

**KESSLER TOPAZ
MELTZER & CHECK, LLP**
Johnston de F. Whitman, Jr.
jwhitman@ktmc.com
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
Facsimile: (610) 667-7056

**BONNETT, FAIRBOURN,
FRIEDMAN & BALINT, P.C.**
Francis J. Balint, Jr.
Andrew S. Friedman
2325 E. Camelback Road, Ste. 300
Phoenix, AZ 85016
Telephone: (602) 274-1100
Facsimile: (602) 274-1199
fbalint@bffb.com
afriedman@bffb.com

-and-

Jennifer L. Joost
jjoost@ktmc.com
Rupa Nath Cook
rcook@ktmc.com
1 Sansome Street, Suite 1850
San Francisco, CA 94104
Telephone: (415) 400-3000
Facsimile: (415) 400-3001

*Attorneys for Lead Plaintiff and the
Proposed Class*

**UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA**

RICHARD DI DONATO, Individually
and On Behalf of All Others Similarly
Situated,

Plaintiff,

v.

INSYS THERAPEUTICS, INC.;
MICHAEL L. BABICH; DARRYL S.
BAKER; JOHN N. KAPOOR; and ALEC
BURLAKOFF,

Defendants.

No. CV-16-00302-PHX-NVW

CLASS ACTION

**SECOND AMENDED
COMPLAINT FOR VIOLATION
OF THE FEDERAL SECURITIES
LAWS**

DEMAND FOR JURY TRIAL

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1 Lead Plaintiff Clark Miller (“Lead Plaintiff”) makes the following
2 allegations against Defendants: (i) Insys Therapeutics, Inc. (“Insys” or the
3 “Company”); (ii) Michael L. Babich (“Babich”); (iii) Darryl S. Baker (“Baker”);
4 (iv) John N. Kapoor (“Kapoor”); and (v) Alec Burlakoff (“Burlakoff”)
5 (collectively, “Defendants”) for violations of Sections 10(b) and/or 20(a) of the
6 Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. §§ 78j(b) and
7 78t(a), and Rule 10b-5 promulgated thereunder by the United States Securities and
8 Exchange Commission (“SEC”), 17 C.F.R. § 240.10b-5, on behalf of a class
9 consisting of all persons who purchased or otherwise acquired Insys common stock
10 (the “Class”) from August 12, 2014 through December 8, 2016 (the “Class
11 Period”).

12 Except as to allegations specifically pertaining to Lead Plaintiff and Lead
13 Plaintiff’s own acts, the allegations herein are based upon a continuing
14 investigation by Lead Plaintiff’s counsel, which includes, but is not limited to, the
15 review and analysis of: (i) Insys’ public filings with the SEC; (ii) securities
16 analysts’ reports about Insys; (iii) transcripts of Insys’ conference calls with
17 securities analysts and investors; (iv) Insys’ press releases; (v) media reports
18 concerning Insys; (vi) court documents containing factual allegations filed in
19 several matters, including *United States v. Alfonso*, No. 3:15-cr-00111-MPS (D.
20 Conn.), *United States v. Perhacs*, 1:16-cr-00024-CG (S.D. Ala.), *United States v.*
21 *Roper*, 1:16-mj-03628 (S.D.N.Y.), *United States v. Serrano*, 1:16-mj-03629
22 (S.D.N.Y.), *United States v. Couch*, 1:15-cr-00088 (S.D. Ala.), and *Insys*
23 *Therapeutics, Inc. v. Ferraro*, 7:15-cv-03613 (S.D.N.Y.); (ix) *People of the State*
24 *of Illinois v. Insys Therapeutics, Inc.*, No. 2016-ch-11216 (Circuit Court of Cook
25 County, Illinois Department – Chancery Division) (the “Illinois Complaint”); (x)
26 *United States v. Jeffrey Pearlman*, No. 16-mj-00437-SALM-1 (D. Conn.); (xi)
27 *United States v. Elizabeth P. Gurrieri, a/k/a Elizabeth Wise*, No. 16-mj-07218-
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1 JCB-1 (D. Mass.); (xii) *United States v. Awerbuch*, No. 16-CR-20636 (E.D. Mich.);
2 (xiii) *United States v. Michael L. Babich, et al.*, No. 16-cr-10343-ADB (D. Mass.)
3 (the “Babich and Burlakoff Indictment”); and (xiv) the Notice of Unlawful Trade
4 Practices and Proposed Resolution issued to Insys on July 10, 2015 by the Oregon
5 Department of Justice (“ODOJ”) in the matter captioned *In re Insys Therapeutics,*
6 *Inc.* (the “Oregon Complaint”). Lead Plaintiff believes that additional evidentiary
7 support will exist for the allegations herein after Lead Plaintiff has had a
8 reasonable opportunity to conduct discovery.

9 **I. SUMMARY OF THE ACTION**

10 1. Insys represents that it is a commercial-stage specialty pharmaceutical
11 company that develops and commercializes supportive care products primarily
12 designed to assist patients with pain management attributable to their disease,
13 treatments, or therapies.

14 2. From the time of the Company’s May 2013 initial public offering
15 through the present, the Company’s principal product and virtually exclusive
16 source of revenues has been the prescription medication Subsys, a sublingual
17 fentanyl spray designed to treat breakthrough cancer pain (“BTCP”) in opioid-
18 tolerant patients. During the Class Period, prescriptions of Subsys accounted for
19 more than 98% of Insys’ net revenues.

20 3. Fentanyl is reportedly *fifty times more potent than heroin* and up to
21 100 times stronger than morphine, making it the most powerful and potentially
22 lethal opioid pain medication available. Like other opioids (including Oxycontin
23 (oxycodone), Opana (oxymorphone), Dilaudid (hydromorphone), and Vicodin
24 (hydrocodone)), fentanyl is highly addictive and is among the medications at the
25 epicenter of the growing opioid epidemic in the United States, which has attracted
26 the attention of United States regulators and other public officials, including
27 President Obama. In an October 21, 2015 Presidential Memorandum, entitled
28

1 “Addressing Prescription Drug Abuse and Heroin Use,” President Obama
2 informed the heads of United States Executive Departments and Agencies, among
3 other things, that:

4 [a]ccording to the Centers for Disease Control and Prevention
5 (CDC), the number of overdose deaths involving prescription
6 opioids quadrupled between 1999 and 2013, with more than
7 16,000 deaths in 2013. In recent years, overdose deaths
8 involving heroin have sharply increased, nearly doubling
between 2011 and 2013. The CDC has identified addiction to
prescription pain medication as the strongest risk factor for
heroin addiction.

9 4. On November 5, 2015, the U.S. Drug Enforcement Agency (“DEA”)
10 announced that drug overdose deaths had become the leading cause of injury death
11 in the United States, ahead of deaths from motor vehicle accidents and firearms.
12 On February 2, 2016, based upon the continuing widespread abuse of prescription
13 opioids and resulting astronomical increase in heroin use nationally, President
14 Obama proposed \$1.1 billion in new funding “to address the prescription opioid
15 abuse and heroin use epidemic.” The Fact Sheet announcing the President’s
16 budget proposal stated, among other things, that:

17 New data from the Centers for Disease Control and Prevention
18 (CDC) show that opioids—a class of drugs that include
19 prescription pain medications and heroin—were involved in
20 **28,648 deaths in 2014**. In particular, CDC found a continued
sharp increase in heroin-involved deaths and an **emerging
increase in deaths involving synthetic opioids, such as
fentanyl**.¹

21 5. Fentanyl is a major contributor to the alarming number of opioid
22 overdose deaths currently plaguing the nation. For example, as reported in a May
23 14, 2016 *Wall Street Journal* article entitled “Hooked: One Family’s Ordeal With
24 Fentanyl,” in twelve states particularly plagued by the opioid epidemic, including
25 New Hampshire, Massachusetts, and Ohio, **more than 5,500 people died of
26 fentanyl-related overdoses between 2013 and 2015**. The opioid epidemic

27 ¹ Unless otherwise indicated, all emphasis herein is added.

1 involving fentanyl is affecting Americans regardless of their socioeconomic status.
2 On June 2, 2016, it was announced that the entertainer Prince Rogers Nelson,
3 known internationally as “Prince,” died on April 21, 2016 from an accidental
4 fentanyl overdose.

5 6. Based upon the dangers and potential for abuse and addiction that
6 fentanyl presents, Subsys was approved by the United States Food and Drug
7 Administration (“FDA”) in January 2012 *only* for BTCP in opioid-tolerant adult
8 patients (those already receiving around-the-clock opioid pain medication).
9 Moreover, the FDA required that distribution of Subsys be subject to the
10 Transmucosal Immediate-Release Fentanyl (“TIRF”) Risk Evaluation and
11 Mitigation Strategy (“REMS”) Access program (the “TIRF-REMS Access
12 Program”). Pursuant to this program, healthcare professionals who prescribe to
13 outpatients, pharmacies, and distributors must be enrolled in order to obtain,
14 prescribe, dispense, or distribute TIRF medications such as Subsys. During the
15 Class Period, all prescriptions of Subsys were registered with the TIRF-REMS
16 Access Program, enabling Defendants to monitor sales of Subsys.

17 7. The FDA-approved label for Subsys includes a “black box warning”
18 (alleged below in Section IV.B), and contains other information restricting the use
19 of Subsys to persons suffering from BTCP.² For example, under the heading
20 “Indications and Usage,” the Subsys’ label states:

21 Subsys is indicated for the management of breakthrough pain in
22 adult cancer patients who are already receiving and who are
23 tolerant to around-the-clock opioid therapy for their underlying
persistent cancer pain.

24 ***

25 Patients must remain on around-the-clock opioids when taking
26 Subsys.

27 ² The Subsys label is available at
http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202788s000lbl.pdf.

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Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

8. Under the heading “Contraindications,” the Subsys label states, among other things, that Subsys is contraindicated: “in the management of acute or postoperative pain including headache/migraine. *Life-threatening respiratory depression and death could occur at any dose in opioid non-tolerant patients.*”

9. Because sales of Subsys accounted for more than 98% of the Company’s net revenues during the Class Period, the Company’s stock price depended heavily on Subsys’ commercial success. Moreover, analysts looked to Subsys sales to gauge the health of the Company’s business. Accordingly, Defendants had a clear incentive to promote Subsys aggressively to current and potential prescribers of the drug. Given the high cost of Subsys prescriptions, Defendants were also motivated to assist persons receiving Subsys prescriptions in obtaining insurance coverage. In this regard, Insys’ filings with the SEC during the Class Period represented that “[o]ur sales of, and revenue from, Subsys, depend in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers.”

10. Nevertheless, Defendants’ promotion of Subsys was and remains subject to federal law, including the FDA’s marketing regulations. As alleged below in Section IV.A, those regulations prohibit marketing drugs for non-FDA-approved uses, commonly referred to as “off-label” uses. For example, because Subsys is approved *only* for the treatment of BTCP in opioid tolerant adult cancer patients promoting Subsys as an appropriate treatment for *anything else*, including as a treatment for migraine, neck, or back pain, would violate FDA regulations.

1 Defendants' promotion of Subsys also was and remains subject to the Medicare-
2 Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-
3 Kickback Statute ("Anti-Kickback Statute"), pursuant to which it is illegal for an
4 individual to knowingly and willfully offer or pay remuneration in cash or in kind
5 to induce a physician to order a good or service that is reimbursed by a federal
6 healthcare program. As a result, providing cash or similar benefits to current or
7 potential prescribers in exchange for Subsys prescriptions would violate the Anti-
8 Kickback Statute.

9 11. From the beginning of the Class Period until April 8, 2016, Insys
10 reported increasing net revenues each quarter from the Company's sales of Subsys.
11 For example, at the beginning of the Class Period on August 12, 2014, Insys'
12 disclosed its financial results for the second quarter of 2014, announcing in a press
13 release issued the same day that "[r]evenues from Subsys (fentanyl sublingual
14 spray) were \$54.6 million, up 195% compared with second quarter 2013 sales of
15 \$18.5 million." During a conference call with investors and analysts conducted on
16 the same day, Defendant Babich stated that "*[w]e believe the success to date of*
17 *Subsys is the result of a clinically superior product, coupled with the focused*
18 *market penetration strategy.*" As alleged below in Section IV.C, Defendants
19 made similar representations throughout the Class Period concerning the factors
20 purportedly responsible for Insys' consistently increasing Subsys sales.

21 12. Defendants also represented throughout the Class Period that Insys
22 obtained increasing sales revenues from Subsys based, in part, upon the
23 Company's putatively diligent and lawful work to obtain coverage for Subsys
24 prescriptions from third-party payers, including Medicare, Medicaid, pharmacy
25 benefit managers ("PBMs"), and private health insurers. For example, during the
26 August 12, 2014 conference call with investors and analysts, Defendant Babich
27 represented that: (i) "[t]he majority of patients have access to Subsys through their
28

1 insurance plans”; and (ii) “*we continue to properly communicate with all the*
2 *major plans and the PBMs to ensure proper access for Subsys.*” As alleged
3 below in Section IV.C, Defendants made similar representations throughout the
4 Class Period concerning Insys’ communications with third-party payers, who
5 provided the insurance coverage required for the Company to continue sell
6 increasing amounts and higher doses of Subsys.

7 13. The truth, however, was far different. In fact, Insys’ Class Period
8 sales of Subsys were the byproduct of a fraudulent scheme to mislead investors
9 involving two interrelated components. Through this scheme, for which the U.S.
10 Government has now arrested and charged Defendants Babich and Burlakoff and
11 other former Insys executives with masterminding and supervising a nationwide
12 criminal racketeering conspiracy, Defendants elevated their desire to report
13 consistently increasing Subsys revenues above the health and welfare of thousands
14 of persons to whom the dangerous drug was improperly prescribed.

15 14. *First*, the Company orchestrated and pursued a deliberate and
16 sustained campaign to promote Subsys for prescription to and use by patients other
17 than those suffering from BTCP – the only FDA approved patient population for
18 the drug – by *paying doctors across the country illegal kickbacks* (in cash, food,
19 alcohol, and other forms of “entertainment”) for prescribing Subsys to patients for
20 off-label use (such as back pain and migraines) at ever-increasing and more
21 expensive doses. As alleged below in Sections III.C and IV.B, at the heart of
22 Insys’ illegal kickback scheme was the Company’s so-called “Speaker Program,”
23 created and supervised by Babich, Burlakoff, and other former Insys executives.
24 As the U.S. Government concluded in the Babich and Burlakoff Indictment, the
25 Speaker Program was a criminal means for Insys to pay illegal kickbacks to
26 prescribers in exchange for off-label Subsys prescriptions. Pursuant to this
27 kickback scheme, Defendants Kapoor, Babich, Burlakoff, and others targeted, and
28

1 instructed Insys sales representatives to target, known high volume opioid
2 prescribers, including those running “pill mills,” to pay bribes, disguised as
3 payments for supposedly educational speaking engagements, in exchange for
4 prescribing Subsys. The Insys Speaker Programs, however, typically had no
5 educational content and no audience, leading Insys sales representatives to
6 routinely forge attendance sheets with Defendants’ knowledge. This was all by
7 design because, as Burlakoff admitted in a text to an Insys sales representative
8 concerning participants in the Speaker Program: “[t]hey do not need to be good
9 speakers, they need to write a lot of [Subsys prescriptions].” See *infra* ¶¶104-105;
10 145-186.

11 15. Certain of the Company’s sales representatives and persons who
12 prescribed Subsys in exchange for illegal kickback payments also have been
13 arrested on federal drug and insurance fraud charges in connection with this
14 scheme, with at least one of Insys’ former sales representatives entering a guilty
15 plea to the crimes for which she was charged. For example, on June 9, 2016, a
16 former Insys sales manager, Jonathan Roper, and one of his Insys sales
17 representatives, Fernando Serrano, were arrested and charged with violations of the
18 Anti-Kickback Statute for offering and paying kickbacks, bribes, and rebates to
19 healthcare professionals as inducements to prescribe large quantities of Subsys
20 from 2013 to 2015. See *United States v. Roper*, No. 1:16-cr-03628 (MJ)
21 (S.D.N.Y.); *United States v. Serrano*, 1:16-cr-3629 (MAG) (S.D.N.Y.). Federal
22 authorities continue to investigate the Company’s nationwide misconduct. Other
23 arrests, criminal charges, and guilty pleas arising from Insys’ illegal off-label
24 promotion of Subsys, including those of Defendants Babich and Burlakoff, and
25 other former Insys executives, are alleged below in Sections III.B and III.C.

26 16. *Second*, because Insys could not receive revenues from Subsys
27 prescriptions unless the prescription recipient was able to pay for it, Defendant
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1 Babich created the Company’s Insurance Reimbursement Center (“IRC”) to
2 interact with third-party payers to obtain prior authorization and insurance
3 coverage for invariably expensive Subsys prescriptions. During the Class Period,
4 *approximately 80% of Subsys prescriptions were written for impermissible off-*
5 *label uses*, such as treating migraines and lower back pain. As alleged below in
6 Section IV.B, to obtain coverage for these or any other expressly contraindicated
7 conditions, IRC employees at the direction and with the approval of Defendants
8 Babich and Burlakoff, and other former Insys executives, among other things: (i)
9 deliberately falsified patient diagnoses; (ii) used Company-generated scripts to lie
10 during telephone conversations with payer personnel; and (iii) pretended to be
11 employees of the prescribing doctor—all to mislead medical insurers, including
12 federally-funded Medicare and Medicaid, into approving payments for Subsys to
13 supposedly treat BTCP in patients who did not have cancer. In the Babich and
14 Burlakoff Indictment, the U.S. Government concluded, among other things, that
15 under the direction and supervision of Defendants Babich and Burlakoff, and other
16 former Insys executives, the IRC perpetrated a nationwide fraud upon insurers and
17 PBMs, including Medicare and Medicaid. Other arrests and criminal charges
18 arising from Insys’ efforts to mislead third party-payers are alleged below in
19 Section IV.B.2.

20 17. Because Defendants’ misrepresented and failed to disclose either: (i)
21 the Company’s rampant off-label promotion of Subsys and kickback payments to
22 prescribers in furtherance of this scheme; or (ii) the IRC’s concerted efforts to
23 mislead insurers into approving payments for Subsys prescriptions to persons who
24 did not have cancer or BTCP, each of Defendants’ statements addressing Insys’ net
25 revenues from Subsys during the Class Period alleged below in Section IV.C was
26 materially false and misleading and/or omitted material facts at the time it was
27 made. Defendants’ materially false and misleading statements and omissions of
28

1 material fact created and/or maintained artificial inflation in the price of Insys
2 common stock during the Class Period.

3 18. As alleged below in Section IV.D, the truth behind the sources of the
4 Company's Subsys sales revenues gradually emerged in a series of partial
5 disclosures of new information that corrected Defendants' material
6 misrepresentations and omissions and/or caused the foreseeable risks concealed by
7 Defendants' fraud to materialize. Each of these partial disclosures removed a
8 portion of the artificial inflation in the price of Insys common stock caused by
9 Defendants' material misrepresentations and omissions.

10 19. For example, on June 23, 2015, news emerged relating to Insys'
11 scheme to pay kickbacks to prescribers in exchange for off-label Subsys
12 prescriptions. Specifically, the District Court of Connecticut entered onto the
13 court's electronic docket (PACER) the Information and Plea Agreement of Heather
14 Alfonso, a Connecticut nurse accused of accepting approximately ***\$83,000 in***
15 ***kickbacks from Insys in exchange for prescribing Subsys to Medicare patients.***
16 The following day, the *New York Times* published an article entitled, "Nurse
17 Pleads Guilty to Taking Kickbacks from Drug Maker." The article reported,
18 among other things, that Ms. Alfonso's "guilty plea may mean that prosecutors are
19 seeking to strike deals with individuals in exchange for providing additional
20 information about the company's practices." In response to the Alfonso plea
21 agreement and the subsequent *New York Times* article, the Company's stock price
22 fell by \$5.17 per share, or 12.64%, over two trading days, from a closing price of
23 \$40.91 on June 23, 2015, to a closing price of \$35.74 on June 25, 2015, on heavy
24 trading volume.³

25
26
27 ³ During the Class Period, the Company announced a 2-for-1 stock split, which was effective as
28 of June 8, 2015.

1 20. By way of further example, on December 3, 2015, news emerged
2 indicating that Insys' IRC deliberately lied to third-party payers to obtain insurance
3 coverage for Subsys prescriptions written to persons who neither had cancer nor
4 BTCP. In this regard, an article published that day by the *Southern Investigative*
5 *Reporting Foundation* ("SIRF") revealed, among other things, that the IRC "was
6 the key piece in helping Insys double the size of the Fentanyl marketplace to more
7 than \$500 million in less than two years." The article further disclosed that
8 *employees in the Insys IRC were paid bonuses for obtaining insurance coverage*
9 *for Subsys prescriptions written for patients who did not have cancer by*
10 *changing the insurance codes on required paperwork to reflect a BTCP*
11 *diagnosis*, or by orally lying to insurance company personnel in claiming that
12 patients had BTCP. In response to this new information, the price of Insys'
13 common stock fell by \$5.93 per share, or 18.54%, from a closing price of \$31.99
14 on December 2, 2015 to a closing price of \$26.06 on December 3, 2015 on heavy
15 trading volume.

16 21. Near the end of the Class Period, increased regulatory scrutiny had
17 demonstrably stifled Insys' ability to increase Subsys revenues through the
18 Company's off-label promotion and kickback scheme, as well as the IRC's ability
19 to obtain insurance coverage for off-label Subsys prescriptions by lying to third-
20 party payers. In the face of these pressures, Insys could no longer maintain its
21 materially false and misleading Class Period streak of reporting consistently
22 increasing quarterly Subsys net revenues. As a result, on April 11, 2016, Insys
23 issued a press release announcing that the Company expected that *Subsys net*
24 *revenues for 1Q16 would be \$61 million to \$62 million – significantly lower than*
25 *consensus expectations of \$86 million for the same period*. In response to this
26 news, the price of Insys' common stock declined by \$3.42 per share, or 19.37%,
27
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1 from a closing price of \$17.66 on April 8, 2016 to a closing price of \$14.24 on
2 April 11, 2016.

3 22. Analysts attributed the April 11, 2016 stock price decline to the
4 Company's announcement regarding lower expected Subsys prescriptions and, in
5 turn, lower Subsys net revenues, for 1Q16. For example, Oppenheimer & Co.
6 ("Oppenheimer") issued a same-day report stating, "[s]hares of Insys traded down
7 ~19% (vs. S&P 500 ~flattish) after the company announced 1Q16 guidance that
8 was roughly 30% below consensus." Analysts also expressed surprise at the
9 Company's disclosure. For example, Piper Jaffray & Co. ("Piper Jaffray") issued a
10 same-day report noting, "*[t]he bottom line is that given the commentary from
11 management prior to today, we are disappointed that [Insys] appeared to present
12 a picture for Subsys that did not entirely square with reality.*"

13 23. On the final day of the Class Period, December 8, 2016, the U.S.
14 Government announced the arrests of and criminal charges (including nationwide
15 racketeering) against Babich, Burlakoff, and other former Insys executives. The
16 new information and supporting internal Insys documents, obtained in the U.S.
17 Government's investigation and revealed to investors on December 8, 2016, are
18 alleged in detail herein, including in Section IV.B. In sum, investors learned that
19 Insys was engaged in a multi-year nationwide criminal scheme, orchestrated and
20 executed by the Company's highest-ranking executives, to increase revenues from
21 selling Subsys, the source of at least 98% of Insys' Class Period Revenues, through
22 the same illegal off-label promotion, kickback payments, and insurance fraud
23 alleged herein. As the U.S. Government proclaimed in its press release
24 announcing the Babich and Burlakoff Indictment, these Defendants "*led a
25 nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe a
26 fentanyl-based pain medication and defraud healthcare insurers.*"

1 24. By the end of the Class Period, on December 8, 2016, the Company's
2 stock price had declined by *more than 79%* from its Class Period high price of
3 \$44.92 per share to close at a price of \$9.43 per share, causing Lead Plaintiff and
4 other Class members to suffer damages.

5 **II. JURISDICTION AND VENUE**

6 25. The claims asserted herein arise under Sections 10(b) and 20(a) of the
7 Exchange Act, 15 U.S.C. §§ 78j(b), and 78t(a), and the rules and regulations
8 promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. This
9 Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C.
10 §§ 1331 and 1337, and Section 27 of the Exchange Act, 12 U.S.C. § 78aa.

11 26. Venue is proper in this District pursuant to Section 27 of the
12 Exchange Act, 15 U.S.C. §§ 78aa and 28 U.S.C. § 1391(b). The Company
13 maintains its principal place of business in this District, and did so throughout the
14 Class Period, and many of the acts that constitute the violations of law complained
15 of herein, including dissemination of materially false and misleading information
16 to the investing public, occurred in or were issued from this District.

17 27. In connection with the acts alleged herein, Defendants, directly or
18 indirectly, used the means and instrumentalities of interstate commerce, including,
19 but not limited to, the mails, interstate telephone communications, and the facilities
20 of the national securities markets.

21 **III. PARTIES**

22 **A. Lead Plaintiff**

23 28. Lead Plaintiff Clark Miller purchased Insys common stock during the
24 Class Period and suffered damages as a result of the violations alleged herein.
25 Lead Plaintiff's Class Period transactions in Insys common stock are reflected in
26 the certification filed on February 4, 2016. *See* ECF No. 34.

B. Defendants

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29. Defendant Insys is incorporated in Delaware and maintains its principal executive offices at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona, 85286. Insys common stock traded on the NASDAQ under the ticker symbol “INSY” at all relevant times.

30. Defendant Babich served as the Company’s President and Chief Executive Officer (“CEO”) throughout much of the Class Period. Between March 2007 and March 2011, Babich served as the Company’s Chief Operating Officer and as a director of Insys’ wholly-owned subsidiary, Insys Pharma, Inc. As noted by the Company’s co-founder, Defendant Kapoor, Babich helped transform the Company “from a development stage enterprise to a successful, commercial, publicly-traded company known for its development of a leading commercial product, Subsys.” Babich abruptly resigned from his role as CEO of Insys, effective immediately, on November 5, 2015. On December 8, 2016, Defendant Babich was arrested and charged with nationwide (i) racketeering, (ii) mail fraud conspiracy to defraud patients of honest services, (iii) conspiracy to commit health care fraud by engaging in kickback schemes in violation of the federal Anti-Kickback Statute, and (iv) conspiracy to defraud insurers and PBMs to obtain authorization of off-label Subsys prescriptions.

31. Defendant Baker was the Company’s Chief Financial Officer (“CFO”) throughout the Class Period. In addition to leading the Company through its initial public offering in May 2013, Baker purports to be well versed in SEC compliance and revenue recognition, having frequently spoken and lectured on such topics. Indeed, Baker’s LinkedIn profile touts his “specialties” as, among other things, “Investor relations, entrepreneurial business operations and finance . . . SEC reporting for non-accelerated filers, [and] Sarbanes-Oxley compliance.” Prior to

1 joining Insys in 2012, Baker served as CFO and Controller for various publicly
2 traded companies.

3 32. Defendant Kapoor, a co-founder of Insys, served as the Company's
4 Executive Chairman of the Board of Directors throughout the Class Period.
5 Kapoor has also acted as the Company's President and CEO since Babich's
6 resignation on or around November 5, 2015. The success of Insys stock from 2013
7 through the Class Period, along with his other pharma-related investments and
8 companies, propelled Kapoor onto the annual *Forbes* billionaire list beginning in
9 2013. Kapoor, who holds a PhD in Medicinal Chemistry, also is a majority owner
10 of Akorn - which, according to Kapoor's *Forbes* profile, is "a niche pharma shop
11 specializing in 'difficult-to-manufacture' prescription drugs ranging from
12 injectables to inhalants."

13 33. Defendant Burlakoff was the Company's Vice President of Sales prior
14 to and during a portion of the Class Period. Prior to serving as Vice President,
15 Burlakoff was the Company's National Sales Chief and Regional Sales Manager.
16 As described in a *SIRF* article, Burlakoff "pushed the boundaries of what defined
17 pharmaceutical sales." While Burlakoff was Vice President of Sales, the
18 Company's sales of Subsys grew nearly 1,800%, from approximately \$16 million
19 to approximately \$300 million by the time he left the Company in July 2015. On
20 December 8, 2016, Defendant Burlakoff was arrested and charged with nationwide
21 (i) racketeering, (ii) mail fraud conspiracy to defraud patients of honest services,
22 and (iii) conspiracy to commit health care fraud by engaging in kickback schemes
23 in violation of the federal Anti-Kickback Statute.

24 34. Prior to joining Insys, Burlakoff was employed with rival
25 biopharmaceutical company, Cephalon. There, Burlakoff ran a training program
26 for several years, in which he and his sales staff worked with doctors to market and
27 sell Cephalon's fentanyl product, Actiq. In 2008, Cephalon settled with the U.S.
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1 Government for \$425 million in a suit for the unapproved (off-label) marketing of
2 Actiq for non-cancer related injuries. According to a *SIRF* article, Burlakoff was
3 also previously employed by pharma-company, Eli Lilly, but later fired “for his
4 role in sending unsolicited samples of Prozac through the mail in a bid to boost the
5 drug’s then slumping sales.” Burlakoff recruited former Cephalon colleagues to
6 join him Insys, including Joseph Rowan, among others.

7 35. Defendants Babich, Baker, Kapoor, and Burlakoff are collectively
8 referred to herein as the “Individual Defendants.”

9 **C. Relevant Non-Parties**

10 **1. Former Insys Employees**

11 36. Michael Gurry (“Gurry”) was hired by Defendant Babich in August
12 2012 as the Company’s Vice President of Managed Markets. Gurry held this
13 position until October 2016. On December 8, 2016, Gurry was arrested and
14 charged with nationwide (i) racketeering, (ii) mail fraud conspiracy to defraud
15 patients of honest services, (iii) conspiracy to commit health care fraud by
16 engaging in kickback schemes in violation of the federal Anti-Kickback Statute,
17 and (iv) conspiracy to defraud insurers and PBMs to obtain authorization of off-
18 label Subsys prescriptions.

19 37. Elizabeth Gurrieri (“Gurrieri”) was hired as a Prior Authorization
20 Specialist in October 2012. In November 2012, Gurrieri assisted Defendants in
21 setting up the IRC. Between January 2013 and July 2016 when she was
22 terminated, Gurrieri, under Defendant Babich’s supervision, directly supervised
23 IRC employees responsible for obtaining prior authorizations for Subsys
24 prescriptions from insurers and PBMs. Gurrieri was promoted to the position of
25 Manager of Reimbursement Services in March 2013.

26 38. According to Gurrieri’s LinkedIn profile, the success of the IRC was
27 responsible for tripling the commissions of the sales force and growing the
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1 Company's share of the TIRF market from 11% to 51% in just one year of
2 operation. While at Insys, Gurrieri stated that she (i) "developed and executed
3 programs designed to support [IRC employees including] Business Relationship
4 Managers [and] District Relationship Managers, and the Sales team in the areas of
5 education and operational execution;" (ii) "served as the liaison between the
6 Patient Services Center [the IRC] and Internal Customers (i.e., Sales, Marketing,
7 BRMs, Training, Compliance, and Managed Markets) as well as External
8 Customers;" (iii) "managed field escalations;" (iv) was "responsible for the
9 analytics and reporting for the training and development department as well as the
10 sales operations department;" and (v) "completed quarterly bonus payouts for the
11 Business Relationship Managers and District Relationship Managers." Gurrieri
12 also "travel[led] to multiple locations nationwide to train, educate, and assist
13 Business Relationship Managers and Specialty Sales Professionals [Subsys sales
14 representatives]."

15 39. On October 12, 2016, Gurrieri was arrested and charged with
16 conspiring to defraud insurers and PBMs across the country to obtain authorization
17 of off-label Subsys prescriptions. On information and belief, Gurrieri is "the co-
18 conspirator" identified in ¶¶65, 176, and 178 and one of the co-conspirators
19 identified in ¶¶10-11, 59-60, 62-63, 65-66, 174-77, 179-82, 185-86, and 189-90 of
20 the Babich and Burlakoff Indictment.

21 40. Rich Simon ("Simon") was hired by Defendants Babich and Burlakoff
22 in September 2012 as the Regional Sales Manager ("RSM") for Insys' Central
23 Region. In June 2013, Simon was promoted to the position of Director of Sales
24 reporting directly to Defendant Burlakoff. In turn, Insys' RSMs, including Sunrise
25 Lee and Joseph Rowan, reported directly to Simon. On December 8, 2016, Simon
26 was arrested and charged with nationwide (i) racketeering, (ii) mail fraud
27 conspiracy to defraud patients of honest services, and (iii) conspiracy to commit
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1 health care fraud by engaging in kickback schemes in violation of the federal Anti-
2 Kickback Statute.

3 41. Sunrise Lee (“Lee”) was hired by Defendants Babich and Burlakoff
4 on August 17, 2012 as the RSM for the Mid-Atlantic Region. On September 2,
5 2013, Lee was promoted by Insys to the position of Regional Sales Director for the
6 Central Region. Prior to her termination from Insys on March 10, 2015, Lee
7 became the Regional Sales Director for the Company’s West Region. On
8 December 8, 2016, Lee was arrested and charged with nationwide (i) racketeering,
9 (ii) mail fraud conspiracy to defraud patients of honest services, and (iii)
10 conspiracy to commit health care fraud by engaging in kickback schemes in
11 violation of the federal Anti-Kickback Statute.

12 42. Prior to joining Insys, Lee was a stripper at Rachel’s, a West Palm
13 Beach adult entertainment club. When asked about Lee in the context of her
14 position at Insys by *SIRF*, Defendant Burlakoff explained that Lee had unusual
15 attributes that were helpful in marketing Subsys to doctors, stating, “Doctors really
16 enjoyed spending time with her and found Sunrise to be a great listener” and
17 noting that “[o]ften the initial contact [with a doctor] was made by another sales
18 person” and “She’s more of a ‘closer.’” Burlakoff further stated that Lee was
19 effective with pain management physicians who appreciated her “empathy.”
20 According to Burlakoff, “[w]hen you are dealing with [doctors] who are around
21 pain and cancer all day, an empathetic and caring sales person is helpful.”

22 43. Joseph A. Rowan (“Rowan”) was hired by Defendants Babich and
23 Burlakoff as the RSM for the Southeast Region in the summer of 2012 and was
24 promoted to Regional Sales Director for the East Region after Simon was
25 promoted to Director of Sales in July 2013. On December 8, 2016, Rowan was
26 arrested and charged with nationwide (i) racketeering, (ii) mail fraud conspiracy to
27 defraud patients of honest services, and (iii) conspiracy to commit health care fraud
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1 by engaging in kickback schemes in violation of the federal Anti-Kickback Statute.
2 Prior to joining Insys, Rowan worked for Cephalon with Defendant Burlakoff and
3 at Teva Pharmaceuticals. Before starting at Insys, Rowan knew Dr. Xiulu Ruan
4 (“Dr. Ruan”) and Dr. John Patrick Couch (“Dr. Couch”). *See infra* ¶¶53-54.

