over \$2.9 million for Subsys that was
13 prescribed by Dr. Lubin. For example, between April 21, 2014 and December 8, 2015,
14 he wrote 24 Subsys prescriptions for Patient # M18, a Medicare beneficiary. Medicare
15 ultimately paid more than \$236,000 for these 24 prescriptions.

16 131. Since 2012, TRICARE has paid over \$1.2 million for Subsys that was
17 prescribed by Dr. Lubin. For example, between April 2014 and October 2016, he wrote
18 31 Subsys prescriptions for Patient #T13, a TRICARE beneficiary. TRICARE
19 ultimately paid more than \$352,000 for these 31 prescriptions.

20 18. Dr. Nilesh Jobalia

21 132. Dr. Nilesh Jobalia was an anesthesiologist in Hamilton, Ohio. In November
22 2017, the State Medical Board of Ohio permanently revoked Dr. Jobalia's medical
23 license, based in part on a finding that he had improperly prescribed certain opioid drugs.
24 The Board's findings did not expressly address his prescriptions of Subsys.

25 133. Between 2013 and 2015, Insys paid Dr. Jobalia more than \$90,000 to give
26 over 20 speeches. Insys paid him \$1,600 per speech.

27 134. Many of the speeches for which Insys paid Dr. Jobalia were actually shams.
28 For example, one speech was attended only by two medical assistants and a psychologist

1 with a PhD, one was attended by a single medical assistant, one was attended by a single
2 pharmacist, and one was attended by a single physician's assistant.

3 135. Since 2012, Medicare has paid approximately \$1.6 million for Subsys that
4 was prescribed by Dr. Jobalia. For example, between February 7, 2014 and October 11,
5 2017, he wrote 32 Subsys prescriptions for Patient # M19, a Medicare beneficiary.
6 Medicare ultimately paid more than \$620,000 for these 32 prescriptions.

7 136. Between February and July 2014, Dr. Jobalia wrote 6 Subsys prescriptions
8 for Patient #T14, a TRICARE beneficiary. TRICARE paid over \$14,000 for these
9 prescriptions.

10 19. Dr. Gregory Gerber

11 137. Dr. Gregory Gerber is a physician who practices in Sandusky, Ohio.
12 Between 2012 and 2015, Insys paid Dr. Gerber over \$130,000 to give approximately 39
13 speeches.

14 138. Many of the speeches for which Insys paid Dr. Gerber were duplicative or
15 pretextual. For example, at three of Dr. Gerber's events, Dr. C.B was the only physician
16 in attendance. Some of Dr. Gerber's events did not include any physicians. Attendance
17 at Dr. Gerber's events was padded with individuals who had no ability to prescribe
18 Subsys, including office managers, billing clerks, receptionists, medical assistants, a
19 specimen processor, and a radiology technician.

20 139. Since 2013, Medicare has paid more than \$1.8 million for Subsys that was
21 prescribed by Dr. Gerber. For example, between October 9, 2013 and September 13,
22 2015, he wrote 19 Subsys prescriptions for Patient # M20, a Medicare beneficiary.
23 Medicare ultimately paid more than \$218,000 for these 19 prescriptions.

24 B. Insys Focused Its Marketing of Subsys
25 on Patients Who Did Not Have Cancer

26 140. As discussed in Section VII, above, Subsys is only approved by the FDA
27 for the management of breakthrough cancer pain. The FDA has never approved Subsys
28 for the treatment of pain in patients who do not have cancer. Use of Subsys, a sublingual

1 fentanyl spray, by persons who do not have cancer is not supported by the Compendia.
2 Nevertheless, Insys has targeted its marketing efforts for Subsys to promote the drug to
3 treat patients who do not have cancer.

4 141. Most of the physicians that Insys has paid to participate in its speaker
5 program were in specialties other than oncology. Only a very small percentage of the
6 attendees at Insys' speaker program events were oncologists.

7 142. Insys management repeatedly urged its sales force to encourage physicians
8 to prescribe Subsys for patients who were suffering from pain that was not cancer-
9 related.

10 143. For example, at a national sales meeting held by the company in April 2013,
11 Insys executive Karen Hill spoke with the audience about "how to throw something out
12 to a doctor without sounding off-label." At the same meeting, Insys executive Dan
13 Tondre told the audience, "When a patient's in pain and it's a severe pain . . . is it
14 different they have cancer pain . . . or is it different they got, like, back pain That's
15 the whole point, pain is pain."