5 44. Jeffrey Pearlman (“Pearlman”) was hired by Insys as a sales
6 representative in September 2012. Pearlman was promoted to the position of
7 District Sales Manager (“DSM”) in February 2013. As a DSM, Pearlman was
8 responsible for managing Insys sales representatives based in, among other states,
9 Connecticut, New York, New Jersey, and Rhode Island. On September 29, 2016,
10 Pearlman was arrested and charged with conspiracy to commit health care fraud
11 including engaging in kickback schemes, in violation of the federal Anti-Kickback
12 Statute. On information and belief, Pearlman is the “manager” identified in ¶¶129-
13 30 of the Babich and Burlakoff Indictment.

14 45. Jonathan Roper (“Roper”) was hired by Insys as a New York-based
15 sales representative prior to the start of the Class Period. In or around October
16 2013, Roper was promoted to District Manager whereby he assumed supervision
17 over other sales representatives in his territory, including Fernando Serrano,
18 described below. In this role, he reported to New York’s Regional Director of
19 Sales, Jeff Pearlman. In late 2015, Insys promoted Roper to the position of
20 Regional Director.

21 46. Fernando Serrano (“Serrano”) was a New York-based sales
22 representative for Insys, from September 2013 through July 2015. In January
23 2015, Serrano was given the additional title of District Sales Trainer. According to
24 his LinkedIn page, Serrano was a top-tier salesman for the Company, “generat[ing]
25 over \$2 million in sales” for Insys in the first and second quarters of 2015 alone.
26 Despite his apparently stellar sales record, Serrano was dismissed by Insys in July
27 2015.

1 47. On June 9, 2016, both Roper and Serrano were arrested and charged
2 with violating the federal Anti-Kickback Statute for offering and paying kickbacks,
3 bribes, and rebates to healthcare professionals as inducements to prescribe large
4 quantities of Subsys. See *United States v. Roper*, No. 1:16-cr-03628 (MJ)
5 (S.D.N.Y.); *United States v. Serrano*, 1:16-cr-3629 (MAG) (S.D.N.Y.).
6 Specifically, as alleged by the United States, Roper and Serrano organized and
7 participated in Insys' Speaker Program in which select doctors were paid to make
8 sham "educational presentations" to other healthcare professionals on the benefits
9 and appropriate uses of Subsys from at least March 2013 to November 2015 and at
10 least October 2013 to June 2015, respectively. The United States' investigation
11 against Roper and Serrano is ongoing.

12 48. Natalie Reed Perhacs ("Perhacs") was employed by Insys as a sales
13 manager prior to and during a portion of the Class Period. Perhacs—a former
14 medical equipment salesperson with no experience in the sale of controlled
15 substances—was hired solely on the recommendation of top-Subsys prescriber, Dr.
16 Xiulu Ruan, discussed further in ¶¶53-54 below, who, according to allegations
17 made by the government, had "developed a certain affection" for Perhacs.
18 Apparently, "Perhacs was hired to induce, and in exchange for, Dr. Ruan
19 continuing to prescribe Subsys"

20 49. Despite her lack of experience in the pharmaceutical industry, and
21 limited training in the product, Perhacs was tasked with sales for Dr. Ruan and, his
22 business partner, Dr. John Couch's practices. On February 17 2016, however,
23 Perhacs was charged with conspiracy to commit health care fraud including
24 engaging in kickback schemes, in violation of the federal Anti-Kickback Statute.
25 See *United States v. Perhacs*, 1:16-cr-00024 (CG) (S.D. Ala.). Perhacs pleaded
26 guilty to these charges on the same day.

1 50. Tim Neely (“Neely”) was employed as an Insys sales representative
2 for Insys from at least October 2013 to October 2015. Prior to his role at Insys,
3 Neely was a fireman living in San Clemente, California. Based on the value of
4 Subsys prescriptions written by his providers, Neely was within the top 15 sales
5 representatives in 2014, putting him in the “President’s Club.” Neely earned
6 \$207,000 in salary and commissions in 2014 and prior to being terminated, was on
7 track to earn \$170,000 to \$180,000 in salary and commissions for 2015. Despite
8 his successes at Insys, Neely was fired from the Company in October 2015
9 following a dispute over a bereavement leave during the summer of 2015.

10 51. Neely has within his possession documents, texts, emails, and
11 personal notes that he took during calls with his managers while he was employed
12 at Insys. Neely also has been extensively interviewed in person by a *SIRF* reporter
13 and, according to the *SIRF* article detailing Neely’s experiences at Insys, his
14 account has been verified by other current and former Insys sales representatives
15 and managers, several of whom also provided documents.

16 52. Danielle Gardner (“Gardner”) was employed in Insys’ IRC from
17 approximately the fall of 2013 to the late fall of 2014. Garner is a pseudonym
18 generated by the author of *SIRF*’s “Murder Incorporated” articles. Gardner was
19 hired by Insys for the IRC after submitting her application through a job-hunting
20 site. Prior to working at Insys, Gardner had been employed in several doctors’
21 offices, making her familiar with the process for obtaining insurance coverage on
22 behalf of patients. According to Gardner, she has cooperated “extensively” with
23 federal law enforcement officials throughout 2015 about the nature of her role at
24 Insys. *SIRF* corroborated her story regarding the IRC by speaking with other Insys
25 employees, including, among others, another IRC employee and sales
26 representatives and managers who had frequent contact with the IRC.

2. Subsys Prescribers

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53. Drs. Ruan and Couch jointly owned and operated two pain management clinics and a pharmacy (which dispensed Subsys) in Mobile, Alabama between January 2011 and May 20, 2015. Though Drs. Ruan and Couch treated several thousands of patients in their clinics, very few of these patients had cancer. Nonetheless, starting in April 2012, Drs. Ruan and Couch began prescribing Subsys to their patients. Their prescriptions for Subsys increased to such a high level that, during certain points in 2012 and 2013, Dr. Ruan became the leading prescriber of Subsys in the United States.

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54. In exchange for their high-volume prescriptions, Drs. Ruan and Couch received over \$210,000 in payments from Insys in 2013 and 2014. These payments came in the form of “speaking fees,” travel, and meals under Insys’ illicit Speaker Program. Notably, the criminal information against Perhacs was based in large part on her relationship with Drs. Ruan and Couch—and, particularly, her ability to increase the volume of Drs. Ruan and Couch’s Subsys prescriptions by providing “speaker fees,” identifying patients whose Subsys dosages could be increased, and her exploitation of Dr. Ruan’s affections. In May 2015, Drs. Ruan and Couch were arrested on drug and fraud charges. Both pleaded not guilty. *See United States v. Couch*, No. 1:15-cr-00088 (CG) (S.D. Ala.). On information and belief, Drs. Ruan and Couch are identified as Practitioner #1 and Practitioner #2, respectively, in the Babich and Burlakoff Indictment.

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55. Dr. Gavin Awerbuch (“Dr. Awerbuch”) operated a clinic in Saginaw, Michigan before he was arrested and charged May 2, 2014 with illegally prescribing Subsys. In 2013, Dr. Awerbuch wrote Subsys prescriptions for Medicare patients worth \$6.4 million, nearly five times as much as the second largest provider. In 2014, Dr. Awerbuch wrote 527 Subsys prescriptions for Medicare patients, totaling \$3.7 million. Dr. Awerbuch was arrested and charged

1 with health care fraud and illegal distribution of controlled substances in May
2 2014. On November 7, 2016, Dr. Awerbuch entered a plea of guilty to illegally
3 prescribing Subsys. Currently, Dr. Awerbuch is scheduled to be sentenced on
4 February 7, 2017. On information and belief, Dr. Awerbuch is identified as
5 Practitioner #3 in the Babich and Burlakoff Indictment.

6 56. Practitioner #4 is identified in the Babich and Burlakoff Indictment as
7 operating a pain management clinic in South Florida.

8 57. Dr. Judson Somerville (“Dr. Somerville”) owned and operated pain
9 management clinics in Laredo, Texas and in Corpus Christi, Texas. Insys paid Dr.
10 Somerville \$67,000 in speaking fees, travel and meals in 2013 while he was under
11 investigation by the Texas Medical Board. In December 2013, the Texas Medical
12 Board restricted his license, preventing him from administering, dispensing,
13 prescribing or refilling a prescription for any Schedule II controlled substance,
14 among others. His license subsequently was suspended on October 6, 2016.
15 According to an April 2015 complaint before the Texas Medical Board, Dr.
16 Somerville prescribed Subsys, among other narcotics, for (i) back pain (ii) leg pain
17 (iii) headaches, (iv) abdominal pain, and (v) lumbar fusion. On information and
18 belief, Dr. Somerville is identified as Practitioner #5 in the Babich and Burlakoff
19 Indictment.

20 58. Dr. Paul Madison (“Dr. Madison”) is an anesthesiologist who
21 practiced in Chicago, Illinois. He is not an oncologist and treated few, if any,
22 cancer patients. According to the Illinois Complaint, Dr. Madison was the highest
23 volume prescriber of Subsys in Illinois “by far,” prescribing approximately 58% of
24 all the Subsys prescriptions in Illinois. Over 95% of these prescriptions were
25 written for patients that did not have cancer. In December 2012, Dr. Madison was
26 indicted on federal false claims charges for allegedly billing insurers for
27 procedures that were never performed. In April 2014, the Illinois Department of
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1 Financial and Professional Regulation reprimanded Dr. Madison for prescribing
2 controlled substances without an Illinois Controlled Substance License. On
3 information and belief, Dr. Madison is identified as Practitioner #6 in the Babich
4 and Burlakoff Indictment.

5 59. Heather Alfonso (“Alfonso”) was an advanced practice registered
6 nurse at a Connecticut-based pain and headache treatment center, who was
7 licensed to and did prescribe highly-potent controlled substances, including
8 Subsys, as part of her employment. Alfonso was identified in public court
9 documents as “one of the highest prescribers of Subsys in New England and
10 nationwide.” In 2013 alone, Alfonso wrote 782 prescriptions for fentanyl—an
11 amount “more than twice the number of the next highest prescriber.” These
12 prescriptions resulted in payments of approximately \$1.6 million to Insys from
13 Medicare and private insurers.

14 60. In June of 2015, Alfonso came under scrutiny by the Federal
15 Government for receiving \$83,000 in kickbacks from Insys in exchange for writing
16 Subsys prescriptions, often to patients who did not have cancer. *See United States*
17 *v. Alfonso*, No. 3:15-cr-111 (MPS) (D. Conn.). As part of her guilty plea, Alfonso
18 admitted that these payments influenced her decision to prescribe Subsys. Since
19 pleading guilty to the charges against her, Alfonso has agreed to cooperate with
20 ongoing state and federal investigations regarding Subsys, in which, according to
21 the *Hartford Courant*, additional “arrests were expected.” On information and
22 belief, Alfonso is identified as Practitioner #7 in the Babich and Burlakoff
23 Indictment.

24 61. Christopher Clough (“Clough”) was a physician assistant with Pain
25 Care of New Hampshire located in Somersworth, New Hampshire. On
26 information and belief, Clough is identified as Practitioner #8 in the Babich and
27 Burlakoff Indictment.

1 62. Practitioner #9 is identified in the Babich and Burlakoff Indictment as
2 owning and managing a pain management practice in southwest Florida.

3 63. Practitioner #10 is identified in the Babich and Burlakoff Indictment
4 as owning and managing a pain management clinic in Sherwood, Arkansas.

5 64. Dr. James Gallant (“Dr. Gallant”) was doctor of general medicine who
6 practiced in Oregon and prescribed Subsys off-label to his patients. Dr. Gallant
7 lacked adequate training in pain management and was not authorized to treat
8 chronic pain or prescribe opioids for the treatment of cancer pain. By 2013, Dr.
9 Gallant and another Oregon doctor (Dr. Rosenblum, discussed further below) were
10 collectively responsible for approximately 80% of all Subsys’ prescriptions in
11 Oregon.

12 65. Dr. Gallant also became a top “speaker” for Insys’ Speaker Programs
13 in Oregon and was frequently visited by Insys’ sales representatives. In exchange
14 for promoting and prescribing Subsys, Dr. Gallant was provided significant
15 compensation by the Company. In October of 2014, Dr. Gallant was reprimanded
16 by the State of Oregon for the unauthorized and unlawful prescription of opioids,
17 including Subsys. The Oregon Medical Board ultimately barred Dr. Gallant from
18 treating chronic pain, imposed a \$10,000 civil penalty, and temporarily suspended
19 Dr. Gallant’s medical license, among other disciplinary measures.

20 66. Dr. Roy Blackburn (“Dr. Blackburn”) was an Oregon-based
21 psychiatrist who was not trained to treat chronic pain or administer pain-related
22 narcotics and, specifically, BTCP opioids. Nonetheless, he became the third most
23 targeted doctor by Insys’ sales representatives and became a regular prescriber of
24 Subsys, which, at least in one instance, was for the treatment of migraine
25 headaches. On June 3, 2014, the Oregon Medical Board issued a complaint against
26 Dr. Blackburn for gross negligence and the prescription of controlled substances
27 without a legitimate medical purpose and/or without accepted examination
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1 procedures. Dr. Blackburn has since settled this complaint and stipulated to an
2 order barring him from prescribing Subsys, among other highly-regulated pain
3 medication.

4 67. Dr. Stuart Rosenblum (“Dr. Rosenblum”) was an Oregon board
5 certified anesthesiologist. Dr. Rosenblum also had experience in promoting off-
6 label pain medication on behalf of pharmaceutical companies. During 2012 to
7 2013, Dr. Rosenblum was a frequent prescriber of Subsys. Given his lack of
8 qualifications in cancer pain treatment, Insys worked closely with Dr. Rosenblum
9 and his patients to ensure third party reimbursement for these prescriptions, which
10 were often for diagnoses of general pain, such as osteoarthritis or myalgia. He was
11 regularly paid by Insys for the promotion of Subsys to other healthcare providers.
12 Dr. Rosenblum became the second most frequent Subsys’ “speaker” in Oregon,
13 next to Dr. Gallant. In 2013, Dr. Rosenblum, together with Dr. Gallant, was
14 responsible for the vast majority of Subsys’ prescriptions in the State of Oregon.

15 **IV. DEFENDANTS’ EXCHANGE ACT VIOLATIONS**

16 **A. Factual Background**

17 **1. Fentanyl**

18 68. Fentanyl, the active ingredient in Insys’ principal product, Subsys, is a
19 potent, highly addictive, and potentially lethal pain medication that is at the
20 epicenter of the growing opioid epidemic in the United States. This epidemic has
21 attracted the attention of United States regulators and other public officials,
22 including President Obama. Fentanyl is approximately 80 to 100 times more
23 potent than morphine.

24 69. Recently, an illicit market for fentanyl has developed in the United
25 States because it is approximately 40 to 50 times more potent than pharmaceutical
26 grade (100% pure) heroin, dealers often lace other drugs with fentanyl to sell to
27 unsuspecting users – a cheap tactic that produces a stronger high and keeps addicts
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1 coming back to purchase more. Fentanyl also can serve as a direct substitute for
2 heroin in adults who have developed an opioid addiction. Because of its potency,
3 however, fentanyl is a dangerous substitute for heroin, leading to more frequent
4 overdoses and death.

5 70. Aptly referred to by the *New York Times* as heroin’s “deadlier
6 cousin,” fentanyl has been linked directly to a dramatic increase in the number of
7 fatal drug overdoses over the past several years. In some areas of New England,
8 for example, fentanyl is now killing more people than heroin, with 158 deaths in
9 New Hampshire caused by fentanyl alone last year versus 32 deaths caused by
10 heroin. Moreover, according to data compiled by the *Wall Street Journal*, in
11 twelve states particularly plagued by the opioid epidemic, “including New
12 Hampshire, Massachusetts, and Ohio, more than 5,500 people died from fentanyl-
13 related overdoses between 2013 and 2015.” On June 2, 2016, it was announced
14 that the entertainer Prince died on April 21, 2016 from an accidental fentanyl
15 overdose.

16 71. As a result of this startling trend, in March 2015, the DEA issued a
17 nationwide alert about fentanyl, saying that overdoses were “occurring at an
18 alarming rate throughout the United States and represent a significant threat to
19 public health and safety.”

20 72. With regard to its prescribed usage, between 2000 and 2016, fentanyl,
21 under any and all of its brand name derivatives, has been included in 44,284
22 adverse reaction reports, of which 32,389 were reported as serious, according
23 to OpenFDA. Of those, fentanyl was the primary suspect in 17,169 of the reports.

24 73. Due to its significant potency and high potential for abuse, fentanyl is
25 categorized by the DEA as a Schedule II substance under the Controlled
26 Substances Act. Consequently, its manufacture, shipment, storage, sale, and use
27 are highly regulated.

2. Insys and Subsys

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2 74. Insys is a commercial-stage specialty pharmaceutical company
3 incorporated in Delaware and headquartered in Chandler, Arizona that develops
4 and commercializes innovative supportive care and therapeutic products.

5 75. Throughout the Class Period, the Company earned more than 98% of
6 its net revenues from the sales of Subsys, a proprietary sublingual fentanyl spray
7 approved by the FDA *only* for BTCP in opioid-tolerant adult patients.

8 76. Insys' only revenue driver during the Class Period, Subsys delivers
9 fentanyl for transmucosal absorption underneath the tongue. On January 2, 2012,
10 the Company received FDA marketing approval for Subsys for only one
11 indication: "the management of breakthrough pain in cancer patients 18 years of
12 age or older who are already receiving and who are tolerant to around-the-clock
13 opioid therapy for their underlying persistent cancer pain. Patients must remain on
14 around-the-clock opioids when taking Subsys." Subsys is Insys' only FDA-
15 approved product.

16 77. Subsys' single-use spray is available in several different dose
17 strengths—100mcg, 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, and 1600mcg.
18 Because fentanyl is so potent, prescriptions of drugs containing fentanyl, including
19 Subsys, are measured in micrograms (mcg), rather than the more common
20 milligrams (mg). Moreover, as fentanyl is a Schedule II opioid, a Subsys
21 prescription only can be obtained from a specialty pharmacy. Subsys is extremely
22 expensive, costing anywhere from \$1,000 per month for a patient prescribed 30
23 doses of Subsys 100mcg, all the way up to over \$21,000 per month for a patient
24 prescribed 240 doses of Subsys 1,200mcg.

25 78. According to the dosing instructions on Subsys' FDA-approved label,
26 "[t]he initial dose of Subsys *is always 100mcg*," unless the person to whom Subsys
27 is prescribed is already using Actiq, a TIRF fentanyl product that has been on the
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1 market since November 1998. For patients using: (i) 200mcg and 400mcg Actiq,
2 the FDA-approved initial Subsys dosage is 100mcg; (ii) 600mcg and 800mcg
3 Actiq, the FDA approved initial Subsys dosage is 200mcg; and (iii) 1200mcg and
4 1600mcg Actiq, the FDA approved initial Subsys dosage is 400mcg. Thus, for the
5 vast majority of new Subsys patients, the appropriate FDA-approved dosage is
6 100mcg to 200mcg. The dosing label instructs prescribers to “only increase the
7 SUBSYS dose when a single administration of the current dose fails to adequately
8 treat the breakthrough pain episode for several consecutive episodes.”

9 79. Due to the dangers of fentanyl, which can be fatal even through
10 contact with the skin or inhalation, the FDA requires Subsys to be dispensed with
11 the following “black box warning”:
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**WARNING: RISK OF RESPIRATORY DEPRESSION,
MEDICATION ERRORS, ABUSE POTENTIAL**

Respiratory Depression

Fatal respiratory depression has occurred in patients treated with transmucosal immediate-release fentanyl products such as SUBSYS, including following use in opioid non-tolerant patients and improper dosing. The substitution of SUBSYS for any other fentanyl product may result in fatal overdose.

Due to the risk of respiratory depression, SUBSYS is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.

Death has been reported in children who have accidentally ingested transmucosal immediate-release fentanyl products. SUBSYS must be kept out of reach of children. [see Patient Counseling Information (17.3) and How Supplied/Storage and Handling (16.1)]

The concomitant use of SUBSYS with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression [see Drug Interactions (7)].

Medication Errors

Substantial differences exist in the pharmacokinetic profile of SUBSYS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose.

- When prescribing, do not convert patients on a meg per meg basis from any other fentanyl products to SUBSYS. [see Dosage and Administration (2.1), Warnings and Precautions (5.2,) and Clinical Pharmacology (12.3)]
- When dispensing, do not substitute a SUBSYS prescription for other fentanyl products.

Abuse Potential

SUBSYS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. SUBSYS can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing SUBSYS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

Because of the risk for misuse, abuse, addiction, and overdose, SUBSYS is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate-Release Fentanyl (TIRF) REMS Access program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program. [See Warnings and Precautions (5.10)] Further information is available at www.TIRFREMSaccess.com or by calling 1-866-822-1483.

80. Specifically, the label warns that “[f]atal respiratory depression has occurred in patients treated with transmucosal immediate-release fentanyl products such as Subsys, including following use in opioid non-tolerant patients and improper dosing.” Even the “substitution of Subsys for any other fentanyl product may result in fatal overdose,” according to the label. The label also clearly warns that “Subsys is contraindicated in the management of acute or postoperative pain

1 including headache/migraine and in opioid non-tolerant patients.” In other words,
2 the label clearly states that Subsys *should not be used* to manage acute pain, such
3 as neck or back pain, or migraines.

4 **3. Legal and Regulatory Framework Governing Insys’ Sales**
5 **and Marketing of Subsys**

6 **a) FDA Regulations on Off-Label Marketing**

7 81. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its
8 implementing regulations, 21 U.S.C. § 301, et seq., a drug manufacturer, such as
9 Insys, is prohibited from distributing drugs in interstate commerce for any intended
10 use that the FDA has not approved as safe and effective. 21 U.S.C. § 355(a) and
11 (b).

12 82. A drug manufacturer may describe the “intended use(s)” of a drug in,
13 among other things, its label or “labeling,” which includes written, printed, or
14 graphic materials accompanying the product. *See* 21 U.S.C. § 321(m); 21 C.F.R. §
15 202.1(l)(2); *see also* 21 CFR 201.128, 801.4.

16 83. To obtain authorization from the FDA to sell a new drug product, a
17 company must first submit and receive the FDA’s approval of its New Drug
18 Application (“NDA”) pursuant to 21 U.S.C. § 355. In the NDA, the company must
19 describe all intended uses proposed for a new drug’s labeling and prove that the
20 new drug is safe and effective for those uses based upon data from its clinical
21 trials. 21 U.S.C. § 355(b).

22 84. In this regard, when the FDA reviews an NDA and approves a drug
23 for commercialization, such approval is only with respect to the intended use(s)
24 proposed in the NDA and approved for the drug’s labeling. In other words, “[a]
25 use that does not appear in the labeling is not approved as safe and effective by
26 FDA and is known as an ‘unapproved’ or ‘off-label’ use.” 65 Fed. Reg. 14286-01.

1 85. When a company promotes an approved drug for an off-label use, the
2 drug becomes an unapproved “new drug” with respect to that use. *See* 21 U.S.C. §
3 355(b), (d), (j). In addition, the approved drug is considered “misbranded” because
4 the labeling of such a drug would not include “adequate directions for use” under
5 21 U.S.C. § 352(f). Both unapproved new drugs and misbranded drugs are
6 prohibited from distribution in interstate commerce. *See* 21 U.S.C. 331(a), (d), (k).
7 Accordingly, such off-label marketing violates the FDCA.

8 86. The FDA has issued regulatory guidance to assist pharmaceutical
9 companies in determining whether their dissemination of information on off-label
10 uses of a drug amounts to illegal off-label marketing prohibited under the FDCA.
11 Among other things, the FDA clearly advises that: (i) information concerning a
12 drug’s off-label use contained in reprints of scientific or medical journal articles,
13 scientific or medical reference texts, or clinical practice guidelines should not be
14 attached to any promotional materials that a sales representative delivers to a
15 physician during an office visit or distributed during promotional speakers’
16 programs, *see* FDA Guidance for Industry, Distributing Scientific and Medical
17 Publications on Unapproved New Uses—Recommended Practices (Feb. 2014);
18 and (ii) statements by sales representatives or paid speakers of a drug’s off-label
19 use followed by requests for more information by physicians or program attendees
20 constitute “solicited requests” evidencing the pharmaceutical company’s intent to
21 promote the drug off-label. *See* FDA Guidance for Industry, Responding to
22 Unsolicited Requests for Off-Label Information About Prescription Drugs and
23 Medical Devices (Dec. 2011).

24 **b) TIRF-REMS Access Program**

25 87. As depicted above, Subsys’ black box warning advises that the drug is
26 subject to the FDA-mandated TIRF-REMS Access Program, in which healthcare
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1 professionals who prescribe to outpatients, pharmacies, and distributors must be
2 enrolled in order to obtain, prescribe, dispense, or distribute TIRF medications.

3 88. The purpose of the TIRF-REMS Access Program is to mitigate the
4 risks of misuse, abuse, addiction, overdose, and serious complications due to
5 medication errors with the use of TIRF medicines. To this end, the TIRF-REMS
6 Access Program implements various protocols designed to, among other things: (i)
7 prescribe and dispense TIRF products only to appropriate patients, including only
8 opioid-tolerant patients; (ii) prevent inappropriate conversion between fentanyl
9 products; (iii) prevent accidental exposure to children and others for whom TIRF
10 products were not prescribed; and (iv) educate prescribers, pharmacists, and
11 patients on the potential for misuse, abuse, addiction, and overdose.

12 **c) Federal Anti-Kickback Provisions**

13 89. In addition to FDA regulations, Insys' marketing practices are subject
14 to federal anti-kickback laws, which prohibit, among other misconduct, offering,
15 paying, or soliciting remuneration to induce the purchasing or ordering, or
16 arranging for the purchase or ordering of any healthcare item, such as a drug,
17 reimbursable under any federally financed healthcare program, such as Medicare
18 and Medicaid.

19 90. Specifically, under the Anti-Kickback Statute, it is illegal for an
20 individual to knowingly and willfully offer or pay remuneration in cash or in kind
21 to induce a physician to order a good or service that is reimbursed by a federal
22 healthcare program. *See* 42 U.S.C. § 1320a-7(b)(2). "Remuneration" refers
23 broadly to anything of value offered or paid in return for purchasing, ordering, or
24 recommending the purchase or order of any item reimbursable by a federal
25 healthcare program. *See* Department of Health and Human Services, Office of
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1 Inspector General Compliance Program Guidance for Pharmaceutical
2 Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003).

3 91. The purpose of the Anti-Kickback Statute is to prohibit such
4 remuneration in order to secure proper medical treatment and referrals and *to limit*
5 *unnecessary treatment, services, or goods that are based not on the needs of the*
6 *patient but on improper incentives given to others*, thus interfering with the
7 patient's right to choose proper medical care and services. See Medicare and
8 Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed.
9 Reg. 3088, 309 (proposed Jan. 23, 1989) (codified at 42 C.F.R. pt. 1001).

10 **4. Third-Party Payer Relationships**

11 92. During the Class Period, Insys' relationships with third-party payers
12 were critical to its ability to generate revenue from Subsys sales. As Insys
13 acknowledged in its SEC filings:

14 Our sales of, and revenue from, Subsys depend in significant
15 part on the coverage and reimbursement policies of third-party
16 payers, including government payers such as Medicare and
17 Medicaid, and private health insurers. All third-party payers
18 are sensitive to the cost of drugs and consistently implement
19 efforts to control these costs, which efforts include, but are not
20 limited to establishing excluded or preferred drug lists. Subsys
21 has been, and will likely continue to be, subject to these
22 restrictions and impediments from third-party payers,
23 particularly [pharmacy benefit managers ("PBMs")] and private
24 health insurers.

25 93. PBMs are employed by insurance companies among others, and they
26 administer prescription drug benefits for employers and health plans and run large
27 mail-order pharmacies. PBMs are primarily responsible for developing and
28 maintaining the formulary (*i.e.*, a list of prescription drugs covered by a
prescription drug plan or another insurance plan offering prescription drug
benefits), contracting with pharmacies, negotiating discounts and rebates with drug
manufacturers, and processing and paying prescription drug claims.

1 94. To ensure adequate reimbursement levels for Subsys from third-party
2 payers, the Company's IRC worked extensively with PBMs to evaluate price
3 increases and secure insurance coverage for Subsys. In particular, the Company's
4 IRC provided administrative reimbursement support services that helped patients
5 work with their insurance companies to obtain approvals for Subsys through the
6 "prior authorization process," which occurs when a patient is denied coverage for a
7 prescription by his or her insurer until the patient's healthcare provider furnishes a
8 justification as to why the medication is needed.

9 95. To use these services, the patient's healthcare provider: (i) was
10 required to "opt-in" to the Insys Patient Services Center program by signing Health
11 Insurance Portability and Accountability Act ("HIPAA") compliant forms for each
12 patient; and (ii) was responsible for providing any medical necessity justifications.
13 Then, according to the Company's website, "at no cost to the patient or healthcare
14 provider," Insys' "dedicated team" of specialists in its IRC would handle the
15 complex insurance paperwork required to be submitted to the PBMs.

16 96. Meanwhile, the Company would offer patients a free trial of Subsys to
17 allow for titration to their "effective dose" and bridge the prior authorization
18 process until third-party payer reimbursement was in place.

19 **B. Defendants Defrauded Class Members, Patients, and PBMs By**
20 **Secretly Marketing Subsys Off-Label and Fraudulently Obtaining**
21 **Insurance Coverage for Off-Label Subsys Prescriptions**

22 97. From its launch in March 2012, Subsys appeared to be a successful
23 drug. The sixth TIRF drug to be launched, Subsys joined an existing market for
24 rapid onset fentanyl medications and had a very limited on-label indication and
25 patient population: opioid-tolerant adult cancer patients with breakthrough pain.
26 Despite these headwinds, during the Class Period Subsys net revenues grew every
27 quarter on average by 91% year-over-year until 1Q16, when net revenues from
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1 Subsys declined 12% year-over-year. Significantly, Subsys net revenue accounted
2 for 98 to 100% of Insys total net revenue for the same period.

	Subsys Net Revenue	% YoY Change	% of Total Net Revenue
2Q14	\$54.6 million	+ 195%	98.03%
3Q14	\$58.2 million	+ 105%	99.83%
4Q14	\$66.1 million	+ 68%	99.40%
FY14	\$219.5 million	+ 229%	98.83%
1Q15	\$70.5 million	+ 73%	99.60%
2Q15	\$76.7 million	+ 40%	98.84%
3Q15	\$91.3 million	+ 56%	99.78%
4Q15	\$91.1 million	+ 39%	100%
FY15	\$330.3 million	+ 50%	100%
1Q16	\$62.0 million	- 12%	100%

13 98. Throughout the Class Period, Defendants publicly reported Insys’
14 financial results, attributing Subsys’ revenue growth to, among other things, the
15 Company’s “successful execution of [its] Subsys strategy,” which included
16 “increased prescriptions and change in mix of prescribed dosages.” For example,
17 Defendant Babich touted Insys’ “double digit growth in Subsys scripts” despite “an
18 overall decline in the TIRF market.” Additionally, Defendant Babich claimed that
19 the “success to date of Subsys is a result of a clinically superior product, coupled
20 with a focused market penetration strategy.” However, unbeknownst to investors,
21 Subsys’ consistent revenue growth was dependent upon persistent illegal off-label
22 marketing, illegal kickbacks to prescribers, and a wide-ranging scheme to defraud
23 third-party payers into authorizing insurance coverage for off-label prescriptions of
24 Subsys by misrepresenting the health conditions of the persons to whom Subsys
25 was prescribed.

1 **1. Defendants Illegally Marketed Subsys for Off-Label Uses**

2 99. During the Class Period, Defendants publicly proclaimed, among
3 other things, that: (i) “[w]e are only selling a breakthrough cancer pain drug”; (ii)
4 “no one at Insys wants to see anyone taking [Subsys] for anything other than
5 cancer pain”; and (iii) Insys was “committed to complying with laws governing
6 [Subsys’] sales, marketing and promotional practices.” The undisclosed reality,
7 however, was very different. Unbeknownst to investors, Insys secretly engaged in
8 an illegal scheme to market Subsys for off-label uses, including uses that were
9 expressly contraindicated in the FDA-approved label—a scheme that the U.S.
10 Government’s investigation has concluded is a nationwide criminal enterprise
11 under the Racketeer Influenced Criminal Organizations Act (“RICO”).

12 100. Defendants’ off-label marketing scheme included a number of tactics,
13 each of which was employed by the Company through its sales and marketing
14 divisions. These tactics included at least the following: (i) targeting physicians
15 who primarily treat patients with pain other than BTCP or are otherwise ill-suited
16 or unqualified to prescribe dangerous Schedule II narcotics; (ii) providing
17 economic incentives and other encouragement to sales representatives and
18 managers to promote Subsys for off-label uses; and (iii) providing monetary and
19 in-kind kickbacks to doctors who maintained high levels of Subsys prescriptions
20 for off-label uses.

21 **a) The Subsys “Speaker Program”**

22 101. Beginning shortly after Subsys’ public launch, and continuing until at
23 least August 2012, Defendants planned and funded a program to market Subsys to
24 medical practitioners through the use of putative peer-to-peer educational events—
25 *e.g.*, lunches or dinners at which another licensed medical practitioner touted the
26 use of Subsys in exchange for an “honoraria” or speaker’s fee (the “Speaker
27 Program”).
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1 102. At the time, Insys’ policy required its sales representatives only to
2 recruit (and management only to approve) for the Speaker Program licensed
3 medical practitioners who met certain criteria, including (i) skill in use of opioids,
4 (ii) experience in prescribing Subsys, (iii) geography, (iv) prominence, and (v)
5 experience as a speaker, among other things.

6 103. However, after the first full fiscal quarter of Subsys sales, Defendants
7 were dissatisfied with the results—just \$1.2 million in net Subsys sales.
8 Accordingly, in late June 2012, Defendant Babich hired Defendant Burlakoff to
9 replace the Company’s then-Southeast Regional Sales Manager. Defendant
10 Burlakoff previously had been involved in Cephalon’s illegal marketing of another
11 fentanyl-based drug, Actiq, for off-label uses.

12 104. One week after hiring Defendant Burlakoff, Defendant Babich sent an
13 email on June 27, 2012 entitled “Live Speaker Targets” which implored Defendant
14 Burlakoff and Insys’ other sales managers, among others, to ensure that the
15 Company’s sales force understood “the important nature of having one of their top
16 targets as a speaker” because it could “pay big dividends for them.”

17 105. Immediately thereafter, Defendant Burlakoff began using in-person
18 meetings, telephone calls, and texts to explicitly instruct sales representatives to
19 ignore the Company’s Speaker Program policy and use the availability of
20 “honoraria” to pay practitioners for prescribing large amounts of Subsys. Indeed, in
21 a text to one member of the Subsys sales force, Defendant Burlakoff expressly
22 stated that while the Speaker Program participants “*do not need to be good*
23 *speakers,*” *they do “need to write a lot of [Subsys prescriptions].”*

24 106. After increased sales in Defendant Burlakoff’s region, Defendant
25 Babich promoted him to VP of Sales in September 2012, giving Burlakoff
26 supervision of the Company’s entire Subsys sales force. On his first day as the VP
27 of Sales, Defendant Burlakoff sent an email to a new sales representative, copying
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1 Defendant Babich, among others, explaining that “it all starts with choosing the
2 right LOCAL speaker” who “should be your ‘business partner’” and noting that “if
3 your speaker does not see it this way (then it is time to identify another
4 speaker).”

5 107. Together, Defendants Babich and Burlakoff hired several new sales
6 employees throughout the summer and fall of 2012, including Rich Simon, who
7 ultimately became Burlakoff’s direct report when he was promoted to Director of
8 Sales in July 2013, and Jeff Rowan and Sunrise Lee, both of whom served as
9 Regional Sales Directors reporting directly to Simon. By the end of 2012, Subsys’
10 net sales had grown 300%.

11 108. Before and during the Class Period, Defendants Babich and Burlakoff,
12 among others, tracked the relative success of competitor offerings in the TIRF
13 market. Along with Simon, Lee, and Rowan, among others, Defendants Babich
14 and Burlakoff supplied Insys employees with lists of practitioners who previously
15 had written off-label prescriptions for TIRF products (including Subsys). These
16 lists ranked the practitioners in “decile” groups, with the lowest TIRF prescribers
17 described as “decile 1” and the highest TIRF prescribers described as “decile 10.”
18 According to the Illinois Complaint, each sales representative was assigned a range
19 of low and high decile prescribers to call on.

20 109. Not surprisingly, Defendants targeted the “high decile” practitioners
21 with Insys’ Subsys marketing programs. Defendants encouraged the Company’s
22 sales representatives to secure the majority of their sales from one or two high-
23 volume prescribers. As a result, Insys sales representatives were instructed to call
24 on high-volume TIRF prescribers frequently—at least three times a week—as
25 compared to the low-volume TIRF prescribers, whom sales representatives only
26 called on twice a month. In a May 1, 2013 email to the sales force, Defendant
27 Burlakoff wrote: *“pick an office that your gut tells you is worth going after –*
28

1 *pack your bags – move in – don’t leave until you have seen the Subsys*
2 *prescription you need on a daily basis ‘with your own two eyes!’”* According to
3 the Illinois Complaint, certain Illinois sales representatives visited high volume
4 prescribers nearly every day.

5 110. At the same time, Defendants Babich and Burlakoff and their direct
6 reports tracked and circulated within the Company the total number of planned
7 Speaker Program events for each participant in the Program, including the number
8 of Speaker Program events completed, as well as at least the following metrics: (i)
9 the number of Subsys prescriptions written by the participant; (ii) the percentage of
10 Subsys prescriptions written by the participant as compared the number of the
11 participant’s competitor drug prescriptions; (iii) the net revenue earned from each
12 speaker, and the total amount of “honoraria” or fees paid to each participant; and
13 (iv) the Company’s “return on investment” or ROI for each participant. Defendants
14 utilized these reports to better identify those practitioners to target for inclusion in
15 the Speaker Program. For example, when Defendant Babich received a list of
16 medical practitioners who had written prescriptions for Subsys competitors, he
17 emailed Defendant Burlakoff directly stating, “I thought we owned the high decile
18 folks? Lots of big names on there.”

19 **b) Insys Targeted Unqualified Healthcare Professionals**
20 **for the Speaker Program**

21 111. Defendants repeatedly represented to investors that Insys focused its
22 Subsys marketing and promotion efforts on healthcare professionals who treated
23 patients for BTCP. For example, the Company’s FY14 Form 10-K claimed that
24 Insys was “taking market share from other competing TIRF products and
25 expanding the usage of Subsys for BTCP by building awareness among
26 oncologists” Likewise, during the March 3, 2015 conference call with
27 investors and analysts to discuss Insys’ 4Q14 results, Defendant Babich touted the
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1 Company's "very unique programs within the oncology setting" as one of the
2 reasons behind Subsys sales growth.

3 112. In fact, despite making public statements to investors to the contrary,
4 Insys was **actively discouraging** its sales representatives from approaching the
5 very doctors who would be able to prescribe Subsys for on-label indications—
6 oncologists, pain management specialists who treated cancer patients, or palliative
7 care offices. For example, Shannon Walsh, a former Insys sales representative
8 until October 2015, told CNBC that when she approached her managers about
9 reaching out to palliative care facilities to tell them about Subsys, she was told not
10 to approach them because "***those patients would die soon anyway and couldn't***
11 ***titrate (increase the dosage).***" Walsh expressed shock when she learned the type
12 of doctors Insys expected its Subsys sales representatives to target, which included
13 mostly family doctors and internal and general medicine physicians: "The
14 physicians I spoke with had never heard of these fentanyl products. They also
15 advised me that they would never have any occasion to use the products in this
16 class, because they did not treat pain nor did they treat cancer." Only in the light
17 of Insys' undisclosed avoidance of oncologists can one make sense of the fact that,
18 according to a May 2014 *New York Times* article, less than 1% of Subsys
19 prescriptions were written by oncologists.

20 113. Ms. Walsh's account was confirmed by remarks made by Defendant
21 Burlakoff at Insys' 2014 National Sales Meeting, during which he instructed the
22 Company's sales force to avoid seeking practitioners to prescribe Subsys for on-
23 label indications because cancer patients were "small potatoes":

24 [t]hese [doctors] will tell you all the time, well, I've only got
25 like eight patients with cancer. Or, I only have, like, twelve
26 patients that are on a rapid-onset opioids [sic]. ***Doc, I'm not***
27 ***talking about any of those patients. I don't want any of those***
28 ***patients. That's, that's small potatoes. That's nothing. That's***
not what I'm here doing. I'm here selling [unintelligible] for
the breakthrough pain. If I can successfully sell you the

1 [unintelligible] for the breakthrough pain, do you have a
2 thousand people in your practice, a thousand patients, twelve of
3 them are currently on a rapid-onset opioids [sic]. That leaves
4 me with at least five hundred patents that can go on this drug.

5 114. Instead, Insys targeted medical professionals who rarely treated
6 cancer patients—the only group of patients for which Subsys could have been
7 prescribed for on-label use. As documented in numerous criminal proceedings,
8 including the Babich and Burlakoff Indictment, and in-depth media analyses, Insys
9 sales representatives marketed and promoted Subsys to pain management or
10 physical medicine and rehabilitation specialists, including those running illicit “pill
11 mills,” who *did not* treat cancer patients.

12 115. The reports regarding the relative success of Subsys competitors, the
13 prescribing habits of medical practitioners and the Speaker Program participants
14 received by Defendants confirmed that physicians who treated cancer patients were
15 not “high decile” TIRF prescribers, leading Insys’ sales force to focus on doctors
16 who were prescribing competitor TIRF products, irrespective of whether these
17 doctors were prescribing these products for off-label indications. For example,
18 Simon, Insys’ Director of Sales and Defendant Burlakoff’s direct report, texted a
19 sales representative stating:

20 I need confirmation from YOU that you had a conversation
21 with [prescriber] where he will not ONLY promote for cancer
22 patients. *If he does this he will single handedly take down the
23 whole company.* He MUST creatively share how doc[tors]
24 write this product everywhere. Please get back to me ASAP
25 with confirmation that he will share with other speakers how
26 effective . . . [Subsys] will be to treat ALL BTP [breakthrough
27 pain].

28 (Capitalized words in original).

116. The Company also made the strategic decision to implement programs
designed to shift market share from other TIRF products to Subsys. The express
purpose of one such tactic—the “Switch Program”—was to “switch” patients from
other TIRF products to Subsys regardless of whether the patients had BTCP.

1 Through the auspices of the Switch Program, Insys instructed its sales
2 representatives to target prescribers of competing TIRFs and offer their patients
3 free product if the patients switched to Subsys. Any patient, regardless of his or
4 her diagnosis, was eligible for the Switch Program. In one instance, an Illinois
5 sales representative was told to report back to the representative’s supervisor “the
6 exact day and time [a potential switch patient] is scheduled back for his or her next
7 visit” and then to “be in the office/when the patient is coming in (with
8 coffee/bagels, etc.)” to ensure that the patient ultimately was switched to Subsys.

9 117. Insys also instructed its sales representatives to solicit sales from
10 doctors already primed by competitor companies, such as Cephalon (at which
11 Defendant Burlakoff previously was employed), to market fentanyl for *off-label*
12 uses. Notably, Cephalon had previously pled guilty to one count of off-label
13 marketing of fentanyl, paying \$425 million to settle criminal and civil claims
14 related, in part, to its marketing of Actiq, a Subsys competitor drug, off label to
15 non-cancer patients for uses that included alleviating migraine headaches. By
16 targeting doctors that prescribed Actiq already, Insys sought to secure more Subsys
17 prescriptions for off-label indications.

18 118. Further, because of the limited number of board-certified pain
19 management specialists, Insys instructed its sales representatives to contact
20 healthcare professionals who had no prior experience in prescribing Schedule II
21 opioids. Indeed, some of the doctors that Insys sales representatives called upon
22 were not even enrolled in TIRF-REMS Access Program—the FDA-run program
23 meant to ensure that fentanyl-based rapid-onset opioids were carefully
24 controlled—when they were first contacted about Subsys. As a result, it was
25 entirely likely that the doctors approached about use of Subsys had never
26 previously prescribed a fentanyl-based rapid-onset opioid to any of their patients.
27 As Neely, one Insys sales representative who spoke with the *SIRF* put it,
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1 “management pushed the sales force to market Subsys ‘to anyone with a
2 prescription pad.’ Anyone who disagreed with that approach, he said, ‘was treated
3 like garbage,’ and eventually fired.” These practices led to nearly 50% of Subsys
4 prescriptions being written by, among others, general practice physicians,
5 neurologists, dentists, and podiatrists.

6 119. For example, the Oregon Complaint identified two healthcare
7 professionals in Oregon targeted by Insys who had no prior experience or
8 specialized training in prescribing rapid-onset opioids, such as Subsys. The first of
9 these two healthcare professionals was Dr. James Gallant, who had never been
10 board-certified in any specialty and, a four-day commercial continuing education
11 program aside, had no post-graduate training in pain management. Despite Dr.
12 Gallant’s lack of experience in pain management, including BTCP, Insys sales
13 representatives visited his office more than 100 times in 2012 and 2013.
14 Moreover, as explained herein, Dr. Gallant also received remuneration from Insys
15 for speaking to other doctors about using Subsys throughout this same period. Dr.
16 Gallant’s medical license subsequently was suspended for 90 days in October
17 2014, in part due to improperly prescribing opioids, and in addition to a \$10,000
18 fine, he was placed on probation for 10 years.

19 120. Likewise, the second of these two healthcare professionals, Dr. Roy
20 Blackburn was a physiatrist who not only did not specialize in pain management
21 (and, therefore, was not knowledgeable or skilled in the use of Schedule II opioids,
22 such as Subsys), but also did not treat any cancer patients for breakthrough pain.
23 Insys sales representatives visited Blackburn at least 80 times. In October and
24 November 2012, the Company paid Dr. Gallant (*see supra*) and Dr. Stuart
25 Rosenblum \$2,400 and \$1,600, respectively, to speak to Dr. Blackburn regarding
26 the use of Subsys, after which Dr. Blackburn prescribed Subsys for migraines. Dr.
27
28

1 Blackburn was investigated and ultimately prohibited from prescribing Schedule II
2 drugs for a one-year period.

3 121. In another example, one of the doctors referenced in the criminal
4 complaint against former Insys sales representative Fernando Serrano told federal
5 investigators that Serrano called on him to promote Subsys even though the doctor
6 did not have many cancer patients in his practice. In or about 2014, after receiving
7 multiple visits from Serrano, the doctor was invited to multiple Subsys speaker
8 programs, eventually attending these events twice per month. Thereafter, Serrano
9 told the doctor that he needed to help Serrano out by writing Subsys prescriptions.

10 122. Moreover, certain Defendants were personally involved in the
11 Company's efforts to attract new Subsys prescribers. The Oregon Complaint
12 described one particular instance in which Insys hired as a sales representative
13 Jonathan (last name withheld), the son of Dr. Roy (last name withheld), a
14 physiatrist, who neither treated patients for BTCP nor prescribed Subsys in his
15 practice. Despite explaining in his interview that his father did not treat BTCP and
16 did not use Subsys in his practice, Jonathan was asked on numerous occasions to
17 convince his father to begin prescribing Subsys. To that end, Insys set up a dinner
18 on October 21, 2013 for Jonathan, Dr. Roy, and Dr. Rosenblum, a frequent speaker
19 on behalf of drug companies, for which Dr. Rosenblum was paid \$1,600 to pitch
20 Subsys to Dr. Roy.

21 123. Shortly after the October 21 dinner with Dr. Rosenblum discussed
22 above, Dr. Roy notified Jonathan about texts he had received from Insys Regional
23 Sales Director Beth McKey proposing "tequila dates" and asking his son if the
24 texts "seemed weird." Then, on November 1, 2013 Jonathan texted his father the
25 following:

26 These people from my company are relentless and it's kind of
27 pissing me off. I have told them multiple times (starting with
28 the interview) that you probably won't be writing my product

1 due to the type of practice you have, but my manager just called
 2 me an[sic] told me that they were “concerned” that I haven’t
 3 gotten you tirtf rems enrolled. *Now they told me that dr.*
 Kapoor contacted you. I need you to help me to figure out what
 to say to them to calm them down.

4 124. Twelve days later, Jonathan texted his father again: “This company
 5 [Insys] really want [sic] to make you a speaker. *Apparently Kapoor had good*
 6 *things to say about you. The VP of sales [Burlakoff] wants to come out and*
 7 *speak with you . . .* I apologize for being pushy.” Given that Dr. Roy had never
 8 prescribed Subsys nor treated patients with BTCP, the fact that both Defendants
 9 Kapoor and Burlakoff wanted to make him a speaker is telling—they were trying
 10 to convince Dr. Roy to prescribe Subsys off-label to his patients, none of whom he
 11 was treating for cancer pain. Dr. Roy never became a speaker and did not
 12 ultimately prescribe Subsys to his patients. Jonathan resigned from his position at
 13 Insys.

14 125. Accordingly, it should have come as no surprise to Defendants that
 15 nearly 80% of Subsys prescriptions were for off-label uses.

16 c) **Defendants Trained and Incentivized the Company’s
 Sales Force To Promote Subsys For Off-Label Uses**

17 (1) **Insys Hired Inexperienced Sales
 18 Representatives to Promote a Schedule II
 19 Drug Fifty Times More Powerful Than
 Heroin**

20 126. Despite the potency, side effects, and addictive nature of Subsys,
 21 Insys did not hire or promote sales representatives with the requisite training to
 22 properly and safely market or promote a Schedule II narcotic. In making hiring
 23 decisions, the Company instead prioritized physical attractiveness, non-medical
 24 sales experience, and the potential employee’s relationships with doctors who
 25 already prescribed or who might be convinced to prescribe Subsys.

26 127. For example, according to a December 2015 *SIRF* article, one sales
 27 representative hired by Defendant Burlakoff, Amanda Corey Emhof, was a former
 28

1 reality-TV show star who had won \$477 on an episode of *Judge Judy* and
2 previously posed for *Playboy*. According to an April 2015 *SIRF* article, the head
3 of sales for the New York region, Jeff Pearlman, ran marketing and sales for a
4 company that sold aquariums before he was hired to manage sales of the highly
5 addictive and dangerous Schedule II opioid. The same article noted that Insys’
6 former head of sales for the Central and Western sales regions, Sunrise Lee, was a
7 dancer at a West Palm Beach strip club and may also have owned an escort agency
8 before she was hired by the Company. Natalie Perhacs was hired as a sales
9 representative solely as a result of her relationship with one of the largest single
10 prescribers of Subsys, Dr. Ruan.

11 (2) **Insys Sales Force Was Trained to Promote**
12 **Subsys for Off-Label Indications**

13 128. In periodic and *ad hoc* meetings and conversations, Insys trained its
14 sales representatives to promote Subsys for off-label indications. A former Insys
15 sales representative, Tim Neely, described Insys as having a form of “corporate
16 schizophrenia.” “Sales training and company-wide phone calls would be by the
17 book, exactly like Merck or someone might do. Then your [district and regional]
18 managers would pull you aside and tell you, ‘Don’t worry about that. Just sell. Do
19 what you need to do.’” According to Neely, Defendant Burlakoff told a training
20 class that Neely attended in October 2013: “*If you keep [patients] on [Subsys] for*
21 *four months, they’re hooked. . . . Then they’ll be on it for a year, maybe longer.*”
22 When Neely privately questioned if by “hooked,” Defendant Burlakoff meant
23 addicted to Subsys, Defendant Burlakoff coyly responded, “It’s not addicted if [the
24 patient] is in pain.” At an early 2014 sales meeting that Neely attended, Defendant
25 Burlakoff also told a group of sales representatives that they needed to watch *The*
26 *Wolf of Wall Street* because it was “the best sales training video in history.”
27
28

1 129. According to a May 2014 *New York Times* article as well as the
2 Illinois Complaint, sales representatives were trained to first mention Subsys’ on-
3 label indication, BTCP, before shifting to a more general discussion of non-
4 specific “breakthrough pain” and the doctor’s non-cancer patients. Sales
5 representatives, like Tim Neely, also were trained to instruct patients on the use of
6 the drug in doctors’ offices. According to the Illinois Complaint, Insys created and
7 distributed a “Breakthrough Pain Tracker” that patients could use as a journal to
8 record and rate their pain. The “Tracker” defined pain without any reference to
9 cancer; in fact the word “cancer,” appears nowhere in the “Tracker.”

10 130. In sworn testimony before the ODOJ, former Insys sales
11 representative Jaimi Hooker—Dr. Blackburn’s sales representative—confirmed
12 that she was “implicitly *encouraged by [her] superiors to try to get doc[tors] to*
13 *write” Subsys prescriptions “for back pain.”* She also confirmed that “marketing
14 for off-label uses by implication” was a fair description of what she was asked to
15 do by her superiors. She further described the concept of asking a doctor to “write
16 to their capability”—a euphemism for asking a doctor to transfer all of its TIRF
17 business to Subsys, and then write more Subsys prescriptions, generally, regardless
18 of whether these patients had BTCP. Ms. Hooker relayed that this type of
19 conversation with doctors typically is “difficult,” in part because “it would
20 probably imply writing more off-label.”

21 131. Sales representatives also were instructed to ensure that patients on
22 Subsys received an “effective dose.” Although the FDA-approved label required
23 that patients begin taking Subsys at the 100mcg lowest available dose (unless they
24 were already taking a high dose of the competitor TIRF product, Actiq), Insys
25 earned more money when a higher Subsys dose was prescribed because higher
26 doses are more expensive. Insys’ Board of Directors, including, on information
27 and belief, Defendant Kapoor, recognized this quandary at a February 5, 2013
28

1 board meeting identifying as a strategic challenge for the Company the low starting
2 dose and titration scheduled approved by the FDA to enhance patient safety. To
3 address this challenge, Insys created the concept of the “effective dose,” which was
4 defined by the Company as 600 mcg to 1600 mcg of Subsys, far higher than the
5 100 mcg initial dose required by the FDA and not consistent with the Subsys’ label
6 titration requirements. Through this marketing strategy, Insys represented to
7 prescribers that patients should receive 6x to 16x more Subsys than the initial
8 dosing, despite the FDA’s requirement, set forth on the Subsys label, that the
9 patient be on the lowest dose possible to prevent pain.

10 (3) **Defendants Provided Sales Representatives**
11 **Material Economic Incentives to Promote**
12 **Subsys Off-Label**

13 132. Once Insys hired its sales representatives, the Company provided a
14 number of incentives to motivate them to convince doctors to write as many
15 prescriptions of Subsys at the highest possible doses. For instance, Defendants
16 motivated Insys sales representatives to promote Subsys off-label through Insys’
17 compensation plan. Dr. Kapoor described his ideal sales people as Ph.D.’s—
18 “poor, hungry and dumb” and paid them utilizing an “incentive-based” model that
19 he previously had employed to great effect at his prior companies. Insys sales
20 representatives were paid a base salary of \$40,000 (less than \$20 per hour)—half
21 of the industry standard of \$80,000—in order to force them to earn sales
22 commissions to make a decent wage.

23 133. Commissions were paid based on the value of the prescriptions
24 written by sales representatives’ prescribers in a given period, which was often
25 dictated by the size of the dose. For Subsys, the higher the dose prescribed by the
26 doctor, the higher the price of the prescription, and, therefore, the higher the
27 commission received by the sales representative. Indeed, the Company’s 4Q13
28 compensation plan provided new Insys sales representatives with a 7% sales

1 commission for Subsys doses between 100 and 800 mcgs and a 10% commission
2 for the highest doses of 1200 to 1600 mcgs. According to an industry expert
3 consulted by the *New York Times*, the practice of paying sales representatives for
4 selling higher doses was “highly unusual because ‘most companies feel that is the
5 doctor’s decision because it is very patient-specific.’”

6 134. An email between Defendant Burlakoff and Joseph Rowan dated July
7 28, 2012 regarding the amount of money a prior sales representative earned from
8 one of the highest prescribers of Subsys (Dr. Ruan), which was quoted in both
9 Perhacs’ criminal information as well as the Babich and Burlakoff Indictment,
10 demonstrated how the value of the prescription could lead to even greater rewards
11 for an Insys sales representative:

12 [Dr. Ruan’s previous sales representative] made 7k off Dr.
13 Ruan last quarter. He wrote 1500 units and 26 prescriptions.
14 So, that’s basically 1 script every 3rd day for 60 days. If he
15 wrote just 1 script every day and a low # of units (like he did
16 last quarter) you would make 22K. If he does 2 Subsys a day
17 for one straight quarter, you would make at least 40 grand for
18 the quarter!

19 135. Shortly after he was hired by Defendant Babich, Defendant Burlakoff
20 hired Rowan and assigned him to Dr. Ruan. Within two weeks, Dr. Ruan
21 participated in his first two Speaker Program events, writing 18 Subsys
22 prescriptions that week. By the end of 3Q13, Dr. Ruan was writing on average 11
23 Subsys prescriptions per week. By December 2012, Defendant Burlakoff informed
24 Rowan that thanks to his efforts with Dr. Ruan, Rowan was “now officially #1 in
25 the company (with only one doctor). I am pretty sure your formula worked, you
26 may want to pass it along to your team.”

27 136. In fact, Natalie Perhacs, the sales representative later responsible for
28 Dr. Ruan and his partner, Dr. Couch, augmented her \$40,000 per year base salary
with nearly \$700,000 in commission compensation between April 2013 and May

1 20, 2015 based almost entirely on Subsys prescriptions written by these two
2 doctors. Rowan, who supervised Perhacs and reported to Defendant Burlakoff,
3 agreed with Perhacs that her “ultimate goal” included getting Dr. Ruan’s partner,
4 Dr. Couch to write as many Subsys prescriptions as Dr. Ruan. After regularly
5 participating in the Speaker Program beginning in 2Q13, Dr. Couch averaged 6.8
6 Subsys prescriptions per week by July 19, 2013. In an August 1, 2013 email,
7 Rowan gloated to Defendant Burlakoff that where Perhacs had taken Dr. Couch
8 was “out of this world,” noting that Dr. Couch was “now a top seven prescriber
9 for” Insys.

10 137. Serrano, another former Insys sales representative, received a
11 \$100,000 bonus in 4Q13, the fifth largest bonus paid to a sales representative for
12 that quarter and a \$70,000 bonus in 1Q14, the eighth largest bonus paid to a sales
13 representative that quarter. Roper, Serrano’s boss, received a bonus based in large
14 part on the sales results of the sales representatives in his district. For 1Q13 and
15 2Q14, Jonathan Roper received \$80,000 and \$60,000 in bonus compensation,
16 respectively as Serrano’s district manager. In 3Q14, Roper received a bonus of
17 over \$100,000 as an Insys sales representative. Another indicted former Insys
18 DSM, Pearlman, received a bonus of more than \$95,000 for 3Q13.

19 138. Given the limited number of potential patients with the on-label
20 diagnosis of BTCP, and the fact that the label required doctors to start at the
21 smallest dose and only titrate to the lowest dose necessary to prevent pain, sales
22 representatives were only able to take advantage of these incentives by engaging in
23 the illegal off-label marketing of Subsys that Babich, Burlakoff, and others
24 required. According to a November 2015 *CNBC* article, emails reviewed by the
25 media outlet revealed Subsys sales representatives to be under immense pressure to
26 get doctors to write more off-label Subsys prescriptions and at higher dosages,
27 including threats of termination. Neely and other former Insys sales
28

1 representatives described the pressure to obtain new Subsys prescribers as
2 unrelenting, leading to many departures from the Insys sales force, including
3 individuals leaving within weeks of being hired.

4 139. As a result, in addition to providing sales representatives with a
5 “carrot” to pressure their doctors to prescribe more Subsys at higher value doses,
6 Defendants also employed a “stick” in the form of constant surveillance and
7 automatic emails chastising sales representatives for failing to ensure that their
8 healthcare professionals wrote prescriptions for new Subsys patients at dosages
9 higher than the initial 100 or 200 mcg dosage provided for by the FDA-approved
10 label.

11 140. According to the ODOJ, if a doctor followed the Subsys label’s
12 instructions and wrote a prescription for the lowest possible Subsys dosage (100
13 mcg), the doctor’s sales representative would receive an email copying “top
14 management” instructing the representative to “report back to your manager within
15 24 hours on WHY the low dose was used and HOW the doctor plans to titrate the
16 patient to effective dose.” These emails were sent automatically when doctors
17 prescribed Subsys at the FDA-recommended initial 100 dose, according to the
18 information attached to Perhacs’ guilty plea.

19 141. Insys also employed several tactics to identify opportunities to renew
20 prescriptions at higher doses, which in turn generated higher revenue for Insys.
21 For example, in Neely’s sales district, sales representatives would receive an email
22 detailing a list of Subsys prescriptions that had not been renewed or picked up or
23 that had been canceled, in order to allow the sales representative to try to work for
24 a renewal of the Subsys prescription or reverse a cancellation. These emails
25 sometimes led to sales representatives contacting the patients directly and
26 encouraging them to ask their prescriber for another, stronger Subsys prescription.

1 142. Neely also described another controversial practice the Company
2 utilized to garner more Subsys prescriptions whereby Insys instructed its sales
3 representatives to seek permission from their doctors' staff to *review patient files*
4 *in order to identify potential Subsys candidates*. Neely recalled that Insys
5 management wanted him to persuade the doctors he worked with to move to a
6 prescribed dosage of 800 mcg or even 1,200 mcg, despite the fact that the patients
7 were comfortable at a 400 mcg dosage. Because the FDA-approved label clearly
8 states that a prescriber should "only increase the SUBSYS dose when a single
9 administration of the current dose fails to adequately treat the breakthrough pain
10 episode for several consecutive episodes," persuading a doctor to titrate a patient to
11 a higher dosage when they are comfortable at 400mcg would be off-label
12 promotion. According to Neely, Defendant Burlakoff was the Insys executive
13 responsible for this practice.

14 143. Perhacs admitted to a similar practice as part of her guilty plea.
15 Specifically, she was able to increase the volume of Subsys prescriptions by Dr.
16 Ruan and Dr. Couch by, among other things, identifying patients who had been at
17 the same strength Subsys prescription for several months and recommending that
18 the doctors increase the patient's prescription strength.

19 144. Sales representatives who successfully convinced their assigned
20 doctors to write substantial numbers of Subsys prescriptions were held out as
21 positive examples to the rest of the sales force. For example, in an October 24,
22 2012 email to regional sales managers quoted in the criminal information against
23 Perhacs, one sales representative was lauded for visiting a "prescribing doctor
24 [who] has written 206 prescriptions to date (Dr. Ruan) . . . at least five days a week
25 . . . (sometime 7)." In a March 19, 2013 email to the entire Insys sales force,
26 Defendant Burlakoff highlighted the top selling sales representatives, including the
27 sales representative assigned to Dr. Somerville: "The below 5 names mentioned at
28

1 the top of the company rankings literally have their entire business being driven by
2 basically 1 customer. . . . Own your territory, own a doctor, and own your
3 destiny.” Additionally, Perhacs was brought on stage at a National Sales Meeting
4 by Insys management, including Defendant Burlakoff, to speak to her fellow sales
5 force members about her successes and the lessons that could be learned from her
6 experiences as the sales representative for Drs. Ruan and Couch.

7 **d) Defendants Paid Subsys Prescribers Kickbacks to**
8 **Ensure Growing Subsys Prescriptions Rates at**
9 **Higher Dosages**

10 145. To ensure that healthcare professionals continued to prescribe Subsys
11 to their patients at increasing dosages, Insys paid frequent Subsys prescribers
12 millions of dollars in fees for speaking at sham educational events. The Company
13 also provided (i) meals, alcoholic drinks, entertainment, and other benefits and (ii)
14 administrative support for the practitioners’ business, in order to reward and obtain
15 business.

16 146. According to the Centers for Medicare & Medicaid Services open
17 payments data, in 2014 Insys paid nearly \$7.4 million to doctors in “general
18 payments,” including “[c]ompensation for services . . . including serving . . . as a
19 speaker at a venue other than a continuing education program,” “food and
20 beverage,” and “travel and lodging” in 2014. As explained herein, both Insys and
21 the Subsys prescribers understood that these payments and benefits carried with
22 them an implicit quid pro quo – remuneration for increased Subsys prescriptions.
23 In other words, Insys’ marketing of Subsys during the Class Period involved a
24 widespread kickback scheme.

25 **(1) Insys Organized Sham “Educational”**
26 **Programs to Illegally Funnel Kickbacks to**
27 **Prescribers for Increased Subsys**
28 **Prescriptions at Higher Dosages**

1 147. Through the Speaker Program, Defendants compensated healthcare
2 professionals for purportedly providing “educational” presentations regarding
3 Subsys to other doctors and medical professionals. These “educational” events
4 were supposed to be run by qualified professionals in a venue conducive to an
5 educational presentation. During the event, speakers were supposed to show and
6 discuss a pre-approved slideshow to a group of appropriate healthcare
7 professionals regarding the use of Subsys. In reality, however, many (if not most)
8 of these speaking engagements were total shams, a cover story to allow Insys to
9 funnel millions of dollars of bribes to doctors in exchange for increased Subsys
10 prescriptions.

11 148. As an initial matter, the events were held at upscale and expensive
12 restaurants and other similar locations that were ill-equipped to accommodate an
13 educational presentation, including, as reported by an April 2015 *SIRF* article,
14 branches of Roka Akor, a Japanese sushi-steak restaurant owned by Defendant
15 Kapoor.

16 149. Additionally, many of these engagements were billed as social events
17 that either included a brief, improvised presentation on Subsys, or, in some cases,
18 no mention of Subsys at all. For example, according to the ODOJ, Insys paid Dr.
19 Rosenblum \$1,600 to host what was essentially a social event for doctors and their
20 wives that aside from a “brief informal presentation” by Dr. Rosenblum was
21 expressly “for socializing and networking.” Insys also paid Drs. Ruan and Couch
22 to speak, at least weekly, at programs during which neither Drs. Ruan nor Couch
23 presented on or even discussed Subsys.

24 150. Likewise, Heather Alfonso was paid to speak at events that amounted
25 to nothing more than social engagements. One such event was held on June 18,
26 2013 at Carmen Anthony’s restaurant in New Haven, CT. As the only attendees
27 were Pearlman (who has been recently indicted) and the sales representative
28

1 assigned to Alfonso, no presentation regarding Subsys was given. When Alfonso
2 pressed Pearlman about the propriety of the Speaker Program, Pearlman responded
3 with words to the effect of, “Don’t worry about the dinners. Let [Alfonso’s sales
4 representative] worry about the dinners. You just worry about writing scripts for
5 [Subsys].” On June 27, 2013, Pearlman responded to an email enclosing the
6 Subsys daily, weekly, and monthly prescription tracking reports stating, “That’s
7 right 5 [Subsys prescriptions] from [Alfonso] today,” less than two weeks after the
8 June 18 Speaker Program “event” for Alfonso.

9 151. Another recently indicted former Insys sales representative based in
10 New York, Serrano, also set up speaker programs for his territory that were
11 predominately social gatherings involving no education regarding Subsys.
12 Moreover, two Insys sales representatives cooperating with the Federal Bureau of
13 Investigation’s (“FBI”) inquiry asserted that Roper, Serrano’s boss who was also
14 recently indicted, knew that many of the speaker programs were largely social
15 events that were not educational in nature. These witnesses reported attending
16 speaker programs with Roper in at least February 2015 where no formal slide
17 presentation or other formal educational presentation regarding Subsys occurred.
18 Indeed, 70% of one of Roper’s former prescriber’s—described simply as Doctor-2
19 in Roper’s indictment—speaking engagements were merely social dinners without
20 an educational component.

21 152. Often, the paid speaker at these programs was not qualified to educate
22 other healthcare professionals regarding the use of Subsys because, among things,
23 he or she was not trained as a pain management specialist. Instead, Insys carefully
24 selected as “speakers” the doctors who the Company most wanted to incentivize to
25 prescribe more Subsys. This included doctors who already were prolific
26 prescribers of Subsys, as well as doctors who had never prescribed Subsys. In fact,
27 many of the doctors who were approached to speak regarding Subsys did not have
28

1 *any* experience in treating cancer patients with break-through pain, or, in some
2 cases, with pain management. For example, according to ODOJ, despite Dr.
3 Gallant’s lack of experience in dealing with pain management issues or, in
4 particular, BTCP, he was frequently paid \$2,400 each time he agreed to meet with
5 one or more doctors, ostensibly to discuss Subsys.

6 153. Likewise, the resume of Clough, a physician assistant in a New
7 Hampshire pain clinic—which he submitted to Insys at the request of his assigned
8 sales representative—reflected that he had never published any articles regarding
9 TIRF drugs or pain management and had no prior experience in speaking about
10 TIRF drugs or other rapid onset opioids. Despite this, one month after Clough
11 wrote his first Subsys prescription, Defendant Burlakoff endorsed Clough for the
12 Speaker Program on August 2, 2013, stating:

13 I noticed that [Clough] out of the Manchester, NH territory
14 has expressed a true passion and enthusiasm for ... [Subsys]
that I have not seen or felt in a very long time.

15 These are the exact type of clinicians we want to put in front of
16 a local audience. Often times we look for the most well-known
17 speakers, however, with this type of product—I believe passion
supersedes all!

18 With this being said, I would like to note my desire to see this
19 clinician have a significant increase in speaking opportunities-
ASAP.

20 In my brief phone conversation with ... [Clough], I could
21 literally feel this clinician’s excitement coming through the
phone.

22 His excitement, made me excited/this is undoubtedly what we
23 need.

24 154. Clough subsequently signed a speaker agreement with Insys on
25 August 8, 2013.

26 155. Further, some of the healthcare professionals who participated in the
27 Speaker Program were under investigation or had been disciplined by their local
28

1 medical board for misconduct related to prescribing Schedule II drugs at the time
2 they accepted fees from the Program. For example, according to a November 2014
3 *New York Times* article, while being paid more than any other doctor to promote
4 Subsys between August and December 2013, Dr. Somerville was under
5 investigation by the Texas Medical Board and subsequently ordered to stop
6 prescribing painkillers after the board found that he had authorized employees to
7 hand out pre-signed prescriptions to patients, and three of his patients had fatally
8 overdosed in 2012.