16 144. At another national sales meeting, held by the company in or about 2014,
17 Alec Burlakoff told the company's sales force:

18 [t]hese [doctors] will tell you all the time, well, I've only got like eight
19 patients with cancer. Or, I only have, like, twelve patients that are on a
20 rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I
21 don't want any of those patients. That's, that's small potatoes. That's nothing.
22 That's not what I'm here doing. I'm here selling [unintelligible] for the
23 breakthrough pain. If I can successfully sell you the [unintelligible] for the
24 breakthrough pain, do you have a thousand people in your practice, a
25 thousand patients, twelve of them are currently on a rapid-onset opioids
26 [sic]. That leaves me with at least five hundred patients that can go on this
27 drug.
28

1 145. In August 2013, Regional Sales Manager Richard Simon sent the following
2 text to an Insys sales representative:

3 I need confirmation from YOU that you had a conversation with ...
4 [the practitioner] where he will not ONLY promote for cancer patients. If he
5 does this he will single handedly take down the whole company. He MUST
6 creatively share how docs write this product everywhere. Please get back to
7 me ASAP with confirmation that he will share with our other speakers how
8 effective ... [the Fentanyl Spray] will be to treat ALL BTP [Breakthrough
9 Pain].

10 146. As a result of Insys' marketing efforts, most of the federal beneficiaries who
11 have used Subsys were not being treated for cancer when they received their Subsys
12 prescriptions.

13 C. Insys Lied to Insurers In Order to Persuade Them
14 to Approve Reimbursement for Subsys Prescriptions

15 147. As discussed above, many insurers, including most Medicare Part D Plans,
16 will not provide reimbursement for Subsys unless the beneficiary has received prior
17 authorization for his or her Subsys prescription. There are a number of medical factors
18 that are material to insurers' decisions on whether to reimburse for Subsys, including (1)
19 whether the patient has cancer, (2) whether the patient is opioid tolerant (i.e., whether the
20 patient is currently taking opioids on a daily basis), and (3) whether the patient is
21 suffering from dysphagia, or difficulty swallowing. (Dysphagia is relevant because
22 Subsys is a sublingual spray, and may be easier to take than pill forms of fentanyl for
23 patients with dysphagia.)

24 148. In order to increase Subsys sales, Insys established an internal unit,
25 sometimes referred to as the Insys Reimbursement Center or IRC, dedicated to
26 facilitating the process of obtaining prior authorization of Subsys prescriptions.

27 149. In many instances, IRC employees lied or made deliberately misleading
28 statements to Part D Sponsors and/or PBMs responsible for evaluating or approving

1 Medicare claims, about material facts in order to obtain federal reimbursement for
2 Subsys prescriptions that otherwise would not have been approved. IRC employees
3 frequently lied about their employer, falsely claiming that they were employed by the
4 physician or nurse practitioner that had prescribed Subsys. Also, IRC employees
5 frequently lied or made deliberately misleading statements about patients' medical
6 conditions in order to obtain insurance authorization that otherwise would have been
7 denied.

8 150. Between early 2013 and mid-2015, the IRC was headed by Elizabeth
9 Gurrieri. In June 2017, Ms. Gurrieri pleaded guilty to one count of conspiracy to
10 commit wire fraud in connection with her work at the IRC.

11 151. The following subparagraphs describe illustrative examples of false
12 representations that Insys made in order to obtain prior approval of Subsys prescriptions
13 for federal beneficiaries. This is not intended as a complete or comprehensive list of the
14 false representations that Insys made.

15 A. Patient #1 obtained Medicare Part D coverage through Horizon
16 Medicare Blue TotalCare. On February 26, 2014, an Insys employee who
17 identified herself as Tracy spoke on the phone with a PBM employee about a
18 Subsys prescription for Patient #1. In that call, Tracy falsely represented or
19 implied (1) that she was calling from the office of Patient #1's prescriber, Dr.
20 Amer Syed; (2) that Patient #1 had cervical cancer, and (3) that Patient #1 would
21 be using Subsys along with Oxycontin. All of these representations were false.
22 The next day, February 27, 2014, the PBM approved a payment of \$3,394.57 for
23 Subsys for Patient #1. Between February and December 2015, the Medicare
24 program paid more than \$53,000 for Subsys for Patient #1.