9 156. In the case of Dr. Madison, Defendant Babich was specifically warned
10 by the assigned sales representative that he ran an illicit operation before Dr.
11 Madison participated in the Speaker Program:

12 I call on ... [him] sometimes twice a week. ... ***Dr. Madison***
13 ***runs a very shady pill mill and only accepts cash.*** He sees
14 very few insured patients but does write some Fentora. He is
15 extremely moody, lazy and inattentive. ***He basically just shows***
16 ***up to sign his name on the prescription pad, if he shows up at***
17 ***all.*** I have been working more with his MA [medical assistant]
18 who is the one that knows what is going on in his office. He
19 has agreed to try and help me out but I know that he is afraid of
20 Dr. Madison's outbursts and is reluctant to input. I think that
21 being in the office at the right time, when the right patient
22 walks in, on a day Dr. Madison is in a good mood is the only
23 way I will get him to write. This is the reason ***I call on him***
24 ***frequently.***

25 157. Thereafter, Lee nominated Dr. Madison for participation in the
26 Speaker Program in an October 18, 2012 email copying Defendant Burlakoff.
27 Defendant Burlakoff forwarded Lee's nomination to Defendant Babich. Despite
28 the fact that Defendant Babich knew that Dr. Madison ran a "pill mill," Dr.
Madison's first speaker event occurred in November 2012.

158. A few months later, Dr. Madison's Insys sales representative reported
to another supervisor that Dr. Madison "did call me personally though later in the
afternoon to tell me it is his Illinois office that is really under the eye of the DEA

1 and that he planned on getting patients started on Subsys in Indiana.” In response
2 to the sales representative’s warning, the supervisor responded, “*I am very*
3 *confident that Dr. Madison will be your ‘go to physician.’ Stick with him.*”
4 Indeed, despite a federal indictment in December 2012 and a reprimand by the
5 Illinois Department of Financial and Professional Regulation in April 2014, Insys
6 continued to pay Dr. Madison to promote Subsys.

7 159. Defendants Babich and Burlakoff also were warned about problems
8 with the pharmacy used by Practitioner #10. In September 2012, the sales
9 representative responsible for Practitioner #10 wrote in the sales representative’s
10 weekly update to Defendants Babich and Burlakoff:

11 9/7 – Spoke to staff and they informed me ... [Practitioner #10]
12 would like to be taken off my call list. They would not give
13 reason and I have been unable to reach [Practitioner #10] or
14 his office manager for at least a month. The pharmacy which is
15 located in the same stand alone building was shut down due to
16 the high percentage of opioids being dispensed. It has recently
been opened but is unable to stock opioids. I spoke to ... [my
sales manager] and we are both under the opinion that they may
be under investigation. I will follow up in 3-4 weeks to let
things settle down.

17 160. Subsequently, the same sales representative told Defendant Babich
18 that Practitioner #10 was “[v]ery pleased with . . . [Subsys]” but that he “[h]as had
19 difficulty with insurance coverage lately” and the “[p]harmacy located within same
20 building cannot order CII Rx from distributors due to ratio of opioids to other Rx.”

21 161. Despite these issues, the sales representative thereafter reported to
22 Defendants Babich and Burlakoff in an October 8, 2012 email that after Simon and
23 the sales representative took Practitioner #10 and his office manager to dinner it
24 had “turned things around 180 degrees.” At the dinner, Simon and the sales
25 representative “set out a plan to conduct dinner programs for ... [Practitioner #10]
26 to speak at his request.” As part of Insys’ efforts, moreover, Simon and the sales
27 representative agreed to speak with the pharmacist in Practitioner #10’s building as
28

1 well as Insys' Director of Trade and Distribution "to resolve the issue" associated
2 with the pharmacy's high ratio of opioid prescriptions with a "guarantee from ...
3 Practitioner #10 to have 'more scripts than we can handle' once the pharmacy issue
4 is resolved" and Practitioner 10 "begins to speak." As noted in the Babich and
5 Burlakoff Indictment, despite concerns about a potential investigation, Insys began
6 paying Practitioner #10 for Speaker Program events in November 2012.

7 162. Guest lists for these speaking engagements sometimes included only
8 the doctor and his or her own staff or Insys employees. For example, according to
9 the ODOJ, Insys paid Dr. Gallant for speaking at engagements (one of which was
10 approved by the Company's Director of Sales, Rich Simon) where the only other
11 attendee was his own physician assistant. The cooperating New York Insys sales
12 representatives reported that Roper attended a speaker program (i) on or about
13 March 25, 2014, where the only attendees were the designated speaker, the
14 speaker's staff, and Insys employees; and (ii) in the summer of 2014 where the
15 only attendees were Insys employees and the speaker. According to the Illinois
16 Complaint, on at least two occasions, Insys paid Dr. Madison \$1,600 to speak at an
17 event the only attendees of which were Dr. Madison and his Illinois sales
18 representative.

19 163. Certain of these events were attended only by individuals who were
20 not licensed to prescribe controlled substances, including medical assistants,
21 receptionists, or friends. The Illinois Complaint confirmed that prescribers who
22 attended Dr. Madison's events did not specialize in treating cancer-related pain but
23 rather in neurology, obstetrics and gynecology, urology, and plastic surgery.
24 Likewise, during Alfonso's plea hearing, the United States Attorney's Office
25 ("USAO") stated that it had located evidence establishing that Alfonso was a
26 speaker at over 70 events, she was paid \$1,000 per event, and the attendees at the
27 majority of her events were not individuals who could prescribe Subsys, thereby
28

1 conferring no legitimate educational benefit on the events' attendees. Roper's
2 indictment also detailed one speaker event that he organized as a sales
3 representative at a restaurant in Manhattan where the doctor scheduled to speak
4 never showed up, and Roper instead had dinner and drinks with his boss and
5 several of his friends, none of whom appeared to be healthcare professionals.
6 Despite this, Roper still submitted the event as a sanctioned speaker program, and
7 the no-show doctor received his compensation for it.

8 164. Moreover, at many putative speaker events, the sign-in sheets were
9 forged to include the names of doctors who had not attended the event in order to
10 make the speaker program appear legitimate—or, in other words, that a sufficient
11 number of healthcare professionals with prescribing authority had attended the
12 program. Both cooperating New York sales representatives reported that they had
13 forged sign-in sheets for speaker programs. As district manager, Roper was not
14 only aware of such misconduct but also condoned it by instructing the cooperating
15 New York sales representatives, among others, to add to speaker program sign-in
16 sheets the names and signatures of prescribers who had not actually attended the
17 event.

18 165. Many times, the same doctors or employees would repeatedly attend
19 speaker events. For example, Drs. Ruan and Couch, both prolific Subsys
20 prescribers now indicted for insurance fraud, repeatedly spoke to the same doctors
21 or staff of their practice about Subsys. Likewise, Serrano organized speaker events
22 for his prescribers that featured the same audience each time. For example, two
23 attendees of a September 8, 2014 program in New York previously had attended
24 six and ten Serrano-organized Subsys speaker programs, respectively. Four
25 attendees of an October 16, 2014 Subsys speaker program previously had attended
26 nine, eleven, fourteen, and fourteen Serrano-organized programs for Subsys,
27 respectively. Two attendees of a February 25, 2015 Subsys event previously had
28

1 attended 14 and 25 prior Subsys speaker programs organized by Serrano,
2 respectively. Finally, two healthcare professionals had previously attended 20 and
3 27 Subsys programs, respectively, prior to an April 16, 2015 speaker event
4 organized by Serrano.

5 166. In fact, one of the cooperating New York sales representatives in the
6 case against Serrano and Roper confirmed that repeat attendees were common at
7 speaker programs because it was extremely difficult to have new attendees at every
8 program given their frequency. However, because the speaker programs were
9 supposed to utilize a pre-approved slide presentation, there was no educational
10 reason for a doctor or other medical professional to repeatedly attend Subsys
11 speaker programs.

12 167. Indeed, the primary purpose of these speaker programs was to find a
13 way to compensate doctors for prescribing Subsys off-label to their patients at
14 ever-increasing dosages. Defendants and the doctors to whom Insys paid illegal
15 kickbacks, understood that the speaker fees came with strings attached—recipients
16 of speaker fees were expected to increase both the number and dosage of their
17 Subsys prescriptions. Moreover, because the vast majority of the healthcare
18 professionals that received speaker fees did not treat cancer patients, these fees
19 were meant to compensate them for off-label prescriptions of Subsys.

20 168. Insys managers frequently confronted underperforming Subsys
21 prescribers when they did not see a return on their investment, *i.e.*, prescribers
22 receiving kickback payments disguised as speaker fees who were not prescribing a
23 satisfactory amount of Subsys. As alleged in the Babich and Burlakoff Indictment,
24 if a Speaker Program participant did not write an appropriate number of Subsys
25 prescriptions, Defendants Babich and Burlakoff and their direct reports, among
26 others, reduced the number of scheduled Speaker Program events for that
27 participant unless and until the participant wrote more Subsys prescriptions.
28

1 169. For instance, in an October 19, 2012 email to Defendant Babich and
2 all of Insys' sales managers, Defendant Burlakoff touted Lee's efforts to cull from
3 the participants in the Speaker Program those doctors who had not written
4 prescriptions or shown interest in Subsys stating, that Lee was a "[g]reat example
5 of how we need to pro-actively manage our speaker data base by both adding and
6 soft deleting speakers on an ongoing basis...."

7 170. In another example, after Practitioner #10 failed to increase the
8 number of Subsys prescriptions he wrote, the manager assigned to that particular
9 territory canceled Speaker Program events in April 2013 due to [Practitioner #10's]
10 failure to give Insys enough business. Several months later, the same manager
11 lamented to Defendant Burlakoff and Simon that the manager was "perplexed by
12 [Practitioner #10's] prescribing habits," noting that the manager did not believe
13 Practitioner #10 was "worth any more of your time." Thereafter, Defendant
14 Burlakoff, Simon, and Rowan hired a new sales representative with a pre-existing
15 relationship with Practitioner #10. After transferring Practitioner #10 to the new
16 employee in December 2013, Defendant Burlakoff noted to the manager that the
17 prior representative

18 did not eat what he killed. He did not KILL anything, he
19 merely braised the doctor! ... I need and want the business
20 TODAY. I need to see if [the new sales representative] can
21 bring me what the other rep could not. I need [the new
22 sales representative] to make his living off this doctor. This is
23 my job.

24 171. By March 2014, Practitioner #10 had gone from having Speaker
25 Program events cancelled due to his failure to write Subsys prescriptions to an
26 increase in the amount of the "honoraria" paid to him to speak at the Program
27 events.

28 172. Sales managers also identified "Speakers" that had not been "Used,"
including instructions to schedule as many office or dinner programs "as possible

1 with your top/targeted physicians.” Indeed, in an August 1, 2012 email, Defendant
2 Babich told the sales representative responsible for Practitioner #9 that Practitioner
3 #9 was among the sales representative’s “top targets,” requesting “a brief weekly
4 email summarizing how, if and when the doctor will write, if he is already and can
5 he be a bigger doctor to you.” In one of these weekly update emails, the sales
6 representative for Practitioner #9 told Defendant Babich and Defendant Burlakoff
7 that prescriptions for Practitioner #9 had:

8 Dropped off as he has told me some of his patients are
9 preferring ... [a competitor]. ... But he continues to tell me he
10 will continue to prescribe ... [the Fentanyl Spray] whenever he
11 can. I think using him as a speaker will cause things to pick
12 back up again. I have two programs planned so far.

13 173. Seven months later, after Practitioner #9 wrote only 90 Subsys
14 prescriptions in 1Q13 (as compared to 328 total prescriptions for rapid onset
15 opioids), Defendant Burlakoff sent an email to Rowan and the sales representative
16 assigned to Practitioner #9 stating, “[w]here is ... [Practitioner #9], we cannot go a
17 single day with out [sic] a prescription from ... [Practitioner #9]. ***I do not want to***
18 ***hear excuses, we pay good money here*** (we need 1 a day from [Practitioner
19 #9]).”

20 174. According to one email described in the Oregon Complaint, District
21 Sales Manager Crystal Skelton emailed Director of Sales Rich Simon regarding
22 how she had confronted one of her speakers about his low number of Subsys
23 prescriptions, to which the doctor responded, “if I am not giving you a full return
24 on investment then I want you to hold me accountable.” On March 11, 2013,
25 Simon sent an email to the sales representative for Dr. Somerville complaining that
26 “3 out of 4 scripts he wrote were refills or were still LOW units Drill into
27 [his] head that every refill has to be 180-240, etc. and that [Dr. Somerville]
28 agreed to do this.”

1 175. In another email quoted in the Oregon Complaint, Subsys sales
2 executive Karen Hill informed Defendants Burlakoff and Babich that she
3 “managed to meet her [Ms. Hooker’s] speakers [Drs. Gallant and Rosenblum] and
4 challenged each of them (we are paying these guys and not seeing a return on our
5 investment.)” In a related email, Simon relayed that Drs. Gallant and Rosenblum
6 “are on a short string with me” which, according to Ms. Hooker’s testimony under
7 oath, meant that Simon “felt like Dr. Gallant could have been writing more
8 prescriptions.” In fact, when Ms. Hooker was asked whether “the problem [was]
9 that the return on investment for payments to Dr. Gallant was low,” Ms. Hooker
10 testified, “yes.” Significantly, Dr. Gallant himself confirmed his understanding of
11 the *quid pro quo* relationship with Insys, stating in a sworn interrogatory response:
12 “As a result of my prescribing numbers being considered too low for the company,
13 I was told that I would not be used as a speaker again.”

14 176. Another frequent speaker and Subsys prescriber, Heather Alfonso,
15 increased the amount of Subsys prescriptions and actively looked for new patients
16 to whom she could prescribe the narcotic in response to requests from Insys sales
17 representatives. Alfonso became a participant in the Speaker Program after the
18 sales representative assigned to her emailed Defendant Babich directly in August
19 2012 stating that Alfonso had expressed an interest in becoming a speaker.
20 Thereafter, in October 2012, Alfonso signed a speaker agreement with Insys.
21 Defendant Burlakoff himself asked the manager responsible for Alfonso to prod
22 the relevant sales representatives to set up programs for Alfonso noting, “[t]his
23 clinician is writing, she has experience.... She needs to speak ASAP.”

24 177. The USAO represented at Alfonso’s plea hearing that it had evidence
25 that Alfonso’s Insys sales representatives scheduled the Speaker Programs for the
26 purpose of being able to pay Alfonso thousands of dollars (ultimately, at least
27 \$83,000 total) to ensure that she continued to increase her Subsys prescriptions.
28

1 This assertion is supported by documents quoted in the Babich and Burlakoff
2 Indictment.

3 178. For example, in April 2013, after Alfonso's Subsys prescriptions
4 averaged less than one per week, Alfonso's Insys sales representative and the sales
5 representative's manager, Pearlman, promised her additional Speaker Program
6 events in exchange for writing more Subsys prescriptions during a private meeting.
7 Shortly thereafter, Pearlman sent Alfonso's sales representative an email titled
8 "alarming" which explained that Pearlman needed to share with the sales
9 representative an "alarming stat" for 1Q13 and advising that if Alfonso did not
10 obtain "1 new patient/week" it would not result in the income both Pearlman and
11 the sales representative expected. On April 12, 2013, Alfonso's sales representative
12 emailed Pearlman, stating,

13 [y]ou and I both know my goals for ... [Alfonso] and what she
14 is verbally agreeing to do. ... on Monday I will email you to get
15 the ... [Speaker Program] when she gives me a firm agreement
on what we discussed earlier this week.

16 179. Subsequently, the Connecticut sales manager expressed frustration
17 with Alfonso's Subsys prescription numbers to the assigned sales representative,
18 stating in June 5, 2013 email:

19 [w]hat I am concerned about is you and I spoke about 6 weeks
20 ago when we were giving her this extra program and asked if
21 her finding 1 new patient a week was a reasonable expectation
22 and something to be accountable to. You told me she said yes
and that you would be able to hold her accountable to that. In
looking at 1 new patient in April and just 1 in May it is clear
that is not happening.

23 Keep in mind these emails are for you and me, not her. But our
24 conversation was very clear about what had to happen. I am
not sure why from the tone of your reply you now are seeming
to hedge off of that commitment?

25 *Very simply when I look at return on investment as she has*
26 *not motivated any new prescriber as of yet and she is not*
27 *significantly increasing her own business, I am going to have*
28 *tremendous difficulty in justifying more programs.*

1 180. For her part, Alfonso admitted to the USAO that the money Insys paid
2 her influenced her prescribing of Subsys to her patients.

3 181. Further, Serrano was instructed by his district manager to expect and
4 demand that doctors selected and compensated by Insys as speakers should
5 prescribe large quantities of Subsys in return. On February 20, 2014, Roper,
6 Serrano's district manager, sent an email to Serrano and other sales representatives
7 in the district, exhorting them to push for prescriptions in advance of the upcoming
8 National Sales Meeting:

9 Everyone on this team has stepped it up the past week or so. . . .
10 We MUST keep pushing as hard as we can to get ever SSP
11 apart of this team on the board daily! NOW is the time to attain
12 as many RXs as possible going into the NSM [National Sales
13 Meeting]. . . .

14 One week until [National Sales Meeting], and I need everyone
15 on this team to work their relationships. *Ask each of your top*
16 *prescribers to do whatever they can to make you look like an*
17 *absolute superstar for the next week do not be hesitant in*
18 *asking your docs to give you business in which you are owed,*
19 *deserve and will help make you shine at [the National Sales*
20 *Meeting]. Show everyone at [Insys] that your time has been*
21 *well spent and the formula has been followed. All of the*
22 *breakfasts, lunches, ISPs [Speaker Programs], and top customer*
23 *service to go along with helping provide your docs pts with the*
24 *best ROO [Rapid-Onset Opioid] product in its class for treating*
25 *BTCP. . . . This has to be reciprocated to you for all of your*
26 *hard work!* If you have a relationship, asking this of your docs
27 should be one of the easiest things you do as an SSP. You all
28 have claimed to have relationships so this should not be a
 problem. *If you feel that you cannot complete this simple task*
 with the most positive results then there is no point in
 attending [the National Sales Meeting].

182. In a March 28, 2014 email with subject line "END IS NEAR," Roper
stated:

 Good luck today, biggest Friday of the quarter is here!! Still 4
 days including today to get RXs filled, put more \$\$ in your
 pockets and for those of you who haven't met your baseline as
 of yet, there's still time left! You have all heard about it before,
 LIVE WITH YOUR TOP DOCS, and even more importantly
 ASK for their business.

1 We all benefit from having the best ROO [Rapid-Onset Opioid]
 2 in its class, that being said, ***there is no excuse for any of your***
 3 ***docs to not take care of you at this crucial time of the quarter.***
 4 For the first time as a company, we are facing the challenge of
 5 meeting our quarterly goal. ***That being said, its time for all of***
 6 ***your your [sic] top prescribers (esp. SPEAKERS) to give back***
 7 ***for all of the hard work, long days and late nights you have***
 8 ***spoiled them with.*** Keep pushing as hard as you all possible
 9 [sic] can and remember why today is especially important being
 10 that it will set you up for a few hopeful RXs sat/sun and a
 11 HUGE Monday!!! (capitalization in original)

12 183. Likewise, Roper sent an email on May 6, 2014, in his capacity as a
 13 district manager, instructing the other Insys sales representatives that he managed
 14 that certain doctors who participated in the speaker programs were expected to
 15 prescribe large volumes of Subsys in return for having been selected and
 16 compensated as program “speakers”:

17 ***Where is the ROI??!!!*** All prescribers from this team that are
 18 on this list are [Insys] speakers. We invest a lot of time, \$,
 19 blood, sweat, and tears on “our guys” and help spreading the
 20 word on treating BTCP. We hire only the best of the best to be
 21 apart [sic] of our speaker bureau ***and dropping script counts is***
 22 ***what we get in return?*** As a team we are lagging behind once
 23 again and once again not on pace to meet our quarterly goal.
 24 ***Time for your main guys to step it up and give you the ROI***
 25 ***you deserve.***

26 The most common question asked at the conclusion of a
 27 speaker program is always [sic], “doc, how many pts [patients]
 28 do you currently have on [Subsys]?” Let’s not even discuss
 what some of these prescribers answers may be but ***I will tell***
you right now, not enough!

This is a slap in the face to all of you and is a good indication
as to why NONE of you are climbing in the rankings this
quarter. DO NOT be afraid to set your expectations and make
them crystal clear as to what they are before, during, and after
HIRING these privileged [sic] set of docs, who are fortunate
 enough to be a part of the best speaker bureau in the market in
 the world of BTCP. ***Please handle this immediately as***
funding will not be given out to anymore “let downs” in the
future.

(capitalization in original).

184. Roper decided which prescribers in his district would be allocated to
 speaker programs on a quarterly basis. According to Roper’s indictment, he

1 instructed one of the cooperating New York sales representatives via email that
2 speaker programs would be allocated to doctors who were prescribing “significant
3 quantities” of Subsys. Roper would inform sales representatives when he was not
4 pleased with the amount of Subsys prescriptions any participant in the speaker
5 program was writing and, on at least one occasion, reduced the number of
6 programs to which the prescriber was assigned as punishment. Roper hoped that
7 actions like this would hit the prescriber “in his pocket,” and might cause the
8 doctor to write more scripts in order to be allocated more lucrative speaking
9 engagements.

10 185. On another occasion, in a “strengths, weaknesses, opportunities, and
11 threats” or “SWOT” analysis Roper prepared prior to the 2013 national sales
12 meeting, Roper shared his goals for two doctors within his territory. Roper wanted
13 one of his prescribers “to write for [Subsys] consistently and achieving ROI” with
14 that doctor. In his SWOT analysis, Roper stated that he needed to “get [] the
15 message across that if [the doctor at issue] wants lunches and to speak for
16 [Subsys], [he] needs to prescribe it.”

17 186. According to a cooperating sales representative who was responsible
18 for the doctor identified in Roper’s SWOT analysis, the representative and Roper
19 had an understanding that if that particular doctor wanted to be allocated speaker
20 programs, he needed to prescribe significant amounts of Subsys. With respect to
21 another doctor, Roper noted in the same SWOT analysis his goal to have that
22 doctor “speaking on our behalf 1-2 times a week, [and] have [Subsys] as his main
23 ‘go to’ medication for all of his patients suffering from breakthrough pain.” In
24 short, Roper wanted to have this particular doctor “speaking on a regular basis as
25 well as writing big scripts on a regular basis.”

26 (2) **Insys Provided In-Kind Kickbacks to**
27 **Healthcare Professionals In Exchange for**
28 **Increased Subsys Prescriptions**

1 187. In addition to paying doctors to participate in speaker programs, Insys
2 provided purchased meals, drinks, and entertainment, as well as non-monetary
3 incentives in exchange for prescribing Subsys for off-label indications. For
4 example, when Defendant Burlakoff was unsatisfied with the number of Dr.
5 Awerbuch's Subsys prescriptions, he flew to Michigan and took Dr. Awerbuch to
6 dinner. The next day Defendant Burlakoff emailed Defendant Babich and Lee
7 telling them to "expect a nice 'bump' fellas."

8 188. In another instance, Defendants Babich and Burlakoff and Rowan
9 invited Practitioner #4 to Arizona, during which time Defendant Burlakoff and
10 Rowan took Practitioner #4 to a club. The next morning Defendant Burlakoff sent
11 Practitioner #4's sales representative a text stating, "*went fantastic last night.*
12 *[Practitioner #4] and I got back around 4AM. He had to have had one of the*
13 *best nights of his life.*" After Practitioner #4 wrote 17 Subsys prescriptions the
14 following week (after previously averaging 3.3 prescriptions per week), Rowan
15 texted him, "we appreciate you more than you could believe. Leaving that meeting
16 Alec [Burlakoff] and I felt very confident and [sic] what was going to happen.
17 And you show loyalty to us like no other. You need anything at all, it is done.
18 Thank you for being you."

19 189. Now indicted by the federal government, Lee often was sent in to
20 close deals with certain practitioners. In one such instance, Lee set up a lunch with
21 Dr. Madison—known by Defendants Babich and Burlakoff to run a "pill mill"—
22 and his assigned Insys sales representative in early October 2012. At the end of
23 the lunch, Lee handed Dr. Madison her card and told him to call her if he wanted to
24 discuss Subsys "in private." A few days after having drinks with Dr. Madison, Lee
25 called the assigned sales representative and informed her that Dr. Madison was
26 going to start writing Subsys prescriptions.

1 190. Likewise, Serrano has been indicted for providing “illegitimate
2 remuneration” to doctors in exchange for Subsys prescriptions, including paying
3 for alcoholic drinks. Serrano also brought strippers to speaker programs he
4 organized, allowed attendees at speaker programs he organized to order as many
5 drinks as they wanted and, on at least one occasion, did shots of liquor with the
6 doctors in attendance.

7 191. According to two cooperating New York sales representatives, the
8 entertainment that Roper provided included visiting strip clubs. In particular, the
9 sales representatives relayed to the U.S. Government that their district manager,
10 Roper, periodically took doctors to strip clubs and appeared to pay for bottles of
11 alcohol for several Subsys prescribers. Roper also frequently went out to bars and
12 clubs with several New York prescribers, and on occasion, hockey games. One of
13 these prescribers in particular increased his volume of Subsys prescriptions
14 dramatically after he began work with Roper.

15 192. Additionally, according to Neely, Insys maintained a credit card to
16 help pay for these types of perks for doctors, provided that Subsys prescriptions
17 were written after the event. Neely was provided the number via text by his
18 district sales manager, Darin Cecil. Neely, among others, used this hidden
19 reimbursement channel to expense thousands of dollars of entertainment charges.
20 Defendant Burlakoff, in particular, was a big proponent of the use of the “secret”
21 credit card by sales representatives to wine and dine doctors in order to obtain
22 additional Subsys prescriptions—despite the fact that the Company had a policy on
23 its books against doing so. Neely also was informed that Defendant Babich was
24 aware of the practice of utilizing the off-the-books credit card to pay for meals,
25 drinks and entertainment for doctors. According to his indictment, when Roper
26 was a sales representative, he used the Company credit card with the permission of
27
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1 his boss and “members of [Insys] management” to take several doctors out to a bar
2 for \$2,000 worth of drinks in July 2013.

3 193. Insys also provided in-kind and one-off kickbacks that were tailored
4 to the specific prescriber. For example, in his role as a New York district manager,
5 Roper provided at least one of the cooperating New York sales representatives the
6 answers to the TIRF-REMS Access Program exam for healthcare professionals so
7 that the sales representative could provide those answers to doctors who were
8 trying to become enrolled in the program and begin prescribing Subsys. Roper
9 also paid for one of his former prescriber’s office Christmas party at a restaurant in
10 Manhattan. The sales representative assigned to Clough catered a lunch for
11 Clough’s pain clinic staff. Neely, a California-based sales representative arranged
12 the weekly rental of a Beverly Hills basketball court for one of his Subsys
13 prescribers to use for a regular pick-up game and celebrated the birthday of another
14 Subsys prescriber with dinner at a sushi restaurant followed by tickets to a Los
15 Angeles Kings hockey game.

16 194. Additionally, in order to incentivize Drs. Ruan and Couch to prescribe
17 even more Subsys, in 2014 Insys agreed to bypass its wholesalers and sell Subsys
18 directly to a pharmacy owned by Drs. Ruan and Couch, C & R Pharmacy (“C &
19 R”). As *The Wall Street Journal* reported in a November 23, 2016 article entitled,
20 “Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription
21 Opioids,” this arrangement provided Drs. Ruan and Couch with a lower price than
22 they would get from a wholesaler which, in turn, allowed them to keep a larger
23 share of the drug’s retail cost when they billed insurers. Dispensing Subsys was a
24 significant part of C & R’s business. In 2013 alone, C & R filled 326 Subsys
25 prescriptions for Tricare (the military insurance program) at a cost of \$1.6 million.
26 C & R billed Tricare \$1.8 million for Subsys prescriptions dispensed in 2014.
27 Insys’ agreement to sell directly to C & R was sealed at a dinner at Ruth’s Chris
28

1 Steak House in Mobile, Alabama which was attended by, among others, Drs. Ruan
2 and Couch, and Defendants Kapoor and Babich.

3 195. Dr. Ruan also was provided his own personal sales representative – a
4 man specifically hired by Insys because of his prior relationship with Dr. Ruan.
5 When Insys promoted this sales representative to regional director in late March
6 2013, the Company feared that it would “lose all of Dr. Ruan’s business.” Finding
7 a suitable replacement was, therefore, extremely important. As a result, Insys
8 hired Perhacs, who had a prior relationship with Dr. Ruan, based solely on the
9 latter’s recommendation. Once installed as his personal Subsys sales
10 representative, Perhacs performed a variety of tasks in order to keep Dr. Ruan’s
11 prescriptions up, including: (i) helping Dr. Ruan with car show registrations during
12 work hours; (ii) joining Dr. Ruan’s health products pyramid scheme at his request;
13 and (ii) writing a fraudulent online “patient review” under an alias to help Dr. Ruan
14 increase his online ratings.

15 196. Insys also gave certain practitioners in-kind kickbacks for prescribing
16 Subsys by providing business-saving administrative services. Because obtaining
17 the necessary prior authorizations for insurance coverage of pain medications was
18 time-consuming and costly for many doctors who prescribed TIRFs like Subsys,
19 Insys gave practitioners who wrote large numbers of Subsys prescriptions the
20 benefit of so-called Area Business Liaisons (“ABLs”) or Business Relations
21 Managers (“BRMs”).

22 197. Employed and compensated by Insys, ABLs and BRMs were support
23 staff assigned to work at the office of high-prescribing practitioners. In particular,
24 the ABL program was developed by Defendant Babich, Defendant Burlakoff,
25 Simon, and Gurry in June 2013 in order to specifically address a problem with the
26 pace of authorizations for Dr. Awerbuch’s Subsys prescriptions. On May 2, 2013,
27 Defendant Burlakoff and Gurry learned that in addition to 153 Subsys prescriptions
28

1 written by Dr. Awerbuch that were in process through the IRC, there were 88 other
2 charts for which work had not yet been started.

3 198. Thereafter, ABLs (as well as sales representatives) were required to
4 assist the practitioner to which they were assigned with filling out and faxing to the
5 IRC prior authorization paperwork and other documentation as needed to obtain
6 insurance coverage. In one such instance, Clough requested assistance from Insys
7 for the administrative work associated with obtaining prior authorization for the
8 large number of Subsys prescriptions he wrote (e.g., 124 in just 12 weeks).
9 Clough gave the medical charts for each patient for whom he had prescribed
10 Subsys to his Insys sales representative or to another Insys employee who assisted
11 the sales representative. The sales representative (or her assistant) then filled out
12 all of the prior authorization paperwork and faxed it to the IRC unit in Arizona.

13 199. Certain of the ABLs and BRMs hired by Insys were family or friends
14 of the targets of these kickbacks. For example, in September 2013, Insys hired
15 Practitioner #9's then-girlfriend as an ABL for [Practitioner #9's practice].
16 However, Defendant Burlakoff was not satisfied with the number of Subsys
17 prescriptions written by Practitioner #9. Accordingly, on October 3, 2013,
18 Defendant Burlakoff emailed the representative responsible for Practitioner #9
19 stating,

20 Where is ... [Practitioner #9]?

21 Not even close to meeting anyone's expectations thus far,
22 perhaps- We had failed in setting our expectations?

23 We were looking to go from 40 percent market share to 90
24 percent? ... ***I have to sit in the corporate office and answer
these questions face to face. It is not fun, and the recent move
we made on an ABL appears as if it is potentially not worth it?***

25 200. Insys also hired one of Dr. Awerbuch's employees as an ABL in
26 September 2013. Concerned about the timing of this hire, on September 12, 2013,
27 Lee sent an email to Insys' HR, copying Defendant Burlakoff and Simon asking
28 "what the status is for the new Detroit ABL, . . . She is very anxious." In response,

1 Defendant Burlakoff emailed HR, copying Defendant Babich stating, “[a]s a point
2 of reference, Mike Babich described this hire as ‘strategic’ This is [Dr.
3 Awerbuch’s] ... niece. ...Mike understands our rationale [sic] for this ABL...” While
4 the proposed hire was, in fact, not Dr. Awerbuch’s niece, she was personally
5 known to Awerbuch and, nevertheless, Babich approved the hire the next day.

6 **(3) The Kickbacks Paid Translated Into Increased**
7 **Subsys Prescriptions**

8 201. Through its Speaker Program payouts, among other methods of
9 providing high decile prescribers with kickbacks, Insys secured ever-increasing
10 numbers of Subsys prescriptions. For example, Dr. Ruan’s average Subsys
11 prescriptions per week grew from 2.2 to 11 in just one quarter. In exchange for
12 receiving \$229,640 in kickbacks and bribes from Insys, Dr. Ruan wrote 2,148
13 Subsys prescriptions for which payment was authorized between August 2012 and
14 May 2015. Likewise, Dr. Couch’s average Subsys prescriptions per week grew
15 from 2 to 3 to 6.8 over one quarter after he started receiving bribes through the
16 Speaker Program. Indeed, between February 2013 and May 2015, Dr. Couch
17 wrote 984 Subsys prescriptions for which payment was authorized in exchange for
18 payment of \$103,350 in kickbacks from the Company.

19 202. Before his first Speaker Program event on October 11, 2012, Dr.
20 Awerbuch wrote just 94 Subsys prescriptions between March 2012 and October
21 2012, an average of four Subsys prescriptions per week. Six weeks later, at the end
22 of November 2012, he had written 120 Subsys prescriptions. By January 11, 2013,
23 Dr. Awerbuch was averaging 19 Subsys prescriptions per week. All told, Dr.
24 Awerbuch wrote 2,847 Subsys prescriptions for which payment was authorized
25 between November 2012 and June 2014, in exchange for at least \$138,435 in
26 kickbacks from Subsys. Dr. Awerbuch was considered an exemplary practitioner
27 by Insys’ executives. In a September 2013 email to Lee and Rowan, copying
28

1 Defendant Babich, Simon and Gurry, Defendant Burlakoff wrote, “[l]ets *make*
2 *some money, and stop playing BS games trying to manage rookies. It’s the [Dr.*
3 *Awerbuch’s] of the world that keep us in business, lets [sic] get a few more and*
4 *the rest ...of this job is a ‘joke.’”*

5 203. Through participation in the Speaker Program, among other things,
6 Practitioner #4’s average per week Subsys prescriptions for which payment was
7 authorized grew from 0.8 per week in August 2012 to 7 per week by January 2014.
8 In fact, between August 2012 and November 2015 Practitioner #4 wrote 2,030
9 Subsys prescriptions for which payment was authorized in exchange for \$260,050
10 in kickbacks from Insys.

11 204. After a personal visit by Defendant Burlakoff and Simon in the
12 beginning of May 2013 and, thereafter, participating in a number of Speaker
13 Program events, Dr. Somerville went from writing eight Subsys prescriptions over
14 12 weeks to averaging 12 Subsys prescriptions per week. In exchange for
15 \$123,185.10 in kickbacks, Dr. Somerville ultimately wrote 527 Subsys
16 prescriptions between January 2013 and January 2014.

17 205. Dr. Madison’s average weekly Subsys prescriptions grew from just 2
18 per week in November 2012 to 10.3 per week by May 2014. Between February
19 2013 and July 2015, Dr. Madison received \$70,800 in kickbacks from Insys in
20 exchange for writing 1,601 Subsys prescriptions which were authorized for
21 payment.

22 206. After much encouragement from the assigned sales representative,
23 Alfonso’s average weekly number of Subsys prescriptions grew from 0.9
24 prescriptions in March 2013 to 3 prescriptions per week. In exchange for writing
25 556 Subsys prescriptions for which payment was authorized between December
26 2012 and April 2015, Alfonso received at least \$78,758.25 in kickbacks from
27 Insys.

1 207. Despite his lack of experience in speaking to audiences about TIRF
2 drugs or rapid onset opioids, Clough received \$44,000 in kickbacks from Insys for,
3 among other things, participating in the Speaker Program, in exchange for writing
4 672 Subsys prescriptions for which payment was authorized. In the 12 weeks after
5 he became a speaker, Clough wrote 124 Subsys prescriptions and by January 2014,
6 was averaging 11.8 Subsys prescriptions per week.

7 208. After receiving approximately \$275,550 in kickbacks from Insys
8 between August 2012 and August 2015, Practitioner #9 increased his average
9 weekly Subsys prescriptions from 1.9 per week at the end of 2Q12 to 7.5 per week
10 in September 2013, writing 1,178 Subsys prescriptions over the three year period
11 he received bribes from the Company. Likewise, after receiving approximately
12 \$143,253.89 in kickbacks from Insys between November 2012 and June 2015,
13 Practitioner #10 wrote 1,454 Subsys prescriptions for which payment was
14 authorized, writing as many as 30 Subsys prescriptions in one week at the end of
15 March 2014.

16 **2. Insys Repeatedly Defrauded Third-Party Payers In Order**
17 **to Ensure Success of the Company's Illegal Off-Label**
18 **Marketing Scheme**

19 209. Defendants' illegal off-label marketing scheme would not have been
20 successful without parallel misconduct within the Company's IRC—conduct now
21 deemed by the U.S. Government to be a nationwide criminal enterprise in
22 violation of the RICO statute. Created by Defendant Babich and others, the IRC
23 was responsible for contacting third-party payers, including, specifically, PBMs on
24 behalf of patients and doctors in order to obtain insurance coverage for Subsys
25 prescriptions. During the Class Period, Subsys cost anywhere from \$1,000 to
26 \$21,000 for a one-month supply of an average dosage of the narcotic. As a result,
27 it was virtually impossible for most patients to pay for Subsys without insurance
28 coverage.

1 210. Based on their published formularies, the largest PBMs only would
2 approve insurance coverage of Subsys if the doctor prescribed it for an on-label
3 indication. Moreover, PBMs typically would not approve a prescription for an
4 expensive drug like Subsys unless the patient had already tried certain alternative
5 medications that failed to provide the desired relief (“tried and failed”
6 medications). Thus, no matter how many off-label Subsys prescriptions Insys
7 convinced doctors to write through off-label promotion and kickbacks,
8 Defendants’ fraudulent scheme would not have been successful unless Insys
9 convinced PBMs to authorize insurance coverage in direct contravention of their
10 formularies limiting authorization to on-label indications.

11 211. Throughout the Class Period, Defendants represented to investors that
12 Defendants “properly communicate with all the major [insurance] plans and the
13 PBMs to ensure proper access for Subsys.” In reality, however, the IRC’s
14 undisclosed mission was to fraudulently induce third party payers to approve
15 insurance coverage for off-label Subsys prescriptions by: (i) misrepresenting and
16 concealing the identity of IRC personnel; (ii) falsifying the patient’s diagnosis; (iii)
17 providing misleading answers to questions meant to determine whether the
18 prescription was for an on-label indication of Subsys; and (iv) misrepresenting a
19 patient’s tried and failed medications.

20 212. And, while Defendants disclosed the existence of the IRC to
21 shareholders during the Class Period in the Company’s SEC filings (“[w]e provide
22 administrative patient support assistance . . . which provides administrative support
23 assistance to help patients work with their insurance companies”), at no time
24 during the Class Period did Defendants disclose the IRC’s true purpose—
25 defrauding third-party payers into approving insurance coverage for off-label
26 prescriptions of Subsys.

1 213. At its height, Insys' IRC ensured that the Company had an insurance
2 authorization rate nearly triple that of its nearest TIRF competitor. Indeed, as
3 reported in a July 2015 *SIRF* article, in an account "corroborated by a senior
4 executive at an Insys rival and three former Insys sales staff members," one Subsys
5 prescriber estimated that "[i]nsurers cover over 90 percent of [Subsys
6 prescriptions] for at least one [90-day] cycle," as compared to rival TIRF drugs
7 which had an insurance approval rate of approximately 33%. Based upon its
8 investigation, the U.S. Government similarly alleges in the Babich and Burlakoff
9 Indictment that Insys obtained an 85% prior approval rate for Subsys prescriptions
10 handled by IRC employees.

11 a) **Insys Created the IRC Shortly After the Subsys
12 Launch**

13 214. In or about October 2012, Babich and Gurry, among others, created
14 the Prior Authorization Tracking Program (the "PA Tracking Program") to collect
15 and monitor a variety of information pertaining to third party payers' prior
16 authorization of prescriptions for Subsys and other TIRF products. That same
17 month, Babich hired Gurrieri to serve as the Company's PA Specialist. By in or
18 about November 2012, the PA Tracking Program revealed to Babich, Gurry,
19 Gurrieri, and others at the Company that PBMs only approved approximately 30-
20 33% of Subsys prescriptions. As a result, Babich, Gurry, Gurrieri, and others
21 mapped out a pilot program designed to increase the percentage of Subsys
22 prescriptions for which PBMs would grant prior authorizations.

23 215. In connection with the pilot program for increasing prior
24 authorizations of Subsys, Babich directed Gurrieri to herself seek prior
25 authorizations directly for prescriptions written by certain prescribers located
26 across the country. During the first week of the pilot program, Gurrieri obtained
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1 prior authorizations for 46% of the prescriptions for which she sought PBM
2 approval.

3 216. By no later than January 2013, based upon information learned and
4 results obtained from conducting the prior authorization pilot program, Babich,
5 Gurry, and others created the IRC. The PA Specialist, Gurrieri, working at the
6 direction of Babich and others, was instrumental in building the IRC from the
7 ground up and ran the day-to-day activities of the unit. By December 2013, the
8 IRC handled Subsys prior authorization requests for prescribers nationwide, and
9 enjoyed an approximately 85% prior approval rate.

10 217. The IRC obtained completed “opt-in” forms from prescribers, onto
11 which the prescribers recorded information pertaining to their practice and its
12 patients, including confidential information such as: (i) name and date of birth; (ii)
13 insurer information; (iii) prescriber information; (iv) pharmacy information; (v)
14 medical diagnoses; and (vi) corresponding insurance code information, commonly
15 referred to as International Classification of Diseases Codes (“ICD Codes”). The
16 completed opt-in forms were faxed or e-mailed by prescriber personnel and/or
17 Insys sales representatives to the IRC in Arizona. The IRC then used the
18 information recorded on the opt-in forms to seek prior authorization directly from
19 PBMs.

20 218. As confirmed by Danielle Gardner, a former IRC employee who
21 spoke with *SIRF* in connection with a December 2015 *SIRF* article, Insys housed
22 the IRC in a separate building, located across the street from Insys’ headquarters.
23 There was no signage or other clear indication that Insys had any operations in the
24 building that housed the IRC. The unit also had a different phone exchange and a
25 separate email server from the rest of the Company. Insys did not want to be
26 associated with the unit or, more importantly, have the unit and its activities tied
27 back to the Company.

1 219. As set forth in the Babich and Burlakoff Indictment, the U.S.
2 Government's investigation also revealed that Babich, Gurry and others took
3 specific steps to conceal the IRC and its employees from PBMs, who were
4 typically unwilling to work with a third party such as the IRC in connection with
5 prior authorizations. For example, to conceal the location from which IRC
6 personnel were calling PBMs, Babich, Gurry, and others established a telephone
7 system for the IRC that blocked access to the IRC's number. As such, PBMs
8 would not notice that IRC personnel were calling from an area code that differed
9 from that of the prescriber.

10 220. The U.S. Government also found that IRC employees did not identify
11 Insys by name when answering incoming telephone calls. In fact, Gardner
12 revealed in connection with a December 2015 *SIRF* article that IRC employees
13 were forbidden from referring to Insys when speaking with PBMs. Gardner further
14 confirmed that the IRC's phone number was permanently blocked from appearing
15 on the caller ID of recipients of calls from the unit, and its employees were
16 instructed to provide a generic toll-free 800 number for follow-up inquiries. The
17 800-number was answered by a colleague named Shannon who quickly transferred
18 the call to the appropriate IRC employee without identifying his or her true
19 affiliation.

20 221. Typically, each individual IRC staff member was responsible for
21 securing 25 Subsys approvals from PBMs each week according to Gardner. Every
22 Monday, Ms. Gurrieri's boss, Gurry (who worked across the street in the corporate
23 office with Babich and others), met with the IRC staff and provided them with
24 their "group gate," or minimum number of total PBM approvals for the week,
25 typically at least 200 PBM approvals. Members of the IRC staff were eligible for
26 bonuses based on exceeding these group "minimums." According to Gardner,
27 after the "group gate" minimum was met, Insys would put \$7 per additional PBM
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1 approval in a “bonus pool.” Assuming the “group gate” minimum was 200 PBM
2 approvals for a given week, if the IRC secured 300 PBM approvals, then the bonus
3 pool would equal \$700 per IRC employee.

4 222. IRC employees also were eligible for bonuses on an individual basis.
5 For example, after an IRC staff member secured 35 PBM approvals in a week,
6 Insys would give the employee a \$50 bonus and \$10 in additional bonus for each
7 incremental approval thereafter. If, for example, an IRC employee secured 52
8 PBM approvals in one week, he or she would earn a \$220 bonus based on his or
9 her individual performance, plus whatever bonus was available in the “bonus
10 pool.” As Gardner explained it, during a “good” week, it was possible to secure as
11 many as 55 PBM approvals. Gurrieri confirmed in her LinkedIn profile that she
12 was responsible for paying these bonuses while she was employed by the
13 Company.

14 223. When Gardner encountered these bonuses, however, she found them
15 odd and not quite believable. After all, the job was really a clerical role—the PBM
16 either said “yes” or “no” to insurance coverage based on a publicly disclosed
17 formulary. But the bonuses were real and meant to encourage IRC employees to
18 go the extra mile to obtain PBM approval, even if the prescription as written by the
19 doctor should not have been approved under the formulary. In other words, such
20 bonuses provided IRC employees a monetary incentive to commit massive
21 insurance fraud at the direction of and for the benefit of Defendants.

22 224. IRC employees also felt pressure from Insys management to obtain
23 the prior authorizations. A former staff member of the IRC unit, Patty Nixon, told
24 the *Wall Street Journal* that she and other employees were pressured to improve
25 the approval rate for prescriptions by Gurrieri. According to Nixon, Gurrieri
26 would say, “Dr. Kapoor’s not happy, we have to get these approvals up.” Nixon
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1 testified about her experience at Insys before a federal grand jury in Massachusetts
2 in 2015.

3 **b) Insys' IRC Lied to PBMs About Their Identity and**
4 **Patient Diagnoses to Obtain Insurance Coverage for**
5 **Off-Label Subsys Prescriptions**

6 225. The IRC conducted team meetings, led by Gurry, in which IRC
7 personnel shared ideas concerning how to obtain prior authorizations of Subsys
8 from PBMs. The practices discussed included IRC personnel misrepresenting who
9 they worked for as well as lying to PBMs about patients' diagnoses and tried and
10 failed medications. Babich approved and encouraged these fraudulent practices,
11 which were used to obtain coverage for Subsys prescribed to treat conditions such
12 as back pain, neck pain, chronic pain syndrome, joint pain involving multiple sites,
13 degeneration of lumbar or lumbosacral intervertebral discs, spinal stenosis,
14 osteoarthritis, myalgia, myositis, post laminectomy syndrome, neuralgia neuritis,
and radiculitis, rather than BTCP.

15 226. Specifically, Babich, Gurry, Gurrieri, and others instructed IRC
16 personnel to mislead PBMs into believing that the IRC personnel were calling
17 from a prescriber's office to create the impression that they were employees of the
18 prescriber. Among other things, Babich, Gurry, and others told IRC staff to tell
19 PBMs that they were calling "from" the prescriber's office, rather than from Insys.
20 Later, IRC staff were instructed to tell prescribers that they were calling "on behalf
21 of" a specific prescriber and/or that they were "with" a specific prescriber's office.
22 Similarly, as Gardner explained in connection with a December 2015 *SIRF* article,
23 when calling PBMs, IRC employees identified themselves as calling "from Dr.
24 _____'s office," in order to hide their true affiliation with the Company. If
25 pressed, IRC employees were allowed to say that they "were working closely with
26 Dr. ____'s office." Eventually, Babich approved of IRC personnel simply hanging
27 up the telephone on a PBM if the PBM pushed on the identity of the IRC staff
28

1 member's employer, with the understanding that the IRC staff member would call
2 that PBM back later in the hopes of reaching a different person with less probing
3 questions.

4 227. To mislead PBMs into believing that they were authorizing Subsys
5 coverage for BTCP, the only on-label use, IRC employees were instructed to reply
6 "yes" when the PBMs inquired as to whether the patient for whom Insys was
7 seeking insurance coverage had "break-through cancer pain." In addition to using
8 fake cancer diagnoses to mislead PBMs into believing that patients had cancer,
9 Gurry and Gurrieri instructed IRC staff to review patients' medical histories for
10 any prior cancer diagnoses. For patients that previously had some form of cancer,
11 IRC personnel were instructed to tell PBMs that the current Subsys prescription
12 was written to treat pain from that prior cancer – even when IRC personnel,
13 including Gurrieri, knew that the patient had fully recovered or was in remission.
14 In this regard, a former IRC employee reported that Gurrieri told her that "if there
15 was any history of cancer to give the breakthrough cancer pain code," even if the
16 patient had skin cancer 20 years ago.

17 228. IRC employees also were instructed to mix-up or change the
18 insurance codes in the patient charts in order to ensure that off-label prescriptions
19 of Subsys would receive insurance coverage. For example, IRC staff members,
20 including Gardner, also were ordered to intentionally mix up insurance codes,
21 substituting 338.30, which was associated with cancer-related chronic pain and
22 338.29, which indicated a diagnosis of general chronic pain unrelated to cancer.
23 Gardner further confirmed that *insurance codes indicating a diagnosis of back or*
24 *joint pain, organ problems, work accidents, military trauma, or menstrual*
25 *cramps, among others, were changed by the IRC into a diagnosis of BTCP.*
26 Another former IRC employee interviewed in connection with the U.S.
27 Government's investigation of Insys reported that Gurrieri told her to assert
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1 fraudulent cancer diagnoses: “Liz [Gurrieri] would come in and she’d be like, *I’ve*
2 *got a chart and you know, I need you guys to do whatever you have to do. If you*
3 *have to give them the cancer code, give it to them and get it approved, because*
4 *it’s a new script. Who wants it?”*

5 229. In another example, the Oregon Complaint quotes from emails
6 between and among Ms. Gurrieri and Ms. Hooker and Ms. Hooker and Dr.
7 Blackburn regarding Dr. Blackburn’s prescription for 240 units per month of 600
8 mcg of Subsys for migraines. On February 6, 2013, Ms. Gurrieri emailed Ms.
9 Hooker, copying Director of Sales Rich Simon and Defendant Burlakoff, among
10 others, stating that she had received Ms. Hooker’s request regarding Dr.
11 Blackburn’s most recent Subsys prescription. Ms. Gurrieri initially responded to
12 Ms. Hooker regarding Dr. Blackburn’s prescription on February 18, 2013,
13 claiming that she did “not think we can get it approved but we can try . . .” Less
14 than six weeks later, Dr. Blackburn’s patient with migraines was approved for
15 Subsys.

16 230. In another instance, the USAO represented at the plea hearing of
17 Heather Alfonso that the U.S. Government had obtained testimony from Medicare
18 Part D beneficiaries who were prescribed Subsys by Ms. Alfonso without a cancer
19 diagnosis. According to the USAO, these witnesses were willing to testify that
20 Insys’ IRC changed the diagnosis codes on the prior authorizations submitted on
21 their behalf to represent that they had cancer in order to ensure that Medicare
22 would cover the Subsys prescription.

23 c) **In the Face of Growing Scrutiny, the IRC Changed**
24 **Its Tactics in Order to Keep PBM Approvals High**

25 231. Between roughly 2012 and December 2013, the IRC worked from a
26 script per instructions from Gurrieri that required IRC employees to lie to PBMs
27 about their affiliation with Insys and the patient’s diagnosis in order to secure
28

1 approval of prescriptions for off-label use of Subsys. However, according to
2 Gardner, after scrutiny by the Office of Inspector General of the United States
3 Department of Health and Human Services in December 2013, Gurrieri authorized
4 changes to the IRC's approach with respect to obtaining PBM approvals for
5 Subsys. Instead of answering "yes" to questions about whether the patient was
6 diagnosed with BTCP, Gurrieri instructed IRC employees, including Gardner, to
7 say "yes, they have breakthrough pain" – an affirmative response that could
8 effectively mean anything (*i.e.*, they had breakthrough pain associated with an
9 ailment other than cancer). According to Gardner, Gurrieri, among others, was
10 hoping to take advantage of a certain amount of bureaucratic inertia associated
11 with the third-party payers use of large call centers, many of which are overseas,
12 with hundreds of employees who have daily (and sometimes hourly) quotas for
13 handling callers seeking authorization for a prescription or procedure, to determine
14 whether prescriptions should be authorized for insurance coverage.

15 232. These subtle changes allowed the IRC to maintain the number of
16 approvals it received from PBMs for off-label Subsys prescriptions. Indeed,
17 through the spring of 2014, approval rates remained high. Despite these numbers,
18 there were incidences of PBMs pushing back, requesting further information or, in
19 some cases, demanding to speak to the prescribing doctor about the diagnosis.
20 However, as Gardner explained, these incidences usually were rectified with the
21 PBMs, who typically accepted an IRC employee's explanation that a chart had
22 been misread or that some form of human error had occurred.

23 233. By late summer of 2014, the IRC's approval levels began to decline,
24 as more PBMs started demanding detailed answers from Insys employees before
25 authorizing Subsys prescriptions. The lower approval rates were not apparent to
26 the public because a sales representative hiring spree allowed Insys to run up the
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1 number of prescriptions coming into the IRC. By the end of 2014, Insys had a
2 total of 250 sales representatives in its sales force.

3 234. The heat on the IRC only increased after Insys' receipt of a subpoena
4 issued pursuant to the Health Insurance Portability and Accountability Act of 1996
5 from the United States Attorney's Office for the District of Massachusetts on
6 September 8, 2014. As a result of both the decrease in PBM approvals and the
7 receipt of the subpoena, Gardner reported that Gurrieri again changed the rules of
8 play for IRC employees. Gardner confirmed that the IRC staff was then required
9 to employ what was known as "the spiel."

10 235. Developed by Gurrieri, "the spiel" was a set of scripted responses to
11 questions typically posed by PBMs to determine whether a patient had been
12 diagnosed with BTCP. For example, Gardner explained that when a PBM inquired
13 about whether the patient had BTCP, IRC employees were instructed to reply: (i)
14 "The physician has stated that Subsys is approved for treating breakthrough cancer
15 pain so [he] is treating breakthrough pain"; or (ii) "[t]he physician is aware that the
16 medication is intended for the management of breakthrough pain in cancer
17 patients. The physician is treating the patient for their pain (or breakthrough pain,
18 whichever is applicable."

19 236. Additionally, instead of saying that they were "from" a doctor's
20 office, IRC employees now were required to say that they were "calling on behalf
21 of [the doctor's] office." IRC employees also were instructed to play up the fact
22 that they were purportedly right inside the doctor's office by engaging in small talk
23 about the patient or the particular case or diagnosis. IRC employees reported that
24 Insys' compliance department told them that it was legal to use "the spiel" when
25 seeking authorization for off-label indications. According to the U.S. Government,
26 "[m]ultiple [IRC] employees were recorded using the approved script to mislead
27 insurers and PBMs."
28

1 237. Among other things, “the spiel” helped to stabilize approval levels to
2 what they were before Insys began experiencing issues with PBMs. However, the
3 largest insurers were becoming more resistant to the IRC’s efforts to obtain
4 insurance coverage for off-label prescriptions of Subsys. Babich, Gurry, and
5 others tracked the IRC’s communications with PBMs to determine why they
6 denied specific claims and used this information to instruct IRC personnel as to
7 how and when to deceive PBMS.

8 238. For example, the U.S. Government found during its investigation that
9 Babich, Gurry, and others learned that a PBM was more likely to grant prior
10 authorization of Subsys in patients diagnosed with dysphagia (difficulty
11 swallowing). Accordingly, with Babich’s and Burlakoff’s knowledge—based
12 upon their attendance at a Company leadership meeting at which the fake
13 dysphagia diagnosis approach to obtaining prior approvals was presented—Gurry
14 and Gurrieri instructed IRC staff to change the ICD Codes in the charts and/or opt-
15 in forms of the most difficult cases to 787.20, which indicated a diagnosis of
16 dysphagia, which sometimes can result from pain or prevent a patient from taking
17 a different narcotic to ease his pain. According to one former IRC employee
18 interviewed by the U.S. Government, Gurrieri told her and other IRC employees to
19 “put dysphagia on every single authorization.” During its investigation, the U.S.
20 Government also learned from another IRC employee that Gurrieri, when
21 questioned about including dysphagia on authorization paperwork for a patient that
22 did not have difficulty swallowing, responded “*we have to say that. That’s what*
23 *we have to do to get it approved or else they won’t approve it.*”

24 239. If a PBM denied authorization of a Subsys prescription for a patient
25 with dysphagia, it ran the illusory risk of the patient receiving no medication for
26 pain due to an inability to swallow. As a result, this tactic pressured the PBM to
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1 accept the purported justification at face-value and secured PBM authorization of
2 insurance coverage.

3 240. The Company's fake diagnosis of dysphagia was so common that it
4 was included in Insys' model letters of medical necessity, which the Company
5 used when appealing a PBM denial of a prior authorization request for Subsys. For
6 example, the Government's investigation revealed that the Company's model
7 letters included, among other things, the following language used to mislead
8 PBMs:

9 I have treated (Full name) in my clinic since (xx/xx/xxxx). (Mr.
10 /Mrs.). Is a (age) year old (man/woman) with severe
11 (Diagnosis). (He/She) has difficulty swallowing and digesting
12 oral medications, and (he/she) is in almost constant severe pain.
13 The pain gives Mr. /Mrs. (Name) a significantly limited quality
14 of life. (He/She) is unable to sit, stand, walk or reach- which
15 includes participating in family life and riding in automobiles -
16 for more than 2 to 3 hours per day.

17 241. Defendants also knew that PBMs were more likely to grant prior
18 authorization of Subsys prescriptions for patients who had tried and failed with
19 other medications, including other TIRF medications. The list of previously tried
20 medications varied among PBMs, and Gurry, Gurrieri, and others monitored
21 communications with PBMs and prepared lists of the prior medications that
22 specific PBMs required. Gurry and Gurrieri used this information to instruct IRC
23 staff regarding when and how to deceive PBMs, and IRC personnel falsely
24 confirmed prior medications to obtain Subsys approvals. As set forth in the Babich
25 and Burlakoff Indictment, Babich and Burlakoff were aware of this practice. An
26 IRC employee interviewed by the U.S. Government in connection with its
27 indictment of Gurrieri stated, "I would take the cheat sheet drugs . . . I would take
28 those medications and I would just add whatever else they did not step edit. . . . So
I would go down my – my cheat sheet and see, okay, well, she didn't try this one,

1 but I'm going to put that one on there. That's exactly how I was instructed by Liz
2 [Gurrieri] to do so."

3 242. Throughout this period, Defendants continued to hide the existence of
4 the IRC's true purpose—to tell enough lies to the PBMs to induce them to approve
5 as many Subsys prescriptions as possible.

6 **d) Additional Scrutiny by Authorities and PBMs**
7 **Rendered the IRC Less Effective in Obtaining**
8 **Approvals for Off-Label Subsys Prescriptions**

9 243. "The spiel" only worked for so long. According to another former
10 IRC employee interviewed by *SIRF*, and identified in a January 2016 article with
11 the pseudonym Jana Montgomery ("Montgomery") (because of her cooperation
12 with the ongoing federal investigation) by the spring of 2015, PBMs became aware
13 of the fact that the use of scripted responses was meant to falsely imply that the
14 patient at issue had been diagnosed with BTCP. Likewise, Insys could not hide
15 from the growing number of investigations, subpoenas, and in-depth media reports
16 regarding the Company's off-label marketing of Subsys and, in some instances, the
17 IRC's involvement in what amounted to a massive company-sponsored insurance
18 fraud.

19 244. As Montgomery recalled, "PBMs learned to approach [Insys] with
20 questions that had non-negotiable answers like, 'On what date did the patient
21 receive their [sic] original cancer diagnosis?'" PBMs also were using "smart-
22 scripting" software analysis to determine if the patient had tried another Fentanyl
23 drug per the FDA's protocol, or had previously used other major opioids, which
24 would suggest that the patient was opioid-tolerant, as required by the on-label
25 indication for Subsys. According to a January 2016 *SIRF* article, PBMs further
26 were frequently calling the office of the prescribing physician in order to confirm
27 every aspect of the diagnosis to ensure that the prescription was for an on-label
28 indication.

1 245. By early autumn 2015, according to Montgomery, PBMs “had begun
2 to deny Insys’ [PA] requests . . . to the point where it was rare to get more than two
3 dozen approvals per week for the unit. . . . That’s a big change from each
4 employee getting 25, at least, per week.” Indeed, whereas in 2013 Gardner was
5 able to secure upwards of 55 PBM approvals for Subsys in a “good” week, now,
6 according to Montgomery, the entire unit secured less than 50% of the same
7 amount in a week. In response Jeff Kobos, the IRC’s new supervisor, drafted a
8 new version of “the spiel,” which was dubbed “Statement 13.”

9 246. As reported by *SIRF* in a January 2016 article, Kobos designed
10 Statement 13 to help IRC employees navigate through heightened PBM scrutiny
11 and additional compliance oversight and secure insurance coverage for off-label
12 prescriptions of Subsys. In particular, Statement 13—a copy of which is linked to
13 the January 2016 *SIRF* article—attempted to clarify when a IRC employee could
14 employ the “spiel” in its conversations with PBMs:

15 **13. Q:** If there are no specific “breakthrough pain” ICD-9
16 codes (i.e., 338.3, 338.29, 338.4) but the HCP [health
17 care professional] is a pain specialist prescribing Subsys
18 and patient has diagnosis of 724.4 Lumbar
19 Radiculopathy/Neuritis or other back diagnosis codes,
20 ***can the IRC still use the comment*** “The physician is
21 aware that the medication is intended for the
22 management of breakthrough pain in cancer patients.
23 The physician is treating breakthrough pain.”

24 **A:** *No*, you cannot say that the physicians is [sic]
25 treating the breakthrough pain if the patient does not have
26 a current cancer ICD-9 code or if there is not a current
27 cancer diagnosis in the HCP’s office records. ***However if***
28 ***the patients has [sic] breakthrough pain ICD-9, pain***
diagnosis you may use the above statement is [sic] you
clearly state that the HCP is treating BTP and give the
exact ICD-9 code that is on the opt-in [form] so that the
insurance company understands that the HCP is treating
the BTP/ICD-9 that you provided during the call. If the
insurance company asks you a clarification question
regarding the ICD-9/diagnosis you must answer their
specific question and not use the above statement a

1 second time. ***** You may not be misleading in any
2 way ***

3 247. Statement 13, however, did not work the way it was intended—as
4 reported by *SIRF*, PBM approvals did not stabilize and continued to decline. As a
5 result, in November 2015, the IRC began brainstorming new ways to secure
6 insurance coverage for off-label Subsys prescriptions given PBMs’ heightened
7 scrutiny of the IRC’s requests. In a recording of a meeting of IRC employees
8 obtained and made public by *SIRF*, Kobos, David Richardson, a trainer with the
9 IRC, Tamara Kalmykova (Richardson’s wife), and an IRC analyst, among others,
10 discussed tactics to address the PBMs’ recent resistance to Insys’ efforts to defraud
11 them.

12 248. During the meeting, Kobos acknowledged the IRC’s prior usage of
13 insurance codes for cancer-related pain diagnoses for patients without cancer pain.
14 He also discussed ways to deflect PBM questions by attempting to engage the
15 PBM representative in a discussion of complete non-sequiturs. To address the
16 problem of “smart scripting,” Richardson proposed having new Subsys patients use
17 a coupon for a free trial of Actiq but not pick up the prescription, such that they
18 would then register as previously having a fentanyl prescription, allowing IRC
19 employees to plausibly claim that the patient was in full compliance with FDA
20 requirements.

21 249. The IRC’s struggles to obtain PBM approval of off-label Subsys were
22 hidden from view by the net revenue from sales of Subsys for 3Q15 and 4Q15.
23 After publicly reporting \$76.7 million in Subsys net revenues in 2Q15, Insys
24 recorded \$91.3 million and \$91.1 million in net revenues from Subsys sales in
25 3Q15 and 4Q15, respectively. Given the extremely low level of PBM approvals
26 the IRC achieved during this same period, the Company’s failure to record a
27 material revenue decline during 4Q15 likely resulted from the Subsys’ sales force
28

1 efforts to convince their prescribers to titrate existing patients to higher and more
2 expensive dosages of Subsys.

3 **C. Class Period Events and Materially False and Misleading**
4 **Statements**

5 **1. 2Q14 Financial Results**

6 250. The Class Period begins on August 12, 2014, when Insys issued a
7 press release announcing its financial results for the second quarter ended June 30,
8 2014 (“2Q14”) (the “August 12 Press Release”). The August 12 Press Release was
9 attached to the Company’s current report on Form 8-K filed with the SEC on the
10 same day. In the August 12 Press Release, the Company highlighted, among other
11 2Q14 results, that “[r]evenues from Subsys (fentanyl sublingual spray) were \$54.6
12 million, up 195% compared with second quarter 2013 sales of \$18.5 million.”

13 251. Also in the August 12 Press Release, Defendant Babich represented
14 that the almost 200% Subsys sales growth for the quarter over the prior year’s
15 quarter was *“largely driven by the successful execution of our Subsys strategy,*
16 *strengthening our cash position and increasing our financial flexibility. In spite of*
17 *an overall decline in the TIRF market in the second quarter, we had double-digit*
18 *growth in Subsys scripts and anticipate that Subsys revenue will continue to grow.”*

19 252. On the same day, Insys hosted an earnings conference call with
20 analysts and investors to discuss its 2Q14 financial results (the “August 12
21 Earnings Call”). During his prepared remarks, Defendant Babich stated, in
22 pertinent part:

23 *We believe the success to date of Subsys is the result of a*
24 *clinically superior product, coupled with the focused market*
penetration strategy. . . .

25 *We continue to proactively work with managed care providers*
26 *to ensure coverage for our patient population. We maintain*
27 *Tier 3 coverage under nearly all major insurance plans. The*
28 *majority of patients have access to Subsys through their*
insurance plans.

1 253. During the second half of the August 12 Earnings Call, Defendant
2 Babich responded to a question regarding the Company’s communications with
3 PBMs regarding Subsys, noting that “[w]e *continue to properly communicate with*
4 *all the major plans and the PBMs to ensure proper access for Subsys.*”

5 254. Insys also filed its quarterly report on Form 10-Q for 2Q14 (“2Q14
6 Form 10-Q”) on the same day, which was signed by Defendants Babich and Baker.
7 The 2Q14 Form 10-Q provided an explanation for the growth in Subsys net
8 revenues for the quarter and year-to-date, stating:

9 *The increase in Subsys revenue is primarily as a result of*
10 *increased prescriptions and change in mix of prescribed*
11 *dosages as Subsys was a relatively new product during the*
12 *three months [and six months] ended June 30, 2013 and also*
13 *price increases in January 2014 and April 2014. . . .*

14 255. Following the Company’s release of its 2Q14 reports, analysts issued
15 positive reports regarding Insys and Subsys. For example, in a report issued on
16 August 12, 2014, JMP Securities noted that there was “[a]nother solid quarter and
17 reinforced confidence in Subsys growth.” The JMP Securities report further
18 concluded, “We view the company’s continued execution on Subsys as strong and
19 remain confident in continued growth for the product.”

20 256. Thereafter, on August 13, 2014, Oppenheimer issued a report, stating
21 that the stock was “up almost 5% despite missing bottom-line 2Q14 expectations”
22 after having “traded up almost 25% over the past week” due to “positive
23 commentary for Subsys’ growth trend.” Wells Fargo likewise issued a report on
24 August 13, 2014 raising its revenue expectations for Subsys for 3Q14 and
25 4Q14/FY14, stating, “Q2 provided reassurance about the strength of INSY’s core
26 franchise (Subsys)” and “was important in providing a sense of stabilization and
27 potential return to growth of Subsys revenues, after a period of Rx declines from
28 May to July following a Medicare fraud indictment of a prescriber in Michigan,
and we believe continued revenue growth in H2 2014 and beyond is achievable.”

1 257. The statements alleged in ¶¶252-254 above were materially false and
2 misleading when made or omitted material information such that they were
3 rendered misleading. Contrary to Defendants’ assertions that Subsys sales’ growth
4 was “largely driven by the continued, successful execution of our Subsys strategy,”
5 the result of “a clinically superior product,” or due to a “change in the mix of
6 prescribed dosages” in reality, Defendants knew or were deliberately reckless in
7 not knowing that the Company’s Subsys revenues during 2Q14 were the result of
8 what the U.S. Government now describes as a criminal enterprise in violation of
9 the RICO statute including (i) Insys’ illegal promotion, including kickbacks to
10 prescribers, of Subsys for off-label indications, *see, e.g.*, ¶¶98-208, 348-368, 371-
11 396, and, in order to ensure third-party payer approval of the resulting off-label
12 prescriptions, (ii) the creation and utilization of a division of the Company, the
13 IRC, to surreptitiously engage in wide-ranging, pervasive insurance fraud, *see, e.g.*,
14 ¶¶209-249, 369-370, 379-385, 394-396.

15 258. More specifically, with respect to the actions of Insys’ IRC, contrary
16 to Defendants’ statements regarding their efforts to “continue to proactively work
17 with managed care providers to ensure coverage for our patient population,”
18 including Defendant Babich’s statement that “we continue to properly
19 communicate with all the major plans and the PBMs to ensure proper access for
20 Subsys,” Defendants knew or were deliberately reckless in not knowing that
21 Subsys’ growing revenues were the result of the IRC’s: (i) fraudulent
22 communications with third-party payers, which included both oral and written
23 statements asserting a prospective Subsys patient had cancer or BTCP; and (ii)
24 efforts to ensure that as many off-label patients as possible received improper
25 access to Subsys under various third-party payer formularies and policies. *See,*
26 *e.g.*, ¶¶209-249; 369-370; 379-385; 394-396. Likewise, Defendant Babich’s
27 assertion that “[t]he majority of patients have access to Subsys through their
28

1 insurance plans” was materially false and misleading when made because, as
2 Defendant Babich knew or was deliberately reckless in disregarding, the only way
3 that a “majority of patients” had insurance coverage for Subsys was through the
4 insurance fraud perpetrated by Insys given that 80% of Subsys prescriptions were
5 off label and insurance carriers typically only covered Subsys for on-label use.