25 B. Patient #2 obtained Medicare Part D coverage through Blue Cross
26 Blue Shield of Florida BlueMedicare Regional PPO. On April 14, 2014, an Insys
27 employee who identified herself as Alisa spoke on the phone with a PBM
28 employee about a Subsys prescription for Patient #2. In that call, Alisa falsely

1 represented or implied (1) that she was calling from the prescriber's office, and (2)
2 that Patient #2 had cancer. Both of these representations were false. The next
3 day, April 15, 2014, the PBM approved Patient #2's Subsys prescription.
4 Between April and July, 2014, the Medicare program paid more than \$8,000 for
5 Subsys for Patient #2.

6 C. Patient #3 obtained Medicare Part D coverage through BlueMedicare
7 Rx (PDP). On May 14, 2014, an Insys employee who identified herself as Alyssa
8 spoke on the phone with a PBM employee about a Subsys prescription for Patient
9 #3. In that call, Alyssa falsely represented or implied that Patient #3 had cancer.
10 This representation was false. The next day, April 15, 2014, the PBM approved
11 Patient #3's Subsys prescription. Between April 2014 and March 2015, the
12 Medicare program paid more than \$56,000 for Subsys for Patient #3.

13 D. Patient #4 obtained Medicare Part D coverage through Blue Cross
14 MedicareRx Basic (PDP) by HISC - Blue Cross Blue Shield of Oklahoma. On
15 June 19, 2014, an Insys employee who identified herself as Alyssa spoke on the
16 phone with a PBM employee about a Subsys prescription for Patient #4. In that
17 call, Alyssa falsely represented or implied that Patient #4 had cancer. The PBM
18 made payments for Subsys for Patient #4 on behalf of Medicare on June 26, July
19 10, and July 14, 2014. The Medicare program paid more than \$22,000 for Subsys
20 for Patient #4. Patient #4 died on or about July 20, 2014 due to complications
21 from Chronic Obstructive Pulmonary Disease (COPD).

22 E. Patient #5 obtained Medicare Part D coverage through Clearstone
23 PDP Group MedicareBlue Rx PDP. On September 8, 2014, an Insys employee
24 who identified herself as Ricki spoke on the phone with a PBM employee about a
25 Subsys prescription for Patient #5. In that call, Ricki falsely represented or
26 implied (1) that she was calling from the office of Patient #5's prescriber; and (2)
27 that Patient #5 had breakthrough cancer pain. Both of these representations were
28 false. The same day, September 8, 2014, the PBM approved Patient #5's Subsys

1 prescription. The Medicare program subsequently paid more than \$40,000 for
2 Subsys for Patient #5.

3 F. Sarah Fuller was a Medicare beneficiary who received a Subsys
4 prescription from a physician, Dr. Vivienne Matalon, in January 2015. (Ms.
5 Fuller's full name is included here because her identity, and the events described
6 in this paragraph, have already been publicly disclosed, as noted below.) Shortly
7 thereafter, an Insys employee who identified herself as Gina called Ms. Fuller's
8 PBM in order to obtain approval for Ms. Fuller's prescription. Gina falsely
9 represented to the PBM that she was "with" Dr. Matalon's office. Through a
10 series of artful and misleading responses, Gina led the PBM representative to
11 believe that Ms. Fuller was suffering from breakthrough cancer pain, when in
12 reality Ms. Fuller did not have cancer at all. The PBM approved Ms. Fuller's
13 prescription. Between January 8, 2015 and March 21, 2016, the Medicare
14 program paid more than \$211,000 for Subsys for Ms. Fuller. Ms. Fuller died of a
15 drug overdose in March 2016. The January 2015 conversations between Gina and
16 representatives of Ms. Fuller's PBM were recorded, and were publicly revealed in
17 a report issued by Senator Claire McCaskill of the U.S. Senate Homeland Security
18 & Governmental Affairs Committee on September 6, 2017. A copy of the report,
19 and an audio recording of the phone calls, can be found at the following link:
20 [https://www.mccaskill.senate.gov/media-center/news-releases/breaking-mccaskill-](https://www.mccaskill.senate.gov/media-center/news-releases/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics-)
21 [opiod-investigation-releases-first-report-detailing-systemic-manipulation-of-](https://www.mccaskill.senate.gov/media-center/news-releases/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics-)
22 [prior-authorization-process-by-insys-therapeutics-.](https://www.mccaskill.senate.gov/media-center/news-releases/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics-)

23 **FIRST CAUSE OF ACTION**

24 (False Claims Act: Presentation of False Claims)

25 (31 U.S.C. § 3729(a)(1)(A))

26 152. Plaintiff incorporates by reference all paragraphs of this complaint set out
27 above as if fully set forth herein.