6 **2. 3Q14 Financial Results**

7 259. On November 11, 2014, Insys issued a press release announcing its
8 financial results for the third quarter ended October 30, 2014 (“3Q14”) (the
9 “November 11 Press Release”). The November 11 Press Release reported, among
10 other things, that “[r]evenues from Subsys (fentanyl sublingual spray) were \$58.2
11 million, up 105% compared with third quarter 2013 sales of \$28.4 million.”

12 260. The November 11 Press Release also stated that the Company was
13 “pleased to report another strong quarter, *in which our revenue and gross profit*
14 *doubled largely driven by the continued, successful execution of our Subsys*
15 *strategy.*”

16 261. On the same day, Insys hosted an earnings conference call with
17 analysts and investors to discuss its 3Q14 financial results. During the call,
18 Defendant Babich elaborated on the “success” of Subsys, stating:

19 *We believe the success to-date of Subsys is the result of a*
20 *clinically [sic] superior product coupled with a focused*
market penetration strategy. . . .

21 *We continue to proactively work with managed care providers*
22 *to ensure coverage for our patient population. We maintain*
23 *Tier 3 coverage under nearly all major commercial plans, and*
the majority of patients have access to Subsys through their
insurance plans.

24 262. On November 12, 2014, Insys filed its quarterly report on Form 10-Q
25 for 3Q14 (“3Q14 Form 10-Q”), which was signed by Defendants Babich and
26 Baker. In reporting the Company’s growing quarterly and year-to-date revenues,
27 the 3Q14 Form 10-Q stated that “[t]he increase in Subsys revenue is primarily as
28

1 *a result of increased prescriptions and change in mix of prescribed dosages as*
2 *Subsys was a relatively new product during the three months ended September*
3 *30, 2013 and also price increases in January 2014 and April 2014.”*

4 263. Following the issuance of the Company’s results for 3Q14, analysts
5 issued positive reports regarding Insys and Subsys’ revenues. For example, JMP
6 Securities issued a November 11, 2014 report citing “[s]olid Subsys growth” as
7 one of the “Investment Highlights.” The following day, Oppenheimer issued a
8 report noting, “Shares of Insys traded up ~12% after the company beat on top-and
9 bottom-line expectations. Subsys growth remains strong with management
10 continuing to forecast share gains in the quarters ahead.”

11 264. The statements alleged in ¶¶260-262 above were materially false and
12 misleading when made or omitted material information such that they were
13 rendered misleading. Contrary to Defendants’ assertions that Subsys sales growth
14 was “largely driven by the continued, successful execution of our Subsys strategy,”
15 the result of “a clinical[ly] superior product,” or due to a “change in the mix of
16 prescribed dosages” in reality, Defendants knew or were deliberately reckless in
17 not knowing that the Company’s Subsys revenues during 3Q14 were the result of
18 what the U.S. Government now describes as a criminal enterprise in violation of
19 the RICO statute which included (i) Insys’ illegal promotion, including kickbacks
20 to prescribers, of Subsys for off-label indications, *see, e.g.*, ¶¶98-208, 348-368,
21 371-396, and, in order to ensure third-party payer approval of the resulting off-
22 label prescriptions, (ii) the creation and utilization of a division of the Company,
23 the IRC, to surreptitiously engage in wide-ranging, pervasive insurance fraud, *see,*
24 *e.g.*, ¶¶209-249; 369-370; 379-385; 394-396.

25 265. More specifically, with respect to the actions of Insys’ IRC, contrary
26 to Defendants’ statements regarding their efforts to “continue to proactively work
27 with managed care providers to ensure coverage for our patient population,”
28

1 Defendants knew or were deliberately reckless in not knowing that Subsys’
2 growing revenues were the result of the IRC’s: (i) fraudulent communications with
3 third-party payers, which included both oral and written statements asserting a
4 prospective Subsys patient had cancer or BTCP; and (ii) efforts to ensure that as
5 many off-label patients as possible received improper access to Subsys under
6 various third-party payer formularies and policies. *See, e.g.*, ¶¶209-249; 369-370;
7 379-385; 394-396.

8 3. 4Q14 and FY14 Financial Results

9 266. On March 3, 2015, Insys issued a press release announcing its
10 financial performance for the fourth quarter ended December 31, 2014 (“4Q14”) and fiscal year 2014 (“FY14”). In the press release, the Company reported
11 “[r]evenues from Subsys (fentanyl sublingual spray) were \$66.1 million, up 69%
12 over fourth quarter of 2013 sales of \$39.2 million.”

13 267. Also on March 3, 2015, Insys held a conference call with analysts.
14 During the call, Defendant Babich noted that “[w]hile we work to bring new
15 products to market, Subsys will continue to be our main driver of revenue in 2015.
16 *We believe this product’s success is the result of a clinical superiority product
17 coupled with a focused market penetration strategy.*”

18 268. More specifically, Defendant Babich stated:

19
20 *I think Q4 is a great indication of what we can do with the
21 product moving forward, as well. I think that is important for
22 folks -- our sales force expansion was based on opportunity.
23 We keep hitting new highs in the number of new doctors that
24 we activate on a weekly basis. We have some very unique
25 programs within the oncology setting that we continue to
26 execute on and any growth that we see in this overall TIRF
27 class is specifically coming from Subsys.*

28 So we feel that this is our market to continue to grow and to
continue to dominate, like we are doing at this point with our
market share. I’ve always talked about, from a market share,
our next total is 50% market share. You can see that in Q4 the
Actiq generic continued to decline, so we continued to take
market share from the generic. *And I think that’s a testament*

1 *to the fact that we have a clinically superior product to the*
2 *Actiq generic out there.* So I think long term we can eventually
3 get to that 60% market share for this product.

4 269. Insys also filed its financial results for FY14 through a Form 10-K
5 submitted to the SEC on the same day (the “FY14 Form 10-K”). The FY14 Form
6 10-K was signed by Defendants Babich, Baker, and Kapoor. Regarding the
7 Company’s interaction with third-party payers for the approval of Subsys, the
8 FY14 Form 10-K explained:

9 Our sales of, and revenue from, Subsys depend in significant
10 part on the coverage and reimbursement policies of third-party
11 payers, including government payers such as Medicare and
12 Medicaid, and private health insurers. All third-party payers
13 are sensitive to the cost of drugs and consistently implement
14 efforts to control these costs, which efforts include, but are not
15 limited to, establishing excluded or preferred drug lists. *Subsys*
16 *has been, and will likely continue to be, subject to these*
17 *restrictions and impediments from third-party payers,*
18 *particularly PBMs and private health insurers. We provide*
19 *administrative patient support assistance, in large part*
20 *through our patient services hub, which provides*
21 *administrative support assistance to help patients work with*
22 *their insurance companies.*

23 270. Similarly, the FY14 Form 10-K stated that:

24 Patient Access: Subsys is a Tier 3 medication available under
25 most major commercial health insurance plans. Some third-
26 party payers require usage and failure on cheaper generic
27 versions of Actiq prior to providing reimbursement for Subsys
28 and other branded TIRF products. *We believe that physicians*
 and payers will develop greater familiarity with both the
 differentiated features of Subsys and the process to achieve
 patient access to the product from continued and broader
 usage of Subsys by their patients. We offer patients a free
 trial of Subsys to allow for titration to their effective dose and
 bridge the prior authorization process. Once third-party payer
 reimbursement is in place, we offer patients coupons to reduce
 out of pocket costs.

29 271. Commenting on the Company’s sales and marketing practices for
30 Subsys, the FY14 Form 10-K stated that “[w]e *commercialize Subsys through a*
31 *cost-efficient commercial organization utilizing an incentive-based sales model*
32 similar to that employed by Sciele Pharma and other companies previously led by

1 members of our board of directors, including our founder and Executive
2 Chairman.”

3 272. Furthermore, with respect to the continued growth of Subsys, the
4 FY14 Form 10-K also explained:

5 *some of the key factors in generating continued growth in*
6 *Subsys usage include taking market share from other*
7 *competing TIRF products and expanding the usage of Subsys*
8 *for BTCP by building awareness among oncologists of its*
9 *rapid onset of action, improved bioavailability, most complete*
10 *range of dosage strengths and ease of administration relative*
11 *to other TIRF products.*

12 273. In response to the Company’s disclosure of its 4Q/FY14 results,
13 analysts issued positive reports about Insys and Subsys. For example, Jefferies
14 issued a report on March 3, 2015 touting the fact that “Subsys Continues to Exceed
15 Expectations” as one of its “Key Takeaway[s].” In particular, Jefferies concluded,
16 “[i]mportantly, neither prior negative media reports nor a formulary exclusion from
17 ESI eff Jan 1 appear to have dampened the drug’s trajectory whatsoever.” The
18 following day JMP Securities issued a report stating,

19 **Raising estimates as we expect strong growth of Subsys to**
20 **continue.** Subsys sales were \$66.1M in 4Q14, vs. JMP of
21 \$61.3M. Management stated that it again saw increases in
22 market share during the quarter and expects to see continued
23 market share, prescription, and revenue growth for the product
24 in 2015. The company has now also completed the planned
25 sales force expansion to 250 people, which was achieved ahead
26 of schedule to maximize on the growth potential of the drug.
27 We have increased our 2015 Subsys net sales estimate from
28 \$259M to \$288M and our 2016 estimate from \$288M to
\$339M. (emphasis in original)

29 274. The statements alleged in ¶¶267-272 above were materially false and
30 misleading when made or omitted material information such that they were
31 rendered misleading. Contrary to Defendants’ assertions that Subsys sales’ growth
32 was the result of “a clinical[ly] superior product,” or due to a “change in the mix of
33 prescribed dosages” in reality, Defendants knew or were deliberately reckless in
34 not knowing that the Company’s Subsys revenues during 4Q14 and FY14 were the

1 result of what the U.S. Government now describes as a criminal enterprise in
2 violation of the RICO statute, which included (i) Insys’ illegal promotion,
3 including kickbacks to prescribers, of Subsys for off-label indications, *see, e.g.*, ¶¶
4 98-208, 348-368, 371-396, and, in order to ensure third-party payer approval of the
5 resulting off-label prescriptions, (ii) the creation and utilization of a division of the
6 Company, the IRC, to surreptitiously engage in wide-ranging, pervasive insurance
7 fraud, *see, e.g.*, ¶¶209-249; 369-370; 379-385; 394-396. Accordingly, and as
8 Defendants knew or were deliberately reckless in disregarding, the only way that
9 Insys “hit[] new highs in the number of new doctors that [it] activated on a weekly
10 basis,” and to grow the “overall TIRF class” was by engaging in illegal off-label
11 promotion, illegal kickbacks to prescribers, and insurance fraud.

12 275. Additionally, contrary to Defendants’ assertion that Insys was
13 “expanding the usage of Subsys for BTCP by building awareness among
14 oncologists” regarding the benefits of Subsys and, in particular, Defendant
15 Babich’s statement that the Company had “some very unique programs within the
16 oncology setting that we continue to execute on,” consistent with Defendant
17 Burlakoff’s reference to cancer patients as “small potatoes,” Insys sales
18 representatives were instructed not only to avoid meeting with oncology doctors
19 and pain specialists at palliative care facilities—the very doctors who would be
20 able to prescribe Subsys on-label—but to aggressively court healthcare
21 professionals who did not have any patients with cancer, much less BTCP, or who
22 did not have any experience in prescribing Schedule II narcotics such as Subsys,
23 *see, e.g.*, ¶¶111-125.

24 276. Defendants’ assertion in the FY14 Form 10-K that “[w]e
25 commercialize Subsys through a cost-efficient commercial organization utilizing
26 an incentive-based sales model” also was materially false or misleading when
27 made because Defendants knew or were deliberately reckless in not knowing that:
28

1 (i) the only way that Insys' sales force could generate the same amount of income
2 as their peers at similar companies was to engage in off-label promotion of Subsys,
3 given the limited population of cancer patients with BTCP and healthcare
4 professionals who treat them, and Insys' sales representatives' extremely low base
5 salary (\$40,000); and (ii) because 90% of Subsys prescriptions were for off-label
6 uses, the only way the IRC could generate individual or group bonuses under the
7 Company's compensation plan was to obtain authorizations for off-label Subsys
8 prescriptions through whatever means necessary, including, *inter alia* changing the
9 diagnosis of the patient to an on-label indication.

10 277. With respect to the actions of Insys' IRC, contrary to Defendants'
11 statements describing the IRC as "provid[ing] administrative support assistance to
12 help patients work with their insurance companies" and regarding Insys' efforts to
13 "continue to proactively work with managed care providers to ensure coverage for
14 our patient population," Defendants knew or were deliberately reckless in not
15 knowing that the growing Subsys' growing revenues were the result of the IRC's:
16 (i) fraudulent communications with third-party payers, which included both oral
17 and written statements asserting a prospective Subsys patient had cancer or BTCP;
18 and (ii) efforts to ensure that as many off-label patients as possible received
19 improper access to Subsys under various third-party payer formularies and
20 policies. *See, e.g.*, ¶¶ 209-249; 369-370; 379-385; 394-396. Likewise,
21 Defendants' statements asserting that third-party payers would "develop greater
22 familiarity with . . . the differentiated features of Subsys . . . from continued and
23 broader usage of Subsys by their patients" were materially false and misleading
24 when made because such statements created the misleading impression that Insys
25 was generating additional Subsys prescriptions through appropriate and lawful
26 interaction with the third-party payers.

1 **4. April 2015 *SIRF* Article**

2 278. On April 24, 2015, *SIRF* published an article entitled “Insys
3 Therapeutics and the New ‘Killing It.’” When asked about allegations against the
4 Company regarding illicit practices such as off-label marketing and compensating
5 doctors under the “Speaker Program,” Defendant Burlakoff responded, “[t]here is a
6 very, very easy way to get fired on your first day at this company, . . . and that is to
7 mention selling off-label. *We are only selling a breakthrough cancer pain drug.*
8 *That’s all we want to address with a doctor. You don’t run a unit at a company*
9 *like this by cutting corners.*”

10 279. Defendant Burlakoff further confirmed, “*I can say that no one at*
11 *Insys wants to see anyone taking [Subsys] for anything other than cancer pain.*”

12 280. The statements alleged in ¶¶278-279 above were materially false and
13 misleading when made or omitted material information such that they were
14 rendered misleading. Contrary to Defendant Burlakoff’s statements that Insys only
15 was “selling a breakthrough cancer pain drug,” that BTCP was all the Company
16 “want[ed] to address with a doctor,” and that “no one at Insys wants to see anyone
17 taking [Subsys] for anything other than cancer pain,” Burlakoff instructed the
18 Company’s sales representatives to avoid doctors who primarily treated cancer
19 patients and, along with the other Defendants, was responsible for what the U.S.
20 Government now describes as a criminal enterprise in violation of the RICO statute
21 which included executing a promotional strategy for Subsys that required Insys
22 sales force to market Subsys to doctors who did not have any cancer patients and
23 included, among other things, the controversial practice of reviewing patient files
24 in order to identify potential Subsys candidates or candidates for which a sales
25 representative could lobby the doctor to obtain a higher dosage prescription.
26 Burlakoff also was responsible, in part, for Insys’ illegal kickbacks to doctors for
27 prescribing Subsys, including setting up sham educational “speaker” programs in
28

1 exchange for increased Subsys prescriptions and advocating for the use of a secret
2 corporate card for providing doctors meals, alcoholic drinks, and entertainment.

3 **5. 1Q15 Financial Results**

4 281. On May 7, 2015, Insys issued a press release to report its financial
5 performance for the first quarter ended March 31, 2015 (“1Q15”) (the “May 7
6 Press Release”). In the May 7 Press Release, Defendant Babich noted that “Insys
7 had another strong quarter, driven by our twelfth consecutive quarter of Subsys
8 sales growth.” Specifically, the May 7 Press Release reported that the Company’s
9 net revenues “were \$70.5 million, up 74% compared with first quarter 2014 sales
10 of \$40.7 million.”

11 282. On the same day, Insys held an earnings conference call with analysts
12 and investors to discuss its 1Q15 financial results. During the call, Defendant
13 Babich touted the growth of Subsys, stating that “[t]hree years post-launch our
14 *Subsys business remains healthy and continues to grow. This clearly*
15 *demonstrates that a better product can succeed in a crowded playing field, and*
16 *we believe there is even more opportunity for Subsys on the horizon.*”

17 283. On May 11, 2015, the Company filed a Form 10-Q for 1Q15 (the
18 “1Q15 Form 10-Q”), signed by Defendants Babich and Baker. Explaining the
19 growth of Subsys sales in the quarter, the 1Q15 Form 10-Q stated that “[t]he
20 *increase in Subsys revenue is primarily as a result of increased prescriptions and*
21 *change in mix of prescribed dosages and also price increases in January 2014,*
22 *April 2014, July 2014 and January 2015.*”

23 284. Notably, the 1Q15 Form 10-Q informed the market that:

24 Our sales of, and revenue from, Subsys depend in significant
25 part on the coverage and reimbursement policies of third-party
26 payers, including government payers such as Medicare and
27 Medicaid, and private health insurers. All third-party payers
28 are sensitive to the cost of drugs and consistently implement
efforts to control these costs, which efforts include, but are not
limited to, establishing excluded or preferred drug lists. *Subsys*

1 *has been, and will likely continue to be, subject to these*
2 *restrictions and impediments from third-party payers,*
3 *particularly PBMs and private health insurers. We provide*
4 *administrative reimbursement support assistance, in large*
5 *part through our insurance reimbursement support hub,*
6 *which provides administrative support assistance to help*
7 *patients coordinate with their insurance companies.*

8 285. Following the Company's disclosure of its 1Q15 financial results,
9 analysts issued positive reports regarding Insys and Subsys. For example, on May
10 7, 2015, Jefferies issued a report entitled, in part, "Subsys Uptake Continues to
11 Impress." JMP Securities issued a report the following day identifying "[a]nother
12 strong quarter of Subsys growth" as one of the "Investment Highlights."

13 286. The statements alleged in ¶¶282-284 above were materially false and
14 misleading when made or omitted material information such that they were
15 rendered misleading. Contrary to Defendants' assertions that Subsys sales' growth
16 was the result of "a better product" or due to a "change in the mix of prescribed
17 dosages" in reality, Defendants knew or were deliberately reckless in not knowing
18 that the Company's Subsys revenues during 1Q15 were the result of what the U.S.
19 Government now describes as a criminal enterprise in violation of the RICO statute
20 which included (i) Insys' illegal promotion, including kickbacks to prescribers, of
21 Subsys for off-label indications, *see, e.g.*, ¶¶ 98-208, 348-368, 371-396, and, in
22 order to ensure third-party payer approval of the resulting off-label prescriptions,
23 (ii) the creation and utilization of a division of the Company, the IRC, to
24 surreptitiously engage in wide-ranging, pervasive insurance fraud, *see, e.g.*, ¶¶209-
25 249; 369-370; 379-385; 394-396. Accordingly, and as Defendants knew or were
26 deliberately reckless in disregarding, the only way that Insys "hit[] new highs in
27 the number of new doctors that [it] activated on a weekly basis," and to grow the
28 "overall TIRF class" was by engaging in illegal off-label promotion, illegal
kickbacks to prescribers, and insurance fraud.

1 287. With respect to the actions of Insys' IRC, Defendants' statements
2 asserting that third-party payers would "develop greater familiarity with . . . the
3 differentiated features of Subsys . . . from continued and broader usage of Subsys
4 by their patients" were materially false and misleading when made because such
5 statements created the misleading impression that Insys was generating additional
6 Subsys prescriptions through appropriate and lawful interaction with the third-
7 party payers. In this regard, Defendants knew or were deliberately reckless in not
8 knowing that Subsys' growing revenues were the result of the IRC's: (i) fraudulent
9 communications with third-party payers, which included both oral and written
10 statements asserting a prospective Subsys patient had cancer or BTCP; and (ii)
11 efforts to ensure that as many off-label patients as possible received improper
12 access to Subsys under various third-party payer formularies and policies. *See,*
13 *e.g.*, ¶¶209-249; 369-370; 379-385; 394-396.

14 6. **2Q15 Financial Results**

15 288. On August 6, 2015, Insys issued a press release announcing its second
16 quarter ("2Q15") financial results ("August 6 Press Release"), including that
17 "[r]evenues from Subsys® (fentanyl sublingual spray) were \$76.7 million, up 40%
18 compared with second quarter 2014 sales of \$54.6 million."

19 289. Notably, after announcing its settlement with the ODOJ of the claims
20 asserted in the Oregon Complaint, as discussed in ¶322, *infra*, and refusing to
21 "admit any violation of law or regulation," the Company represented in the August
22 6 Press Release that it was "*committed to complying with laws governing its sales,*
23 *marketing and promotional practices and has implemented a comprehensive*
24 *compliance program based on the elements of an effective compliance program*
25 *and industry practices.*"

26 290. The Company also held an earnings conference call on August 6,
27 2015 ("2Q15 Earnings Call"), during which Defendant Babich announced that
28

1 2Q15 “was another strong quarter for Insys and our 10th straight quarter of
2 profitability.”

3 291. Regarding the Company’s settlement with the ODOJ, Defendant
4 Babich reiterated to investors and analysts that “*[t]he Company continues to be*
5 *committed to complying with laws governing in sales, marketing and*
6 *promotional practices. And then we’ve implemented a comprehensive*
7 *compliance program based on the elements of an effective compliance program*
8 *and industry practices.*”

9 292. In addition to its August 6 Press Release and 2Q15 Earnings Call, the
10 Company also filed with the SEC the 2Q15 Form 10-Q (“2Q15 Form 10-Q”),
11 signed by Defendants Babich and Baker. Regarding the growth of Subsys
12 revenues, the 2Q15 Form 10-Q represented that, in the quarter, “*[t]he increase in*
13 *Subsys revenue is primarily as a result of increased prescriptions and change in*
14 *mix of prescribed dosages and also price increases in July 2014 and January*
15 *2015.* Similarly, for the six months ending June 30, 2015, “*[t]he increase in*
16 *Subsys revenue is primarily as a result of increased prescriptions and change in*
17 *mix of prescribed dosages and also price increases in January 2014, April 2014,*
18 *July 2014 and January 2015.*”

19 293. The 2Q15 Form 10-Q also explained third-party payers’ approval
20 process for Subsys:

21 Our sales of, and revenue from, Subsys depend in significant
22 part on the coverage and reimbursement policies of third-party
23 payers, including government payers such as Medicare and
24 Medicaid, and private health insurers. All third-party payers
25 are sensitive to the cost of drugs and consistently implement
26 efforts to control these costs, which efforts include, but are not
27 limited to, establishing excluded or preferred drug lists. *Subsys*
28 *has been, and will likely continue to be, subject to these*
restrictions and impediments from third-party payers,
particularly PBMs and private health insurers. We provide
administrative reimbursement support assistance, in large
part through our insurance reimbursement support hub,

1 *which provides administrative support assistance to help*
2 *patients coordinate with their insurance companies.*

3 294. The statements alleged in ¶¶289-293 above were materially false and
4 misleading when made or omitted material information such that they were
5 rendered misleading. Contrary to Defendants' assertions that Subsys sales' growth
6 was the result of, *inter alia*, a "change in the mix of prescribed dosages" in reality,
7 Defendants knew or were deliberately reckless in not knowing that the Company's
8 Subsys revenues during 2Q15 were the result of what the U.S. Government now
9 describes as a criminal enterprise in violation of the RICO statute which included
10 (i) Insys' illegal promotion, including kickbacks to prescribers, of Subsys for off-
11 label indications, *see, e.g.*, ¶¶ 98-208, 348-368, 371-396, and, in order to ensure
12 third-party payer approval of the resulting off-label prescriptions, (ii) the creation
13 and utilization of a division of the Company, the IRC, to surreptitiously engage in
14 wide-ranging, pervasive insurance fraud, *see, e.g.*, ¶¶209-249; 369-370; 379-385;
15 394-396. Additionally, contrary to Defendants' representation that Insys was
16 "committed to complying with laws governing its sales, marketing and
17 promotional practices," in reality, Defendants knew or were deliberately reckless
18 in not knowing that the Company was then-actively marketed Subsys for off-label
19 uses, including, among things, through the payment of illegal kickbacks to doctors,
20 and was misleading third-party payers to approve off-label Subsys prescriptions in
21 contravention of the third-party payers' formularies or policies through the
22 Company's IRC.

23 295. With respect to the actions of Insys' IRC, contrary to Defendants'
24 statements describing the IRC as "provid[ing] administrative patient support
25 assistance to help patients work with their insurance companies," Defendants knew
26 or were deliberately reckless in not knowing that the growing Subsys' revenues
27 were the result of the IRC's: (i) fraudulent communications with third-party
28 payers, which included both oral and written statements asserting a prospective

1 Subsys patient had cancer or BTCP; and (ii) efforts to ensure that as many off-label
2 patients as possible received improper access to Subsys under various third-party
3 payer formularies and policies. *See, e.g.*, ¶¶209-249; 369-370; 379-385; 394-396.

4 **7. 3Q15 Financial Results**

5 296. On November 5, 2015, Insys issued a press release to, as Defendant
6 Kapoor stated, “report record results and our twelfth consecutive quarter of
7 profitability at Insys.” Specifically, as part of its third quarter (“3Q15”) financial
8 performance, the Company reported “[r]evenue from Subsys (fentanyl sublingual
9 spray) was \$91.1 million, up 57% compared with third quarter 2014 revenue of
10 \$58.2 million.”

11 297. On the same day, the Company held an earnings call to discuss its
12 3Q15 financial performance with investors and analysts. During the call,
13 Defendant Kapoor touted the success of Subsys, stating that:

14 ...I want to emphasize, this is --we have a product that works in
15 three to five minutes and it’s delivered instantaneously. I mean
16 these are two advantages that the patients -- if you have a
17 patient who is having a breakthrough cancer pain, which is off
18 the chart, you know scale of 10, it’s beyond 10, every minute is
19 important to the patient. So we believe that those features of
20 our product is driving our product. Once the patients try it,
21 they’ll like the product. They like it because it helps them, it
22 helps their lives. It’s not that they get addicted to it, as some
23 people imply. ***It’s a product that they -- it helps their lives and
24 that’s why the product gained the market share and will
25 continue to gain market share.***

26 298. With respect to Subsys’ target market, Defendant Kapoor also
27 represented during the call that “[w]e only call on REMS, [sic] doctors, and so --
28 ***once we get to 50%, further growth is going to be slower than it has been in the
past and that’s why we have accelerated the development of Subsys in other
indications.***”

29 299. In addition to announcing the Company’s 3Q15 results, Defendant
30 Kapoor announced that, effectively immediately, Defendant Babich had resigned

1 from his role as CEO of Insys. Defendant Kapoor affirmatively denied that
2 Defendant Babich's November 5, 2015 resignation was related to ongoing
3 investigations against the Company. In particular, Defendant Kapoor stated, "[i]n
4 our press release -- Mike and I've worked together for 14 years. We've done many
5 projects besides Insys, very successful ones and all of them have been very
6 entrepreneurial type projects. *And Insys, our progress has far exceeded than*
7 *even I imagined and it came a time when Mike has decided to move on.* As you
8 know, recently he got married, had a boy, wanted to spend some time and pursue
9 other interests. *So, that's what led to the change that we made.*"

10 300. In a Form 10-Q for 3Q15, signed by Defendants Kapoor and Baker,
11 also filed on November 5, 2015 ("3Q15 Form 10-Q"), the Company announced the
12 following regarding the increase in Subsys sales for the quarter:

13 *[t]he increase in Subsys revenue is primarily as a result of a*
14 *31% increase in shipments to pharmaceutical wholesalers* for
15 *the three months ended September 30, 2015 as compared to the*
16 *three months ended September 30, 2014, as well as a 26%*
17 *increase in net sales price, which was impacted by price*
18 *increases in July 2014, January 2015 and July 2015,*
19 *combined with changes in mix of prescribed dosages and*
20 *changes in provisions for wholesaler discounts, patient*
21 *discounts, rebates and returns.*

22 301. Similarly, with respect to Subsys growth for the nine months ending
23 September 30, 2015, the 3Q15 Form 10-Q stated,

24 *The increase in Subsys revenue is primarily as a result of a*
25 *38% increase in shipments to pharmaceutical wholesalers* for
26 *the nine months ended September 30, 2015 as compared to the*
27 *nine months ended September 30, 2014, as well as a 17%*
28 *increase in net sales price, which was impacted by price*
increases in January 2014, April 2014, July 2014, January
2015 and July 2015, combined with changes in mix of
prescribed dosages and changes in provisions for wholesaler
discounts, patient discounts, rebates and returns.

302. In addition to addressing Insys' financial performance, the 3Q15 Form
10-Q also discussed the Company's relationship with PBMs, stating that:

1 Our sales of, and revenue from, Subsys depend in significant
2 part on the coverage and reimbursement policies of third-party
3 payers, including government payers such as Medicare and
4 Medicaid, and private health insurers. All third-party payers
5 are sensitive to the cost of drugs and consistently implement
6 efforts to control these costs, which efforts include, but are not
7 limited to, establishing excluded or preferred drug lists. ***Subsys
has been, and will likely continue to be, subject to these
restrictions and impediments from third-party payers,
particularly PBMs and private health insurers. We provide
administrative reimbursement support assistance, in large
part through our insurance reimbursement support hub,
which provides administrative support assistance to help
patients coordinate with their insurance companies.***

8 303. Further, regarding the allegations made in the Alfonso case, as
9 discussed in ¶¶59-60 above, the 3Q15 Form 10-Q noted, “[i]n connection with the
10 review of this matter by the Compliance Committee of the Board of Directors, with
11 the assistance of outside legal counsel reporting directly to the Compliance
12 Committee, ***we have taken a number of remedial actions and implemented
13 enhancements to the Company’s compliance controls regarding relationships
14 with health care providers. We will continue to assess these matters to ensure we
15 have an effective compliance program.***”

16 304. The statements alleged in ¶¶297-303 above were materially false and
17 misleading when made or omitted material information such that they were
18 rendered misleading. Contrary to Defendants’ assertions that Subsys sales’ growth
19 was the result of, *inter alia*, a “change in the mix of prescribed dosages” or because
20 Subsys “helps” patients, in reality, Defendants knew or were deliberately reckless
21 in not knowing that the Company’s Subsys revenues during 3Q15 were the result
22 of what the U.S. Government now describes as a criminal enterprise in violation of
23 the RICO statute which included (i) Insys’ illegal promotion, including kickbacks
24 to prescribers, of Subsys for off-label indications, *see, e.g.*, ¶¶ 98-208, 348-368,
25 371-396, and, in order to ensure third-party payer approval of the resulting off-
26 label prescriptions, (ii) the creation and utilization of a division of the Company,
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28

1 the IRC, to surreptitiously engage in wide-ranging, pervasive insurance fraud, *see*,
2 *e.g.*, ¶¶209-249; 369-370; 379-385; 394-396.

3 305. With respect to the actions of Insys' IRC, contrary to Defendants'
4 statements describing the IRC as "provid[ing] administrative patient support
5 assistance to help patients work with their insurance companies," Defendants knew
6 or were deliberately reckless in not knowing that the growing Subsys revenues
7 were the result of the IRC's: (i) fraudulent communications with third-party
8 payers, which included both oral and written statements asserting a prospective
9 Subsys patient had cancer or BTCP; and (ii) efforts to ensure that as many off-label
10 patients as possible received improper access to Subsys under various third-party
11 payer formularies and policies. *See, e.g.*, ¶¶ 209-249; 369-370; 379-385; 394-396.

12 306. Defendant Kapoor's statements regarding the reasons surrounding
13 Defendant Babich's sudden resignation were materially false and misleading when
14 made because, among other things, Kapoor knew or was deliberately reckless in
15 not knowing that Babich had been forced out as a result of the intensity and focus
16 of multiple related regulatory investigations, which have now resulted in Babich
17 being charged with running a nationwide racketeering conspiracy in connection
18 with: (i) illegally promoting Subsys for off-label use; and (ii) lying to PBMs and
19 other third party payers. *See, e.g.*, ¶30. Further, Defendant Kapoor's statement
20 that "[w]e only call on REMs doctors," was materially false and misleading when
21 made because, as Defendant Kapoor knew or disregarded with deliberate
22 recklessness, Insys targeted doctors without any experience in prescribing
23 Schedule II drugs and, in particular, were not yet enrolled in the TIRF-REMs
24 program. *See, e.g.*, ¶¶111-125.

25 307. Further, Defendants' reassurances that they had "taken a number of
26 remedial actions and implemented enhancements to the Company's compliance
27 controls regarding relationships with health care providers," were materially false
28

1 and misleading when made because Defendants knew or were deliberately reckless
2 in disregarding that the Company was then-actively marketing Subsys for off-label
3 uses, including, among things, through the payment of illegal kickbacks to doctors,
4 and was misleading third-party payers to approve off-label Subsys prescriptions in
5 contravention of the third-party payers' formularies or policies through the
6 Company's IRC. *See, e.g.*, ¶¶98-249; 348-396. As set forth in the Babich and
7 Burlakoff Indictment, Insys was continuing to pay illegal kickbacks to prescribers
8 and defrauding insurers at the times these statements were made. *See, e.g.*, ¶¶201-
9 208.

10 **8. Insys' November 23, 2015 Press Release**

11 308. On November 4, 2015, CNBC published an article entitled, "The
12 painkiller: A drug company putting profits above patients," which reported,
13 among things that the U.S. Department of Health and Human Services' ("DHHS")
14 Office of Inspector General had placed Subsys on a list of "new diversion drugs of
15 concern. Diversion is a form of medical fraud that can include doctors prescribing
16 drugs for unintended uses." The CNBC article also quoted the Oregon Assistant
17 Attorney General as saying that the Subsys case settled by the ODOJ in August
18 2015 "was among the most unconscionable that [he has] seen," noting that "[t]here
19 was harm done to patients on a level [he was] not used to seeing." Then, one week
20 later, news broke that Express Scripts had cut ties with one of Insys' main specialty
21 pharmacies which provided patients with Subsys due to the pharmacy's sale of
22 narcotics without appropriate licenses, among other things, (*see, e.g.*, November
23 11, 2015 *New York Times* Article, entitled "Express Scripts cut ties with New York
24 specialty pharmacy").

25 309. Thereafter, to address these recent developments, on November 23,
26 2015, Insys released an "Issue Statement," regarding Subsys. In particular, the
27
28

1 statement discussed the FDA-mandated TIRF REMS Access Program. Regarding
2 its compliance with this program, the Company stated:

3 ***Insys has a compliance program in place with protocols that***
4 ***are designed to ensure its sales and marketing practices***
5 ***comply with applicable laws. . . .*** While Subsys' share of the
6 TIRF market has grown significantly since it was launched in
7 2012, the overall total number of TIRF prescriptions in 2014
8 was only slightly higher than the total number of TIRF
9 prescriptions in the year of the launch of Subsys (2012) and was
10 actually materially lower than the total number of prescriptions
11 in the year prior to the launch of Subsys and the TIRF REMS
12 program (2011). Given these facts and other relevant
13 information, ***Insys believes that existing data strongly support***
14 ***that prescribing decisions have been driven primarily by the***
15 ***clinical attributes of Subsys and its market share gains have***
16 ***come from patients and HCP's switching to Subsys from other***
17 ***TIRF products...***

18 310. The statements alleged in ¶309 above were materially false and
19 misleading when made or omitted material information such that they were
20 rendered misleading. Contrary to Defendants' assertions that "the prescribing
21 decisions have been driven primarily by the clinical attributes of Subsys" in reality,
22 Defendants knew or were deliberately reckless in not knowing that the Company's
23 Subsys revenues during this time period were the result of what the U.S.
24 Government now describes as a criminal enterprise in violation of the RICO statute
25 which included (i) Insys' illegal promotion, including kickbacks to presenters, of
26 Subsys for off-label indications, *see, e.g.*, ¶¶ 98-208, 348-368, 371-396, and, in
27 order to ensure third-party payer approval of the resulting off-label prescriptions,
28 (ii) the creation and utilization of a division of the Company, the IRC, to
surreptitiously engage in wide-ranging, pervasive insurance fraud, *see, e.g.*, ¶¶209-
249; 369-370; 379-385; 394-396.

311. Additionally, contrary to Defendants' representation that Insys "has a
compliance program in place with protocols that are designed to ensure its sales
and marketing practices comply with applicable laws," in reality, Defendants knew
or were deliberately reckless in disregarding that the Company was then-actively

1 marketing Subsys for off-label uses, including, among things, through the payment
2 of illegal kickbacks to doctors, and was misleading third-party payers to approve
3 off-label Subsys prescriptions in contravention of the third-party payers'
4 formularies or policies through the Company's IRC. *See, e.g.*, ¶¶209-249; 369-
5 370; 379-385; 394-396.

6 **9. Insys' January 25, 2016 Press Release**

7 312. On January 25, 2016, *SIRF* published an article entitled, "The
8 Brotherhood of Thieves: Insys Therapeutics." The article confirmed that despite
9 the receipt of subpoenas and the initiation of investigations by both DHHS and the
10 DOJ, Insys continued to ensure the success of its illegal off-label marketing and
11 kickback scheme by fraudulently inducing third-party payers to approve off-label
12 Subsys prescriptions in contravention of their published formularies, practices, and
13 policies. Specifically, relying on Insys' documents and a recorded meeting of the
14 IRC, the article reported that as of late autumn 2015, the Company's IRC was still
15 brainstorming ways to obtain third-party payer approvals for off-label Subsys
16 prescriptions.

17 313. In direct response to the article, the Company issued a press release
18 relating to its Patient Services Center (IRC), stating, unequivocally, "***Insys rejects***
19 ***the recent media reports' account of the Company's practices as misleading and***
20 ***unreliable***, especially in light of the biased agenda held by the individuals who
21 made these misrepresentations." Notably, regarding its practice of helping patients
22 gain access to Subsys through, *inter alia*, its IRC, the Company stated that "***Insys***
23 ***requires its Patient Services Center personnel undergo specific training on***
24 ***applicable laws and regulations and continues to strive to comply with applicable***
25 ***laws and regulations through its compliance policies and procedures.***"

26 314. The statements alleged in ¶313 above were materially false and
27 misleading when made or omitted material information such that they were
28

1 rendered misleading. With respect to the actions of Insys' IRC, contrary to
2 Defendants' assertion that "Insys requires its Patient Services Center personnel
3 undergo specific training on applicable law as and regulations and continues to
4 strive to comply with applicable laws and regulations," Defendants knew or were
5 deliberately reckless in not knowing that, throughout the Class Period, the IRC
6 engaged in what the U.S. Government now describes as a criminal enterprise in
7 violation of the RICO statute, which included (i) fraudulent communications with
8 third-party payers, which included both oral and written statements asserting a
9 prospective Subsys patient had cancer or BTCP, *see, e.g.*, ¶¶98-208, 348-368, 371-
10 396, and (ii) efforts to ensure that as many off-label patients as possible received
11 improper access to Subsys under various third-party payer formularies and policies
12 *see, e.g.*, ¶¶209-249; 369-370; 379-385; 394-396.

13 **D. The Truth Behind Subsys' Success Is Slowly Revealed**

14 315. On September 12, 2014, Insys filed a Form 8-K with the SEC
15 announcing that the Company had received a subpoena from the U.S. Attorney's
16 office for the District of Massachusetts. Issued on or about September 8, 2014, the
17 subpoena requested "documents regarding Subsys®, including Insys' sales and
18 marketing practices related to this product."

19 316. On November 27, 2014 (Thanksgiving Day), the *New York Times*
20 published an article regarding Insys' use of kickback payments to doctors to
21 promote Subsys entitled, "Using Doctors With Troubled Pasts to Market a
22 Painkiller." According to the article, during the "final five months of 2013," Insys
23 paid doctors \$2.8 million to market Subsys—an amount equal to the marketing
24 budget of major pharmaceutical companies for products used to treat conditions
25 like diabetes or heart disease. Of the 20 doctors paid by Insys to promote Subsys
26 (many of which also were top prescribers of Subsys) reviewed by the *New York*
27 *Times*, at least three "were said to have inappropriately prescribed painkillers."
28

1 The article also cited “[s]everal former sales representatives” who stated that “they
2 were encouraged by the company to call on pain doctors who treated patients with
3 a wide range of ailments, and to reward high-prescribing physicians with perks like
4 paid speaking engagements.” In response to this article, the price of Insys common
5 stock fell 8.58% over two trading days, from a closing price of \$40.09 on
6 November 26, 2014 (the last trading day before Thanksgiving), to a closing price
7 of \$36.65 on December 1, 2014, on heavy volume.

8 317. After the close of the market on April 24, 2015, *SIRF* published an
9 article entitled, “Insys Therapeutics and the New ‘Killing It.’” Among other
10 things, the article reported that *SIRF* had “repeatedly encountered former Insys
11 employees who had received subpoenas requiring their appearance in front of a
12 Department of Justice grand jury . . . empaneled in Boston” and “interviewed for . .
13 . the Department of Health and Human Services’ Office of the Inspector
14 General[‘s]” of the Company. The article also noted that the Company did not
15 require its Subsys sales representatives to have completed college-level science
16 courses or have any pharmaceutical sales background prior to selling one of the
17 most potent prescription painkillers.

18 318. In addition to providing disturbing details regarding Insys’ sales and
19 marketing employees, the article also highlighted the high Subsys prescription
20 rates of Drs. Xiulu Ruan and John Couch, partners in a Mobile, Alabama based
21 practice and owners of C & R Pharmacy, which dispensed Subsys to Drs. Ruan
22 and Couch’s patients. In response to this news, the price of Insys common stock
23 fell 9.61% from a closing price of \$62.42 on April 24, 2015 to a closing price of
24 \$56.42 on April 27, 2015, the first trading day after the article was published, on
25 heavy trading volume.

26 319. Less than one month later, on May 20, 2015, the United States
27 Attorney for the Southern District of Alabama announced that Drs. Ruan and
28

1 Couch had been arrested. According to an April 2015 indictment, Drs. Ruan and
2 Couch were charged with “conspiracy to distribute controlled substances outside
3 the usual course of professional practice and not for a legitimate medical purpose,”
4 and “conspiracy to commit healthcare fraud.” According to a second superseding
5 indictment filed after the end of the Class Period on April 28, 2016, between April
6 2012 and May 20, 2015, Drs. Ruan and Couch issued thousands of Subsys
7 prescriptions to their patients, nearly none of whom had cancer. The superseding
8 indictment further stated that, *as a result of receiving over \$110,000 in kickbacks*
9 *from Insys, Ruan and Couch would switch their patients to Subsys, even if their*
10 *current medical needs were being met by their original medication.*

11 320. In response to this news, the price of Insys common stock fell 4.43%
12 from a closing price of \$59.77 on May 19, 2015 to a closing price of \$57.12 on
13 May 20, 2015, on heavy trading volume.

14 321. Thereafter, on June 23, 2015, the United States District Court for the
15 District of Connecticut entered onto the court’s electronic docket (PACER) the
16 Information and Plea Agreement of Heather Alfonso, a nurse accused of accepting
17 approximately \$83,000 in kickbacks from Insys in exchange for prescribing Subsys
18 to Medicare patients who did not have BTCP. The following day, the *New York*
19 *Times* published an article entitled, “Nurse Pleads Guilty to Taking Kickbacks
20 from Drug Maker.” According to the article, at the time of her arrest and guilty
21 plea, Ms. Alfonso was a top prescriber of Subsys to Medicare patients. The article
22 reported that Ms. Alfonso’s “guilty plea may mean that prosecutors are seeking to
23 strike deals with individuals in exchange for providing additional information
24 about the company’s practices.” In response to the plea agreement and the
25 subsequent *New York Times* article, the Company’s stock price fell 12.64% over
26 two trading days, from a closing price of \$40.91 on June 23, 2015, to a closing
27 price of \$35.74 on June 25, 2015, on heavy volume.

1 322. On August 5, 2015, the ODOJ issued a press release announcing that
2 it had settled with Insys claims regarding the Company’s illegal promotion,
3 including kickbacks to prescribers, of Subsys. According to the press release, the
4 settlement, which included a \$1.1 million fine and agreement to an “Assurance of
5 Voluntary Compliance,” resolved “allegations that the powerful drug approved by
6 the Food and Drug Administration (FDA) to treat cancer pain was marketed in
7 Oregon for off-label uses such as non-cancer neck and back pain” and “that the
8 company provided improper financial incentives to some doctors to increase
9 Subsys prescriptions, targeted doctors for aggressive promotion of Subsys when
10 the doctor was not qualified to prescribe the drug, and deceptively promoted
11 Subsys for treatment of mild pain.”

12 323. On November 4, 2015, *CNBC* published an article entitled, “The pain
13 killer: A drug company putting profits above patients.” According to the article,
14 “an officer from the Inspector General’s Office of the United States Department of
15 Health and Human Services placed Subsys on a list of ‘new diversion drugs of
16 concern,’” where diversion is defined as “a form of medical fraud that can include
17 doctors prescribing drugs for unintended uses.” Citing “several sources,” as well
18 as “emails obtained from current and former employees of Insys, as well as
19 physicians,” the article also concluded that the Company’s sales representatives
20 “were under immense pressure, including threats of termination, to get doctors to
21 write more prescription and higher doses of Subsys for everything from neck pain
22 to migraines.”

23 324. The *CNBC* article further quoted the Oregon Assistant Attorney
24 General as follows: “I’ve been investigating drug cases for about 15 years now,
25 and the conduct that we saw in this case was among the most unconscionable that
26 I’ve seen There was harm done to patients on a level I’m not used to seeing.”
27 In response to this news, the price of Insys common stock fell 8.50%, from a
28

1 closing price of \$28.83 on November 3, 2015 to a closing price of \$26.38 on
2 November 4, 2015, on heavy trading volume.

3 325. On the following day, in addition to announcing its results for 3Q14,
4 the Company disclosed that Defendant Babich had resigned from his position as
5 CEO of the Company, effective immediately. Insys attempted to downplay this
6 surprising news by emphasizing Defendant Kapoor's leadership of the Company
7 and asserting that Babich's decision was the natural progression of succession
8 planning long in the works. Despite these containment efforts, the price of Insys
9 common stock declined by 3.60%, from a closing price of \$26.38 on November 4,
10 2015 to a closing price of \$25.43 on November 5, 2015, on heavy trading volume.

11 326. On December 3, 2015, *SIRF* published an article entitled, "Murder
12 Incorporated: Insys Therapeutics, Part I." According to the article, Defendant
13 Kapoor forced out Defendant Babich (who suddenly resigned on November 5,
14 2015) as a result of the "intense regulatory scrutiny" of the Company's marketing
15 of Subsys. While both executives were the subjects of this scrutiny, the article
16 reported that Defendant Kapoor believed that "Babich was closest to the issues"
17 under investigation and that a change was necessary to appease government
18 regulators. The article also detailed Defendant Babich's relationship with his wife,
19 Natalie Levine, one of the Subsys sales representatives involved with Heather
20 Alfonso, including that Levine had "arranged and attended many of the 70 speaker
21 events" identified in the U.S. Government's indictment of Alfonso.

22 327. With respect to Insys' IRC, the article disclosed that it "was the key
23 piece in helping Insys double the size of the Fentanyl marketplace to more than
24 \$500 million in less than two years." Before various government regulators began
25 investigating Insys, the article reported that employees in the IRC were paid
26 bonuses for obtaining insurance coverage of Subsys on behalf of patients, the
27 majority of whom were not being treated for BTCP, by changing the insurance
28

1 codes on the paperwork to reflect a BTCP diagnosis or orally confirming to
2 insurance companies that the patient had BTCP. The article further described how
3 the methods employed by the IRC changed after the Company began receiving
4 subpoenas regarding the improper marketing and sale of Subsys, becoming less
5 overt, but no less brazen, in its efforts to obtain insurance coverage for off-label
6 Subsys prescriptions. In response to this article, the price of Insys common stock
7 fell by 18.54%, from a closing price of \$31.99 on December 2, 2015 to a closing
8 price of \$26.06 on December 3, 2015 on extremely heavy trading volume.

9 328. The following day Oppenheimer issued a report stating, in relevant
10 part:

11 While there certainly does appear to be value tucked into Insys’
12 R&D programs, the spotlight unfortunately for the company
13 rested on another *Southern Investigative Reporting Foundation*
14 (SIRF) article that was bearish on Insys. Shares of INSY traded
15 down ~19% (vs. the S&P 500 -1.5%) after the SIRF article
16 alleged improprieties in Subsys reimbursement. We note that a
17 prior SIRF article published in April 2015, focusing on alleged
18 off-label marketing and physician kickbacks, sent the shares
19 down ~10% then. Considering that investors, in our opinion,
20 still have some time until potential meaningful revenue
21 contribution from the pipeline, and considering the continued
22 background noise on the company, we remain on the sidelines.

23 329. Approximately one week later, on December 9, 2015, *SIRF* published
24 part II of its “Murder Incorporated” exposé. The article described the experiences
25 of Tim Neely, a former Insys sales representative, based in California, which
26 included utilizing patient data to identify lapsing prescriptions or opportunities to
27 increase dosages, and paying for alcoholic drinks, meals and entertainment for
28 prescribing doctors and Insys speakers with a secret company credit card, tactics
that were either developed or approved by Defendant Burlakoff.

330. On January 25, 2016, *SIRF* published another article regarding Insys
and Subsys entitled, “The Brotherhood of Thieves: Insys Therapeutics.” The
article provided further details regarding Insys’ use of its IRC to trick insurers into

1 covering off-label prescriptions of Subsys, including an audio recording of a
2 meeting within the unit, wherein Insys IRC employees discussed how to distract
3 PBMs in order to obtain pre-authorization for off-label uses of Subsys. The article
4 also disclosed that approvals for insurance coverage of Subsys prescriptions had
5 begun to drop in the fall of 2015 in response to various articles documenting the
6 activities of the IRC and continued government scrutiny of Insys' marketing
7 practices with respect to Subsys. In response to this article, the price of Insys
8 common stock declined by 4.72%, from a closing price of \$22.65 on January 22,
9 2016 to a closing price of \$21.58 on January 25, 2016, on heavy trading volume.

10 331. Less than one month later, on February 17, 2016, former Insys sales
11 representative, Natalie Reed Perhacs, pleaded guilty in the United States District
12 Court for the Southern District of Alabama to illegally paying Drs. Ruan and
13 Couch kickbacks to induce and reward their prescribing Subsys to their patients.
14 Perhacs admitted to receiving nearly \$700,000 in commissions as a result of Drs.
15 Ruan and Couch's willingness to prescribe Subsys to their patients, who did not
16 have BTCP.

17 332. On April 11, 2016, Insys issued a press release entitled, "Insys
18 Therapeutics Reports Preliminary Estimated Revenue from Subsys for the First
19 Quarter 2016." In the press release, *Insys preannounced that Subsys net revenues*
20 *for 1Q16 would be \$61 million to \$62 million – significantly lower than*
21 *consensus expectations of \$86 million for the same period.* Insys attributed the
22 shortfall to "heightened publicity surrounding the national opioid epidemic," which
23 "has resulted in a sensitivity by some healthcare providers to prescribe opioids."
24 In response to this press release, the price of Insys common stock declined 19.37%,
25 from a closing price of \$17.66 on April 8, 2016 to a closing price of \$14.24 on
26 April 11, 2016.

1 333. Analysts attributed to the stock price decline on April 11, 2016 to the
2 Company's announcement regarding lower expected Subsys sales and, in turn,
3 lower Subsys revenues, for 1Q16. For example, Oppenheimer issued a same-day
4 report stating, "[s]hares of Insys traded down ~19% (vs. S&P 500 ~flattish) after
5 the company announced 1Q16 guidance that was roughly 30% below consensus."
6 RBC Capital Markets ("RBC") issued a report on April 12 concluding that "INSY
7 closed -19% on a preannounced 1Q2016 Subsys shortfall."

8 334. Analysts also expressed surprise at the Company's disclosure. For
9 example, Piper Jaffray & Co. ("Piper Jaffray") issued a same-day report calling
10 "the commentary from management . . . a head scratcher," and concluding that
11 "[t]he sudden change in commentary" by the Company regarding Subsys
12 prescriptions was "troubling," likely because the "publicity surrounding the
13 national opioid epidemic had existed since, at least, the beginning of the Class
14 Period. In particular, the Piper Jaffray report noted, "[t]he bottom line is that given
15 the commentary from management prior to today, we are disappointed that INSY
16 appeared to present a picture for Subsys that did not entirely square with reality."

17 335. Several analysts further concluded that the size of the shortfall in
18 Subsys prescriptions and revenues for 1Q16 preannounced by Insys was larger
19 than expected. For example, RBC also issued a same-day report calling the
20 "magnitude of the shortfall" in Subsys scripts announced by Insys "significant."
21 Jefferies issued a report on April 12, 2016 concluding that "the impact" of the
22 lower Subsys prescriptions "was much more pronounced than anticipated," calling
23 "the magnitude of the expected sales miss . . . quite surprising."

24 336. Still other analysts questioned the veracity of the Company's assertion
25 that the lower Subsys scripts and revenues were due to broader concerns in the
26 TIRF market. In a report related to Endo International (a competitor of Insys),
27 Gabelli said that "*Subsys blame lacks substance,*" *finding that "the majority of*
28

1 *the problems with Subsys . . . are likely specific to that company and that*
2 *product.*” Similarly, in an April 11, 2016 report regarding Insys, JMP attributed to
3 decline in scripts of Subsys to “price and payer coverage considerations,” noting
4 that the “decline in scripts was more prominent at the lower doses of Subsys . . .
5 suggest[ing] that fewer patients were initiating therapy.”

6 337. Then, on June 9, 2016, the United States Attorney for the Southern
7 District of New York, along with representatives of the FBI and the Office of the
8 Inspector General for the U.S. Department of Health and Human Services issued a
9 press release announcing that Jonathan Roper, a former Insys District Manager and
10 Fernando Serrano, a former Insys sales representative “were charged today with
11 violating the Anti-Kickback Statute in connection with their participation in a
12 scheme to pay doctors thousands of dollars to participate in sham educational
13 programs in order to induce the doctors to prescribe millions of dollars’ worth of
14 [Subsys].”

15 338. On August 25, 2016, Illinois Attorney General, Lisa Madigan, filed a
16 complaint against Insys in Illinois state court alleging consumer fraud claims and
17 seeking civil penalties and injunctive relief based upon the impact of the
18 Company’s illegal off-label marketing and kickback payments and related
19 insurance fraud in the State of Illinois. Among other things, as alleged herein, the
20 Illinois Complaint alleges that Insys deliberately targeted and enlisted “pill mill”
21 doctors and other high volume opioid prescribers who did not treat cancer patients
22 to increase Subsys prescriptions by paying kickbacks to these practitioners. The
23 Illinois Complaint further alleges that Insys sales representatives inserted
24 themselves into the prior authorization of Subsys to help convince PBMs to
25 approve Subsys prescriptions for patients that did not have cancer. In an August
26 25, 2016 press release issued in connection with the filing of the Illinois
27 Complaint, the Illinois Attorney General stated: “[t]his drug company’s desire for
28

1 *increased profits led it to disregard patients' health and push addictive opioids*
2 *for non-FDA approved purposes. It's this type of reprehensible and illegal*
3 *conduct that feeds the dangerous opioid epidemic and is another low for the*
4 *pharmaceutical industry."*

5 339. On September 29, 2016, the United States Attorney's Office for the
6 District of Connecticut issued a press release announcing that it had arrested and
7 filed a criminal complaint against Pearlman, who served as Insys' District Sales
8 Manager for Connecticut, New York, New Jersey, and Rhode Island, and was
9 employed by Insys from September 2012 until December 2015. Among other
10 things, the Pearlman Complaint alleges that Pearlman violated the Anti-Kickback
11 Statute by paying kickbacks to prescribers, including Alfonso, in exchange for off-
12 label Subsys prescriptions. The Pearlman Complaint further alleges that the
13 kickbacks were paid through the Company's sham Speaker Program, which
14 included speaking events with no audience, no educational content, and no
15 legitimate purpose. As a result, the Pearlman Complaint alleges, the attendance
16 sheets for many such speaking events were forged to include as attendees people
17 who were not present. The Pearlman Complaint further alleges that the
18 Company's illegal promotion of Subsys through Pearlman and the Insys sales
19 representatives that he managed, including Serrano, defrauded federal healthcare
20 programs.

21 340. On October 11, 2016, United States Senator Edward J. Markey for
22 Massachusetts wrote a letter to Andy Slavitt, the Acting Administrator of the
23 Centers for Medicare and Medicaid Services, raising concerns regarding Medicare
24 coverage for Subsys in light of "off-label prescriptions driven by the drug
25 manufacturer's aggressive and illegal marketing activities." Among other things,
26 Senator Markey's letter noted that from 2013-2014, Medicare paid more than \$125
27 million to cover Subsys prescriptions, most of which were written for off-label use.
28

1 Accordingly, Senator Markey demanded information concerning, among other
2 things, steps that the Medicare program is taking to recoup the payments made to
3 cover Subsys prescriptions written to people who did not have cancer. As *The*
4 *Wall Street Journal* reported in a November 23, 2016 article entitled, “Fentanyl
5 Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids,”
6 the amount that Medicare paid for Subsys prescriptions ballooned to \$171.3
7 million in 2015, for a ***2013-2015 total of more than \$300 million in Medicare***
8 ***payments to cover primarily off-label prescriptions of a deadly drug.***

9 341. On October 17, 2016, the Gurrieri Complaint was unsealed and
10 entered onto the electronic docket for the United States District Court for the
11 District of Massachusetts. As alleged herein, the Gurrieri Complaint contains
12 detailed facts from the U.S. Government’s investigation pertaining to the IRC’s
13 fraudulent practices directed by Babich and executed by Gurry, Gurrieri, and
14 others. The facts alleged in the Gurrieri Complaint demonstrate that the
15 misrepresented and concealed purpose of Insys’ IRC was to obtain insurance
16 coverage for off-label Subsys prescriptions by, among other things: (i)
17 misrepresenting and concealing the identity of the IRC and its personnel; (ii)
18 falsifying the patient’s diagnosis; (iii) providing misleading answers to questions
19 meant to determine whether the prescription was for an on-label indication of
20 Subsys; and (iv) misrepresenting a patient’s tried and failed medications. As a
21 result, the U.S. Government charged Gurrieri with federal wire fraud violations in
22 connection with defrauding PBMs nationwide into covering Subsys prescriptions
23 for patients who did not have BTCP.

24 342. On November 7, 2016, a top national Subsys prescriber, Dr. Gavin
25 Awerbuch of Michigan, pled guilty to: (i) Health Care Fraud in violation of 18
26 U.S.C. §1343; and (ii) Distribution of Controlled Substances in violation of 21
27 U.S.C. §841(a)(1). In his plea agreement filed that day in the United States
28

1 District Court for the Eastern District of Michigan, the U.S. Government alleged,
2 among other things, that Dr. Awerbuch knowingly and intentionally prescribed
3 Subsys for no legitimate medical purpose. As *The Wall Street Journal* reported in
4 a November 23, 2016 article entitled, “Fentanyl Billionaire Comes Under Fire as
5 Death Tolls Mount from Prescription Opioids,” Insys paid Dr. Awerbuch
6 approximately \$90,000 in kickbacks in 2013 alone. Dr. Awerbuch is “Practitioner
7 #3” in the Babich and Burlakoff Indictment, which alleges, among other things,
8 that: (i) Burlakoff personally met with Dr. Awerbuch in Michigan in October 2012
9 to encourage Dr. Awerbuch to write more Subsys prescriptions; and (ii) from the
10 time of the meeting between Burlakoff and Dr. Awerbuch and Dr. Awerbuch’s
11 arrest in 2014, Insys paid Dr. Awerbuch more than \$138,000 in kickbacks. Dr.
12 Awerbuch’s off-label prescribing of Subsys pursuant to Insys’ illegal kickback
13 scheme was so prolific that Burlakoff sent a September 2013 e-mail to Babich and
14 others proclaiming: “[l]et’s make some money, and stop playing BS games trying
15 to manage rookies. It’s the [Awerbuchs] of the world that keep us in business,
16 lets [sic] get a few more and the rest . . . of this job is a ‘joke.’”

17 343. On December 8, 2016, the Babich and Burlakoff Indictment was
18 unsealed. In its press release announcing the racketeering and other criminal
19 charges against Babich, Burlakoff, and other former Insys executives, the United
20 States Attorney’s Office for the District of Massachusetts stated, among other
21 things, that Babich and Burlakoff “led a nationwide conspiracy to bribe medical
22 practitioners to unnecessarily prescribe a fentanyl-based pain medication and
23 defraud healthcare insurers.” As alleged herein, the Babich and Burlakoff
24 Indictment contains detailed facts from the U.S. Government’s investigation
25 demonstrating that these Defendants orchestrated and directly participated in a
26 Company-wide and nationwide fraud that, according to the U.S. Government,
27
28

1 “contributed to the growing opioid epidemic and placed profit before patient
2 safety.”

3 344. In response to the information set forth in the Babich and Burlakoff
4 Indictment, the price of Insys common stock declined 11.87%, from a closing price
5 of \$10.70 per share on December 7, 2016 to a closing price of \$9.43 per share on
6 December 8, 2016.

7 345. Commenting on the Babich and Burlakoff Indictment, the *New York*
8 *Times* published an article on December 12, 2016 entitled, “RICO Charge in
9 Pharmaceutical Case May Signal Tougher Tactics,” stating:

10 *What takes the case outside the usual allegations of fraud*
11 *found in any number of health care prosecutions is the RICO*
12 *conspiracy charge, which accuses the defendants of forming*
13 *an enterprise to violate federal and state laws over a three-*
14 *year period to enrich themselves.* To prove the crime,
15 prosecutors have to show that the defendants agreed to engage
16 in a “pattern of racketeering activity,” which the indictment lists
17 as violations of the federal mail and wire fraud statutes along
18 with commercial bribery laws in Connecticut, Florida, New
19 Hampshire and Texas.

20 The benefit of a RICO charge is that it brings together disparate
21 acts by different defendants into a single case, allowing the
22 Justice Department to paint with a broad brush to show that this
23 was not isolated misconduct but part of a widespread effort to
24 violate the law.

25 346. Insys common stock is currently trading at prices around \$9.00 per
26 share.

27 **E. Summary of Scienter Allegations**

28 347. As alleged in detail above in Section IV.B, numerous facts give rise to
a strong inference that, throughout the Class Period, Defendants knew or were
deliberately reckless in disregarding that the statements identified in Section IV.C
above were materially false and misleading when made and/or omitted material
facts necessary to make those statements not misleading.

1 **1. The Individual Defendants’ Senior-Level Positions, Hands-**
2 **On Management, and Access to Adverse Information**
3 **Support a Strong Inference of Scienter**

4 348. Defendant Kapoor, Insys’ co-founder, was Chairman of the Board
5 throughout the Class Period and the Company’s CEO/President beginning as of
6 November 5, 2015. As the most senior officer of the Company, Kapoor had
7 ultimate responsibility for directing and managing the Company’s financial
8 performance, public statements, and business affairs. As Chairman of the Board,
9 moreover, Defendant Kapoor was required to keep himself and Insys’ non-
10 management directors apprised of the state of the Company’s business and
11 operations. Furthermore, as co-founder, Kapoor had unlimited access to the
12 confidential and proprietary information of the Company.

13 349. In addition to the general business and operational knowledge he
14 acquired through his high-level positions, Defendant Kapoor was a hands-on
15 executive with day-to-day involvement with the Company’s operations. During a
16 December 1, 2015 Piper Jaffray Healthcare Conference, for instance, Kapoor
17 described how closely he monitored the “Subsys market,” *including tracking daily*
18 *scripts:*

19 The factual information is that the Subsys market, when we
20 entered, had about roughly 10,000 scripts a month, and today
21 roughly the same. And we started with zero and today we have
22 almost 50% market share. *And if you analyze this, which we*
23 *do every day, we have a meeting everyday at 8:30 in the*
24 *morning looking at what happened yesterday. I can tell you*
25 *how many scripts we did yesterday. And we do that every*
26 *single day, because Subsys is so important to us.*

27 350. Indeed, when allegations of misconduct against the Company surfaced
28 in December 2015, a Company-insider and whistleblower confirmed to *Fusion* that
Kapoor was at the top-levels of the fraud, stating: “I really hope they get Kapoor
and the people at the very top who are behind all this greed . . . The sales reps were
part of it, but *Kapoor? He built this whole thing.*”

1 351. As a result of his roles with both Insys and other pharmaceutical
2 companies which he founded, Kapoor also was aware of FDA regulations
3 regarding the appropriate marketing and promotion of pharmaceuticals and the
4 prohibitions on promoting off-label uses and paying monetary or in-kind kickbacks
5 to induce doctors to write prescriptions. Likewise, in light of his experience and
6 PhD in Medicinal Chemistry, Kapoor was aware of and understood the limits of
7 Subsys FDA-approved label, including the fact that Subsys could *only* be
8 prescribed to opioid tolerant adults with BTCP, at an initial dosage of 100mcg,
9 titrating thereafter only to the highest dose necessary to ensure that the patient was
10 comfortable, and was contraindicated to treat any other conditions, such as non-
11 malignant pain (*e.g.*, back or neck pain) and migraines.

12 352. Defendant Babich served as the CEO and President of Insys prior to
13 and during the Class Period, until his sudden resignation on November 5, 2015.
14 Babich, like Kapoor, exercised ultimate control over the Company's financial
15 performance, public statements, and business affairs, and had unlimited access to
16 confidential and proprietary Company information by virtue of holding the highest
17 positions at the Company.

18 353. Now indicted for his role in what the U.S. Government describes as a
19 nationwide criminal enterprise in violation of the RICO statute, Babich has been
20 directly tied to the Company's improper marketing and sales practices and
21 insurance fraud. Babich's specific acts in furtherance of this enterprise are set
22 forth in at least ¶¶13-16, 23, 30, 104, 106-110, 134-135, 156-157, 159-161, 168-
23 169, 172, 175-176, 187-188, 192, 194, 197, 200, 202, 209, 214-216, 219, 225-226,
24 237-238, 241 above. Additionally, Babich and his wife, former Insys salesperson,
25 Natalie Levine, were revealed to be complicit in the fraud committed by the
26 indicted Connecticut nurse, Alfonso, by approving and/or providing Alfonso with
27 \$83,000 in kickbacks. As a December 3, 2015 *SIRF* article entitled "Murder
28

1 Incorporated: Insys Therapeutics, Part I” disclosed, Levine was one of the sales
2 representatives who called on Alfonso and arranged and attended many of the 70
3 speaker program events for which Alfonso was paid illegal kickbacks. The *SIRF*
4 article also confirmed that Babich approved two years-worth of budgeted kickback
5 payments to Alfonso. Furthermore, former Insys’ sales representative Neely told
6 *SIRF* that he was “led to believe that then CEO Michael Babich knew about the
7 practice” of utilizing an illicit corporate credit card to pay for Subsys prescribers’
8 meals, alcoholic drinks, and entertainment, among other things.

9 354. As CEO of a pharmaceutical company, moreover, Babich was aware
10 of FDA regulations regarding the appropriate marketing and promotion of
11 pharmaceuticals and the prohibitions on promoting off-label uses and paying
12 monetary or in-kind kickbacks to induce doctors to write prescriptions. Likewise,
13 Babich was aware of and understood the limits of Subsys FDA-approved label,
14 including the fact that Subsys could *only* be prescribed to opioid tolerant adults
15 with BTCP, at an initial dosage of 100mcg, titrating thereafter only to the highest
16 dose necessary to ensure that the patient was comfortable, and was contraindicated
17 to treat any other condition, such as non-malignant pain (*e.g.*, back or neck pain)
18 and migraines.

19 355. Defendant Baker held the executive position of CFO throughout the
20 Class Period. In this capacity, Baker led and directed the Company’s investor
21 relations program, speaking directly to investors and analysts on the majority of the
22 Company’s earnings release calls and developing the Company’s public statements
23 on its financial performance. Moreover, given his extensive experience as CFO
24 and controller of publicly-traded companies, Baker was responsible for the
25 Company’s compliance with SEC regulations, including the filing of required
26 documents with the SEC. Moreover, Baker signed Insys SEC filings during the
27 Class Period. Given these responsibilities and his authority thereunder, Baker
28

1 knew about Subsys' sales and the Company's financial performance and business
2 operations, and had unlimited access to confidential and proprietary Company
3 information.

4 356. Defendant Burlakoff acted as Insys' Vice President of Sales
5 throughout the Class Period. As the Company's primary sales executive, Burlakoff
6 was responsible for the Company's sales force and had control over the
7 Company's marketing and sales of Subsys. By reason of this position, Burlakoff
8 also had access to confidential Company information.

9 357. Now indicted for his role in what the U.S. Government describes as a
10 nationwide criminal enterprise in violation of the RICO statute, Burlakoff has been
11 directly tied to the Company's improper marketing and sales practices and
12 nationwide insurance fraud. Burlakoff's specific acts in furtherance of this
13 enterprise are set forth in at least ¶¶13-16, 23, 33-34, 42, 103-110, 113, 124, 127-
14 128, 134-136, 138, 142, 144, 153, 157, 159, 161, 168-170, 172-173, 175-176, 187-
15 189, 192-197, 199-200, 202, 204, 213, 229, 238, 241 above. Burlakoff was also a
16 hands-on executive. In this regard, Burlakoff implemented aggressive sales
17 procedures and pressured sales representatives to engage in questionable practices
18 such as "searching through patient files" to identify candidates for impermissible
19 off-label Subsys use and incentivizing doctors with Speaker Program fees and
20 other kickbacks. Burlakoff also exercised direct control over the hiring of new
21 sales representatives, often hiring inexperienced women "based on their looks."
22 Under Burlakoff's administration, sales representatives were urged to become
23 "indispensable" to doctors by offering patient consultation on the proper usage of
24 Subsys and helping to bridge the gap between patients and insurance companies,
25 and were pressured to convince doctors to increase the dosage in their Subsys
26 prescriptions. As *SIRF* reported, Burlakoff "pushed the boundaries of what
27 defined pharmaceutical sales."
28

1 358. In his role as Vice President of Sales, moreover, Burlakoff, knew of
2 FDA regulations regarding the appropriate marketing and promotion of
3 pharmaceuticals and the prohibitions on promoting off-label uses and paying
4 monetary or in-kind kickbacks to induce doctors to write prescriptions. Likewise,
5 Burlakoff knew and understood the limits of Subsys FDA-approved label,
6 including the fact that Subsys could *only* be prescribed to opioid tolerant adults
7 with BTCP, at an initial dosage of 100mcg, titrating thereafter only to the highest
8 dose necessary to ensure that the patient was comfortable, and was contraindicated
9 to treat any other condition, such as non-malignant pain (*e.g.*, back or neck pain)
10 and migraines.