28 153. Defendant Insys knowingly presented, or caused to be presented, materially

1 false and fraudulent claims for payment or approval to the United States, including
2 (1) claims for reimbursement by Medicare Part D Plan Sponsors and TRICARE that
3 were materially false and fraudulent because they were for services ordered or prescribed
4 by persons to whom Insys had paid kickbacks in violation of the Anti-Kickback Statute,
5 and (2) claims for reimbursement by Medicare Part D Plan Sponsors and TRICARE that
6 were materially false and fraudulent because they were for patients that were not
7 covered.

8 154. Said claims were presented with actual knowledge of their falsity, or with
9 reckless disregard or deliberate ignorance of whether or not they were false.

10 **SECOND CAUSE OF ACTION**

11 (False Claims Act: Using False Statements to Get False Claims Paid)

12 (31 U.S.C. § 3729(a)(1)(B))

13 155. Plaintiff incorporates by reference all paragraphs of this complaint set out
14 above as if fully set forth herein.

15 156. Defendant Insys made, used, and caused to be made or used, false records
16 or to get false or fraudulent claims paid and approved by the United States. Defendant
17 Insys' false certifications and representations were made for the purpose of getting false
18 or fraudulent claims paid, and payment of the false or fraudulent claims was a reasonable
19 and foreseeable consequence of the Defendant's statements and actions.

20 157. The false certifications and representations made and caused to be made by
21 Defendant Insys were material to the United States' payment of the false claims.

22 158. Said false records or statements were made with actual knowledge of their
23 falsity, or with reckless disregard or deliberate ignorance of whether or not they were
24 false.

25 **THIRD CAUSE OF ACTION**

26 (Payment by Mistake)

27 159. Plaintiff incorporates by reference all paragraphs of this complaint set out
28 above as if fully set forth herein.

160. This is a claim for the recovery of monies paid by the United States to Defendant Insys (directly or indirectly) as a result of mistaken understandings of fact.

161. The United States paid Defendant Insys for claims submitted by Defendant Insys for prescriptions that were written by physicians and nurse practitioners who had financial relationships prohibited by the Anti-Kickback Statute, without knowledge of material facts, and under the mistaken belief that Defendant Insys was entitled to receive payment for such claims when it was not. The United States also paid Defendant Insys for Medicare and TRICARE claims that had been approved based on false factual representations by Insys employees regarding patients' medical conditions and histories. The United States' mistaken belief was material to its decision to pay Defendant Insys for such claims. Accordingly, Defendant Insys is liable to make restitution to the United States of the amounts of the payments made to it in error by the United States.

FOURTH CAUSE OF ACTION

(Unjust Enrichment)

162. Plaintiff incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

163. As a consequence of the acts set forth above, Insys was unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

164. The United States claims the recovery of all monies by which Insys has been unjustly enriched.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendant Insys as follows:

1. On the First and Second Counts, under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

2. On the Third Count, for payment by mistake, for the damages sustained

1 and/or amounts by which Defendant Insys was paid by mistake, or by which Defendant
2 Insys retained illegally obtained monies, plus interest, costs, and expenses, and for all
3 such further relief as may be just and proper.

4 3. On the Fourth Count, for unjust enrichment, for the amount by which Insys
5 was unjustly enriched.

6 Dated: April 13, 2018

Respectfully submitted,

7 CHAD A. READLER
Acting Assistant Attorney General
8 Civil Division
NICOLA T. HANNA
9 United States Attorney
DOROTHY A. SCHOUTEN
10 Chief, Civil Division
DAVID K. BARRETT
11 Chief, Civil Fraud Section
DAVID M. HARRIS
12 Deputy Chief, Civil Fraud Section
Assistant United States Attorneys

13 MICHAEL D. GRANSTON
14 PATRICIA L. HANOWER
DAVID T. COHEN
15 Attorneys, Civil Division
United States Department of Justice

16
17 
18 _____
JOHN E. LEE
Assistant United States Attorney

19 Attorneys for the United States of America
20
21
22
23
24
25
26
27
28