11 359. By virtue of their high-level executive positions, the Individual
12 Defendants directly participated and were involved in both the management and
13 day-to-day operations of the Company at the highest levels, and were privy to
14 confidential proprietary information concerning the Company's core operations,
15 including its only FDA-approved product, Subsys. Moreover, each of the
16 Individual Defendants was a hands-on executive, directly involved with the sale,
17 marketing, and/or financial reporting of Subsys.

18 360. The Individual Defendants controlled the contents of, and had
19 ultimate authority over, the Company's public statements during the Class Period.
20 Each Individual Defendant was provided with, or had access to, copies of the
21 documents or were aware of oral statements alleged herein to be false or
22 misleading prior to, or shortly after, their issuance, and had the ability and
23 opportunity to prevent their issuance or cause them to be corrected. Moreover, at
24 all relevant times, the Individual Defendants were involved in drafting, producing,
25 reviewing, and/or disseminating the statements at issue in this case, approved or
26 ratified these statements, and knew or were deliberately reckless in not knowing
27 that these statements were being issued regarding the Company. As a result, the
28

1 Individual Defendants had ultimate authority for the accuracy of Insys' corporate
2 statements, and are therefore responsible and liable for the damages caused by the
3 misrepresentations contained therein and/or the material facts omitted therefrom.

4 361. Thus, given their respective positions, hands-on control, and access to
5 material non-public information concerning the Company, each Individual
6 Defendant knew or was deliberately reckless in not knowing that the adverse facts
7 alleged herein had not been disclosed to, and were being concealed from the
8 public, and that the representations that were made were materially false,
9 misleading, and deceptively inaccurate.

10 **2. The Individual Defendants Knew or Were Deliberately**
11 **Reckless in Disregarding Information Concerning the**
12 **Company's Core Operations**

13 362. As discussed in Section IV.E.1, *supra*, the Individual Defendants were
14 Insys' most senior executives with direct control and supervision over its business,
15 operations, and public statements. By virtue of their executive positions and
16 hands-on management styles, the Individual Defendants knew nonpublic material
17 facts concerning Subsys, which was Insys' core business during the Class Period,
18 ***accounted for more than 98% of the Company's revenues***, and now has been
19 described by the U.S. Government as a nationwide criminal enterprise in violation
20 of the RICO statute.

21 363. As Defendants consistently acknowledged during the Class Period,
22 Subsys was the Company's "primary revenue driver" or "main driver of revenue."
23 In fact, any growth in Insys' revenues during the Class Period was attributed
24 "primarily to the increase in sales of Subsys." Subsys' net revenues accounted for
25 more than 98% of Insys total net revenue throughout the Class Period. *See* ¶97,
26 *supra*. These revenues grew by an average of 91% every quarter year-over-year,
27 from 2Q14 until 1Q16. As a result, the Company, including Defendant Kapoor,
28 monitored Subsys sales "***every single day, because Subsys is so important to us.***"

1 364. Throughout the Class Period, the Company's net revenues, profit
2 margins, and sustainability depended almost entirely upon sales of Subsys. By
3 virtue of their high-level positions and the fact that selling Subsys was the
4 Company's core operation during the Class Period, the Individual Defendants
5 knew or were deliberately reckless in not knowing that sales of Subsys depended
6 upon widespread off-label marketing, illegal kickback payments, and the related
7 scheme to fraudulently induce third party providers to agree to cover off-label
8 Subsys prescriptions, which emanated from the Company's national headquarters.

9 365. For example, as a result of their high-level positions at Insys and their
10 knowledge that Insys' success during the Class Period was dependent almost
11 entirely upon selling Subsys, Defendants knew at least the following facts:

- 12 • Subsys had a limited on-label patient population—opioid
13 tolerant adults already receiving around-the-clock opioid
14 medication for BTCP—who often did not live long after their
15 BTCP diagnosis;
- 16 • Given the limited on-label patient population, there was also a
17 limited number of prescribers who had patients to whom they
18 could prescribe Subsys for on-label indications; and
- 19 • Subsys was launched in a market that already had five other
20 TIRF drugs to treat BTCP, including a lower cost generic
21 version.

22 366. Accordingly, Defendants knew or were deliberately reckless in not
23 knowing that Subsys' consistent revenue growth resulted from marketing the drug
24 to doctors who did not treat cancer patients with BTCP and who did not specialize
25 in pain management. As a result, Defendants knew or were deliberately reckless in
26 not knowing that Subsys was widely prescribed to non-opioid tolerant patients who
27 were diagnosed with non-malignant forms of pain, including uses that were
28 expressly contradicted by Subsys' FDA-approved label (*e.g.*, migraines), and
therefore were at a heightened risk for adverse reactions, including fatal overdose.

1 367. Additionally, given Insys' virtually total dependence upon Subsys
2 sales, and Defendants' positions as the most senior Insys executives, Defendants
3 knew or were deliberately reckless in not knowing of at least the following facts:

- 4 • Despite the limited number of cancer patients receiving around-
5 the-clock opioid medication for BTCP, and by extension, the
6 limited number of health care professionals treating that
7 population, Insys increased its Subsys sales force to 250
8 persons;
- 9 • Insys' sales representatives, whose base salary was less than
10 \$20 per hour, and was at least 50% lower than the salaries that
11 other companies paid sales representatives whose
12 responsibilities included calling on oncologists and pain
13 specialists, could only equal or exceed the base salaries of the
14 sales representatives of other companies by earning massive
15 amounts in commissions from the sale of Subsys; and
- 16 • Sales commissions, which were necessary for Insys' sales
17 representatives to achieve a competitive salary, were based
18 upon the value of Subsys prescriptions written by the sales
19 representative's prescribers—the higher the number of single
20 use sprays and dosage prescribed, the higher the sales
21 representative's commission.

22 368. As a result, Defendants knew or were deliberately reckless in not
23 knowing that Insys' sales force was encouraged to and, in fact, promoted Subsys
24 for off-label use, including, in particular, (i) repeatedly calling on doctors who did
25 not have cancer patients and/or who were not experienced in prescribing Schedule
26 II opioids, like fentanyl; and (ii) pressuring doctors to prescribe initial doses of
27 Subsys that were higher than the FDA-mandated 100mcg initial Subsys dose and
28 titrating patients comfortable at lower doses to a higher dose of Subsys in order to
obtain increased commissions.

 369. Further, based upon their positions at Insys and their knowledge that
Subsys sales were critical to Insys' success during the Class Period, Defendants
knew or were deliberately reckless in not knowing of at least the following facts
concerning insurance coverage for Subsys:

- Approximately 80% of Subsys prescriptions were for off-label
use;

- 1 • Given Subsys' high cost, which generally ranged from \$1,000
2 to \$21,000 per month per prescription, patients needed to rely
3 on their insurance, including Medicare and Medicaid, to pay for
4 the drug;
- 5 • Based on their publicly-available formularies, plans, and
6 policies, however, a majority of third-party payers only
7 authorized insurance coverage for on-label Subsys
8 prescriptions; and
- 9 • In spite of the number of third-party payers who refused to
10 approve insurance coverage for off-label Subsys prescriptions,
11 Insys' IRC obtained approval from third-party payers for 80%
12 of Subsys prescriptions, which was nearly 3 times the approval
13 rate of its competitors.

14 370. Defendants, therefore, knew or were deliberately reckless in not
15 knowing that the Company's IRC was fraudulently inducing third-party payers to
16 approve off-label Subsys prescriptions in order to ensure that Subsys would
17 continue to report increasing revenues throughout the Class Period.

18 371. Defendants' positions and active involvement with the Company,
19 including meeting every weekday morning at 8:30 to discuss Subsys prescriptions,
20 and the importance of Subsys to Insys' net revenues, also made Defendants aware
21 of the Company's payment of kickbacks to prescribers of Subsys. This is
22 particularly true given the sheer size of Insys' payments to prescribers, including
23 those for meals, entertainment, and "speaker" fees, and the limited number of
24 prescribers who were candidates for such payments.

25 372. In 2014, for example, Insys' total payments to prescribers were *at*
26 *least double* those of its closest competitor and *over 55 times* higher than its
27 furthest competitor. Likewise, the average payment Insys made to prescribers was
28 *over five times* as much as its rivals. As Insys had only one revenue-generating
product, Subsys, all of these payments are attributable to the promotion of Subsys.
By contrast, each of Insys' competitors (referenced on the chart below), with the
exception of Galena, had multiple revenue-generating products, allowing for their
payments to be spread across various drugs. ///

1 373. The following chart illustrates the broad differences in Insys’
2 payments to prescribers versus its competitor’s payments, according to the Centers
3 for Medicare & Medicaid Services’ open payments data:

4 COMPANY 5 NAME	6 TOTAL 7 GENERAL 8 PAYMENTS	9 TOTAL 10 TRANSACTIONS	11 AVERAGE 12 PAYMENT 13 AMOUNT
14 Insys	15 \$7,390,871.97	16 10,007	17 \$738.57
18 Mallinckrodt LLC	19 \$3,478,009.45	20 49,354	21 \$70.47
22 Depomed, Inc.	23 \$3,041,458.99	24 23,908	25 \$127.22
26 Meda 27 Pharmaceuticals, 28 Inc.	\$1,573,413.35	22,678	\$69.38
Galena Biopharma, Inc.	\$132,372.44	893	\$148.23

Because these amounts were so significant, both relative to the Company’s revenues and profits and in comparison to competitors, they were well within the purview of Defendants.

374. Furthermore, in light of the restricted market for patients and, accordingly, prescribers of Subsys, Insys’ payments were concentrated on a select number of prescribers. Given the size of each payment, they were likely reflected on the Company’s books and records, and within Defendants’ knowledge. Thus, not only were Insys’ payments to prescribers substantial—far-exceeding those of its competitors—but they were made entirely for the Company’s sole product and provided to a limited number of prescribers.

375. Defendants accordingly knew or were deliberately reckless in not knowing that the Company was providing kickbacks to Subsys prescribers.

3. Defendants’ Contemporaneous Knowledge of Adverse Facts Contradicting Their Public Statements

376. Defendants were also aware of adverse facts that directly belied their public statements during the Class Period. For example, in addition to the facts alleged above in Section IV.B demonstrating his knowledge, Defendant Babich knew that the Company was providing illegal kickbacks to doctors through its

1 speaker programs because his wife, Natalie Levine, was an Insys sales
2 representative who called on Alfonso and attended many of the speakers events for
3 which Alfonso received her illegal kickback payments. In this regard, Babich
4 approved two years-worth of budgeted kickback payments to Alfonso. Defendant
5 Babich was also aware of the Company's practice of utilizing an off-the-books
6 credit card to pay for meals, drinks, and entertainment for doctors.

7 377. Similarly, in addition to the facts alleged above in Section IV.B
8 demonstrating his knowledge, Defendant Burlakoff was aware of the Company's
9 off-label marketing of Subsys because, among other things, he was the Company's
10 most senior sales executive who: (i) participated in Insys' efforts to target Subsys
11 promotion to doctors who neither treated cancer nor specialized in treating pain, let
12 alone BTCP; (ii) trained sales employees to market Subsys off-label; and (iii)
13 encouraged Insys sales employees to use the Company's "secret credit card" to
14 wine, dine, and otherwise entertain Subsys' highest prescribers.

15 378. The Babich and Burlakoff Indictment confirms that Defendants
16 Babich and Burlakoff had direct knowledge of, and were complicit in both paying
17 illegal kickbacks to prescribers and defrauding insurers, misconduct that the U.S.
18 Government now describes as a nationwide criminal enterprise in violation of the
19 RICO statute.

20 **4. Defendants' Repeated Denials of Wrongdoing**

21 379. When confronted with information relating to Insys' illegal off-label
22 marketing of Subsys, Defendants repeatedly denied any wrongdoing. Such denials
23 are further evidence of scienter. For example, as reported in an April 24, 2015
24 *SIRF* article, when asked about Insys' controversial marketing practices, Defendant
25 Burlakoff expressly denied that the Company promoted off-label use of Subsys,
26 stating: "[t]here is a very, very easy way to get fired on your first day at this
27 company, and that is to mention selling off-label. *We are only selling a*
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1 *breakthrough cancer pain drug. That's all we want to address with a doctor.*
2 *You don't run a unit at a company like this by cutting corners."* Defendant
3 Burlakoff further stated, "*I can say that no one at Insys wants to see anyone*
4 *taking [Subsys] for anything other than cancer pain."*

5 380. Similarly, the Company issued a statement on January 25, 2016
6 defending the IRC's practices as lawful despite recent contrary information: "*Insys*
7 *rejects the recent media reports' account of the Company's practices as*
8 *misleading and unreliable. . . . Insys requires its Patient Services Center*
9 *personnel undergo specific training on applicable laws and regulations and*
10 *continues to strive to comply with applicable laws and regulations through its*
11 *compliance policies and procedures."*

12 381. In denying that Insys engaged in any misconduct in promoting Subsys
13 and obtaining insurance coverage for Subsys prescriptions, Defendants knew or
14 were deliberately reckless in not knowing, that the vast majority of Subsys sales
15 were the byproduct of wrongdoing. Indeed, beyond the fact that Defendants
16 orchestrated and directed Insys' illegal nationwide kickback scheme and insurance
17 fraud, had Defendants done any due diligence prior to making these statements
18 regarding *how* Insys was able to: (i) grow Subsys net revenues by 1,800% in just
19 two years in a limited market which already had five more mature entrants
20 (including a lower cost generic TIRF); or (ii) obtain insurance coverage for 80% of
21 Subsys prescriptions when at least 80% of those prescriptions were for uncovered
22 off-label use, they would have known that Insys was marketing Subsys for off-
23 label use and fraudulently inducing third-party payers to cover off-label Subsys
24 prescriptions. Defendants knew or were deliberately reckless in not knowing such
25 information, particularly in light of the Subsys meetings that Defendant Kapoor
26 stated were conducted every weekday morning at 8:30 to discuss "*how many*
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1 *scripts we did yesterday. And we do that every single day, because Subsys is so*
2 *important to us.”*

3 **5. Defendant Babich’s Resignation**

4 382. In addition, the termination or resignation of Defendant Burlakoff in
5 July 2015, and Defendant Babich’s sudden resignation as the Company’s CEO,
6 just one day after the publication of the CNBC article on November 4, 2015
7 exposing information concerning the Company’s fraudulent practices, gives rise to
8 a strong inference of scienter. As later reported by *SIRF* on December 3, 2015,
9 Defendant Kapoor forced Defendant Babich to resign because he was “closest to
10 the issues that federal prosecutors were looking at[,] and . . . a change had to be
11 made should settlement talks become serious” gives rise to a strong inference of
12 scienter, particularly in light of Babich’s recent indictment for directing a
13 nationwide illegal kickback scheme and insurance fraud.

14 **6. Government Investigations, Criminal Charges, and Guilty**
15 **Pleas**

16 383. The announced regulatory investigations, criminal charges, and guilty
17 pleas in connection with Insys’ off-label marketing of Subsys and related kickback
18 payments are also probative of Defendants’ scienter. Specifically, on December 8,
19 2016, Defendants Babich and Burlakoff along with four other former Insys sales
20 and marketing executives were arrested and charged with nationwide violations of
21 the RICO statute as well as a nationwide conspiracy to commit various health care
22 frauds.

23 384. Insys also is subject to federal investigations pursuant to subpoenas
24 issued by the United States Attorney’s Office for the District of Massachusetts on
25 September 8, 2014. In addition, the Company received multiple civil investigative
26 demands from the Attorney Generals of Arizona, Massachusetts, Illinois, and
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1 Oregon, and the Chief Consumer Protection and Antitrust Division of New
2 Hampshire into its sales and marketing of Subsys and the conduct of Insys' IRC.

3 385. Moreover, Insys' illegal kickback scheme has resulted in Alfonso,
4 Perhacs, and Dr. Awerbuch separately pleading guilty, on June 23, 2015 and
5 February 18, 2016, and November 7, 2016, respectively, to a conspiracy to violate
6 the federal Anti-Kickback Statute. Finally, criminal charges have been brought
7 against numerous physicians and former sales representatives based upon their
8 involvement in Insys' off-label marketing of Subsys, including, among others, Dr.
9 Couch, Dr. Ruan, Dr. Awerbuch, Gurrieri, Pearlman, Serrano, and Roper.

10 **7. Insys' Retaliation Against Employees for Raising Concerns**
11 **Regarding the Company's Misconduct**

12 386. The Company's retaliation against employees for reporting its illegal
13 conduct further strengthens the inference of scienter. For example, in its Code of
14 Business Conduct and Ethics, Insys expressly forbids its employees from
15 "communicat[ing] with the press on behalf of the Company" or "provid[ing] any
16 information to the media about us off the record, for background, confidentially or
17 secretly, including, without limitation, by way of postings on internet websites,
18 chat rooms or 'blogs.'"

19 387. Moreover, numerous former Insys employees providing detailed
20 accounts of the Company's fraudulent practices in the *SIRF* articles elected to be
21 identified by pseudonyms to protect their identities.

22 388. Indeed, when one former Insys sales representative, Michael Ferraro
23 ("Ferraro"), attempted to raise his concerns about the Company's unlawful sales
24 practices with his supervisor and Insys' HR Director and Director of Compliance,
25 he was immediately terminated, purportedly for having an outside business venture
26 with a compounding pharmacy, a relationship which he repeatedly disclosed to at
27 least Defendants Babich and Burlakoff during the course of his employment, after
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1 which disclosure he experienced no changes in his employment status. Shortly
2 after his termination, he was sued by the Company “to the fullest extent of the law”
3 for the alleged breach of his employment contract.

4 389. Specifically, as alleged in support of his May 28, 2015 counterclaims
5 against Insys in the matter captioned, *Insys Therapeutics, Inc. v. Ferraro*, 7:15-cv-
6 03613 (S.D.N.Y.), Ferraro, who was employed with Insys between August 2014
7 and April 2015, “witnessed and observed statements and actions by [Insys’]
8 leadership and representatives, which [he] strongly believed were non-compliant
9 with the laws and guidelines governing [Insys] and the pharmaceutical industry”
10 during the Insys National Sales Meeting, which took place between March 10 and
11 March 14, 2015,

12 390. The next month, on April 17, 2015, Ferraro had a lunch meeting at a
13 physician’s office with his new District Manager, Michelle Breitenbach
14 (“Breitenbach”). During his lunch meeting with Breitenbach, Ferraro “felt very
15 uncomfortable because she was instructing [him] to take certain actions in regard
16 to selling on behalf of [Insys] that [he] strongly believed were non-compliant with
17 the laws and guidelines governing [Insys] and the pharmaceutical industry.”

18 391. Following his conversation with Breitenbach, Ferraro sent a “Letter of
19 Concern” to Breitenbach later that day “expressing [his] valid concerns and strong
20 beliefs of the conflicts between [Insys’] Sales Model and processes, and the laws
21 and guidelines governing [Insys] and the pharmaceutical industry, including the
22 actions that [she] was expecting and requesting that [he] participate in.”

23 392. On that same day, April 17, 2015, Ferraro received a phone call from
24 Insys’ HR Director and Director of Compliance to discuss his “Letter of Concern.”
25 During that conversation, Ferraro provided “additional details and examples
26 regarding [his] valid concerns and strong beliefs about [Insys’] non-compliance
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1 with the laws and guidelines governing [Insys] and the pharmaceutical industry,
2 and [his] reluctance to participate in [Insys'] non-compliant actions.”

3 393. Rather than address Ferraro’s concerns, however, on April 23, 2015,
4 Insys’ HR Director and General Counsel called to inform him that he was being
5 terminated from the Company, citing the previously (and repeatedly) disclosed
6 business relationship with the compounding pharmacy as the basis for his
7 termination. Insys’ General Counsel further told him that Insys “would sue [him]
8 to the fullest of the law for breach of employment contract”—a threat the Company
9 acted on by filing suit for alleged breach of contract and fiduciary duties on May 8,
10 2015. Approximately six weeks after Ferraro filed his counterclaims, however, the
11 parties filed a stipulation of settlement with the Court, dismissing the action with
12 prejudice.

13 **8. Defendants’ Incentive Compensation**

14 394. The fact that the incentive compensation of Defendants Baker and
15 Babich was tied to the Company’s financial performance, which was based almost
16 entirely upon Subsys sales, is further indicia of scienter.

17 395. For example, in 2014, as a result of the Company’s strong revenues
18 from Subsys, Defendant Babich received a cash bonus of \$500,000, which was
19 125% of his base salary, and Defendant Baker received a cash bonus of \$130,000,
20 which was 50% of his base salary.

21 396. The following year, however, the Company expressly acknowledged
22 in its annual proxy that, despite strong financial results for the year, Insys was
23 reducing Defendant Baker’s cash bonus to 95% of his bonus potential of 50% of
24 his base salary because, among other reasons, “*the Company needed to improve in*
25 *2016 in instilling a culture of accountability in all areas including . . . regulatory*
26 *and compliance matters.*”

F. Loss Causation

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397. As a direct result of Defendants' materially false and misleading statements, omissions of material facts, and fraudulent course of conduct, as alleged above in Sections IV.B-D, Insys' publicly traded common stock traded at artificially inflated prices during the Class Period. Specifically, Defendants' material misrepresentations and omissions regarding Subsys, including those statements and omissions identified above in Section IV.C, caused and/or maintained the artificial inflation in Insys common stock price during the Class Period. Relying on the integrity of the market price for Insys common stock and public information relating to Insys, Lead Plaintiff and other Class members purchased or otherwise acquired Insys common stock at prices that incorporated and reflected Defendants' misrepresentations and omissions of material fact alleged herein. As a result of their purchases of Insys common stock during the Class Period at artificially inflated prices, and the removal of that artificial inflation upon the partial disclosures set forth in ¶¶316-321, 323-328, 330, 332-336, 343-345, *supra*, Lead Plaintiff and other Class members suffered economic losses, *i.e.*, damages under the federal securities laws.

398. The artificial inflation in Insys common stock price that Defendants' misrepresentations and omissions of material fact created and/or maintained was gradually removed through a series of partial disclosures of information to the market, which corrected Defendants' misrepresentations and omissions and/or caused the foreseeable risks concealed by Defendants' fraud to materialize. As alleged above in ¶¶316-321, 323-328, 330, 332-336, 343-345, these revelations occurred through public disclosures of information on the following ten days: November 27, 2014, April 24, 2015, May 20, 2015, June 23 and 24, 2015, November 4, 2015, November 5, 2015, December 3, 2015, January 25, 2016, April 11, 2016, and December 8, 2016. The timing and magnitude of the declines in the

1 price of Insys common stock in response to the new Company-specific news
2 provided to investors on each of the foregoing days, as detailed herein, negate any
3 inference that the losses suffered by Lead Plaintiff and other Class members were
4 caused by changed market conditions or other macroeconomic factors unrelated to
5 Defendants' fraud.

6 399. As set forth in ¶316, on November 27, 2014, the *New York Times*
7 published an article identifying certain doctors who had received some of the
8 largest illegal kickback payments from Insys for purportedly educating other
9 doctors about Subsys through Insys' speaker program. This article revealed that
10 the doctors in question were under scrutiny for, among other things, over-
11 prescribing opioids and defrauding Medicare and other insurers. The article
12 further described additional in-kind benefits that the Company provided to the top
13 prescribers of Subsys – a practice that investors would later learn was an
14 unabashed illegal kickback scheme.

15 400. The disclosure of the questionable ethics of certain key Subsys
16 prescribers, and the benefits they received from Insys for prescribing Subsys, were
17 foreseeable consequences of, and within the zone of risk concealed by,
18 Defendants' misrepresentations and omissions of material facts concerning the
19 Company's marketing and promotion of Subsys alleged herein. Moreover, the
20 November 27, 2014 disclosure revealed new information that was previously
21 concealed by Defendants' misstatements, omissions, and fraudulent course of
22 conduct. This disclosure partially (but incompletely) revealed some of the relevant
23 truth concealed and/or obscured by Defendants' prior misstatements and omissions
24 concerning Subsys. Thus, the November 27, 2014 disclosure also partially (but
25 incompletely) revealed the materialization of the known foreseeable risks
26 surrounding Insys' illegal promotion of Subsys for off-label use, illegal kickback
27 payments, and the related efforts to defraud third-party payers into approving
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1 insurance coverage for off-label Subsys prescriptions that Defendants deliberately
2 and/or recklessly concealed from investors.

3 401. As a direct and proximate result of these partial corrective disclosures
4 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
5 price of Insys common stock declined over two trading days by \$3.44 per share, or
6 8.58% from a closing price of \$40.09 on November 26, 2014 to a closing price of
7 \$36.65 on December 1, 2014 on heavy trading volume, thereby removing a portion
8 of the artificial inflation in the price of Insys common stock.

9 402. Despite this partial disclosure relating to Subsys, Insys' stock price
10 remained artificially inflated due to Defendants' failure to fully disclose their
11 illegal off-label promotion of Insys, illegal kickback payments, and related effort to
12 lie to third-party payers to secure insurance coverage for off-label Subsys
13 prescriptions.

14 403. As set forth in ¶¶317-318, a second partial disclosure occurred on
15 April 24, 2015. On that day, *SIRF* published an article disclosing the scope of the
16 investigation of the United States Attorney for the District of Massachusetts into
17 Insys' promotion of Subsys and identifying kickbacks received by two of Insys'
18 largest Subsys prescribers, Drs. Ruan and Couch, each of whom would be indicted
19 for their misconduct a month later.

20 404. The widening scope of the investigation by the United States Attorney
21 for the District of Massachusetts and the kickbacks received by top Subsys
22 prescribers confirmed in the April 24, 2015 *SIRF* article were foreseeable
23 consequences of, and within the zone of risk concealed by, Defendants'
24 misrepresentations and omissions of material facts concerning their illegal
25 promotion of Subsys for off-label use, kickback payments, and the related efforts
26 to lie to third-party payers to obtain insurance coverage for off-label Subsys
27 prescriptions alleged herein. Moreover, the April 24, 2015 *SIRF* article revealed
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1 new information that was previously concealed by Defendants' misstatements,
2 omissions and fraudulent course of conduct. These disclosures partially (but
3 incompletely) revealed some of the relevant truth concealed and/or obscured by
4 Defendants' prior misstatements and omissions concerning Subsys, including the
5 amount and identity of some of the recipients of monetary and in-kind kickbacks
6 from the Company in exchange for increased Subsys prescriptions. Thus, the April
7 24, 2015 *SIRF* article also partially (but incompletely) revealed the materialization
8 of the known foreseeable risks surrounding Defendants' illegal promotion of
9 Subsys for off-label use, illegal kickback payments, and the related efforts to
10 defraud third-party payers into approving insurance coverage for off-label Subsys
11 prescriptions that Defendants deliberately and/or recklessly concealed from
12 investors.

13 405. As a direct and proximate result of these partial corrective disclosures
14 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
15 price of Insys common stock declined by \$6.00 per share, or 9.61% from a closing
16 price of \$62.42 on April 24, 2015 to a closing price of \$56.42 on April 27, 2015,
17 the first trading day after the article was published, on heavy trading volume,
18 thereby removing a portion of the artificial inflation in the price of Insys common
19 stock.

20 406. Despite this partial disclosure relating to Subsys, Insys common stock
21 price remained artificially inflated due to Defendants' failure to fully disclose their
22 illegal off-label promotion of Insys, illegal kickback payments, and related effort
23 to lie to third-party payers to secure insurance coverage for off-label Subsys
24 prescriptions.

25 407. As set forth in ¶¶319-320, a third partial disclosure occurred on May
26 20, 2015. On that day, the United States Attorney for the Southern District of
27 Alabama announced that Drs. Ruan and Couch, two of Insys' top Subsys
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1 prescribers and recipients of monetary and in-kind kickbacks, had been arrested
2 and charged with conspiracy to distribute controlled substances, including Subsys.

3 408. The indictment of Drs. Ruan and Couch was a foreseeable
4 consequence of, and within the zone of risk concealed by, Defendants'
5 misrepresentations and omissions of material facts concerning their illegal
6 promotion of Subsys for off-label use, illegal kickback payments, and the related
7 efforts to lie to third-party payers to obtain insurance coverage for off-label Subsys
8 prescriptions alleged herein. Moreover, the May 20, 2015 disclosure revealed new
9 information that was previously concealed by Defendants' misstatements,
10 omissions and fraudulent course of conduct. These disclosures partially (but
11 incompletely) revealed some of the relevant truth concealed and/or obscured by
12 Defendants' prior misstatements and omissions concerning Subsys. Thus, the May
13 20, 2015 disclosure also partially (but incompletely) revealed the materialization of
14 the known foreseeable risks surrounding Defendants' illegal promotion of Subsys
15 off-label, illegal kickback payments, and the related efforts to defraud third-party
16 payers into approving insurance coverage for off-label Subsys prescriptions that
17 Defendants deliberately and/or recklessly concealed from investors.

18 409. As a direct and proximate result of these partial corrective disclosures
19 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
20 price of Insys common stock fell by \$2.65 per share, or 4.43%, from a closing
21 price of \$59.77 on May 19, 2015 to a closing price of \$57.12 on May 20, 2015, on
22 heavy trading volume, thereby removing a portion of the artificial inflation in the
23 price of Insys common stock.

24 410. Despite this partial disclosure relating to Subsys and the resulting
25 stock price decline, Insys common stock price remained artificially inflated due to
26 Defendants' failure to fully disclose their illegal off-label promotion of Insys and
27

1 related efforts to lie to third-party payers to secure insurance coverage for off-label
2 Subsys prescriptions.

3 411. As set forth in ¶321, a fourth partial disclosure occurred on June 23
4 and 24, 2015. On June 23, 2015, the United States District Court for the District of
5 Connecticut entered on its public docket the Information and Plea Agreement of
6 Heather Alfonso, a nurse accused of accepting \$83,000 in kickbacks from Insys in
7 exchange for prescribing Subsys to Medicare patients, many of whom did not have
8 cancer or BTCP. On June 24, 2015, the *New York Times* published an article
9 entitled, “Nurse Pleads Guilty to Taking Kickbacks from Drug Maker.” Among
10 other things, this article noted that Alfonso’s guilty plea was a signal that
11 prosecutors were intensifying their investigation of the Company’s marketing
12 practices.

13 412. Alfonso’s information and guilty plea was a foreseeable consequence
14 of, and within the zone of risk concealed by, Defendants’ misrepresentations and
15 omissions of material facts concerning their illegal promotion of Subsys for off-
16 label use, illegal kickback payments, and the related efforts to lie to third-party
17 payers to obtain insurance coverage for off-label Subsys prescriptions alleged
18 herein. Moreover, the June 23 and 24, 2015 disclosures revealed new information
19 that was previously concealed by Defendants’ misstatements, omissions and
20 fraudulent course of conduct. These disclosures partially (but incompletely)
21 revealed some of the relevant truth concealed and/or obscured by Defendants’ prior
22 misstatements and omissions concerning Subsys. Thus, the June 23 and 24, 2015
23 disclosures also partially (but incompletely) revealed the materialization of the
24 known foreseeable risks surrounding Defendants’ illegal promotion of Subsys off-
25 label, illegal kickback payments, and the related efforts to defraud third-party
26 payers into approving insurance coverage for off-label Subsys prescriptions that
27 Defendants deliberately and/or recklessly concealed from investors.

1 413. As a direct and proximate result of these partial corrective disclosures
2 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
3 price of Insys common stock fell by \$5.17 per share, or 12.64%, over two trading
4 days, from a closing price of \$40.91 on June 23, 2015, to a closing price of \$35.74
5 on June 25, 2015, on heavy trading volume, thereby partially removing the
6 artificial inflation in the price of Insys common stock.

7 414. Despite this partial disclosure relating to Subsys and the resulting
8 stock price decline, Insys common stock price remained artificially inflated due to
9 Defendants' failure to fully disclose their illegal off-label promotion of Insys,
10 illegal kickback payments, and related efforts to lie to third-party payers to secure
11 insurance coverage for off-label Subsys prescriptions.

12 415. As set forth in ¶¶323-324, a fifth partial disclosure occurred on
13 November 4, 2015. On that day, *CNBC* published an article regarding Subsys
14 which disclosed, in relevant part, that "an officer from the Inspector General's
15 Office of the United States Department of Health and Human Services placed
16 Subsys on a list of 'new diversion drugs of concern,'" where diversion is defined
17 as "a form of medical fraud that can include doctors prescribing drugs for
18 unintended uses. The *CNBC* article further revealed that Insys' achieved increased
19 sales of Subsys based upon the work of the Company's IRC.

20 416. The designation of Subsys as a "new diversion drug of concern" was a
21 foreseeable consequence of, and within the zone of risk concealed by, Defendants'
22 misrepresentations and omissions of material facts concerning their illegal
23 promotion of Subsys for off-label use, illegal kickback payments, and the related
24 efforts to lie to third-party payers to obtain insurance coverage for off-label Subsys
25 prescriptions alleged herein. Moreover, the November 4, 2015 *CNBC* article
26 revealed new information that was previously concealed by Defendants'
27 misstatements, omissions and fraudulent course of conduct. These disclosures
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1 partially (but incompletely) revealed some of the relevant truth concealed and/or
2 obscured by Defendants' prior misstatements and omissions surrounding Subsys.
3 Thus, the November 4, 2015 CNBC article also partially (but incompletely)
4 revealed the materialization of the known foreseeable risks surrounding
5 Defendants' illegal promotion of Subsys for off-label use, illegal kickback
6 payments, and the related efforts to defraud third-party payers into approving
7 insurance coverage for off-label Subsys prescriptions that Defendants deliberately
8 and/or recklessly concealed from investors.

9 417. As a direct and proximate result of these partial corrective disclosures
10 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
11 price of Insys common stock declined by \$2.45 per share, or 8.50%, from a closing
12 price of \$28.83 on November 3, 2015 to a closing price of \$26.38 on November 4,
13 2015, on heavy trading volume, thereby removing a portion of the artificial
14 inflation in the price of Insys common stock.

15 418. Despite this partial disclosure relating to Subsys, Insys common stock
16 price remained artificially inflated due to Defendants' failure to fully disclose their
17 illegal off-label promotion of Insys, illegal kickback payments, and related effort to
18 lie to third-party payers to secure insurance coverage for off-label Subsys
19 prescriptions.

20 419. As set forth in ¶325, a sixth partial disclosure occurred on the
21 following day, November 5, 2015. On that day, Insys announced the sudden
22 resignation of Defendant Babich from the Company.

23 420. Defendant Babich's surprising resignation was a foreseeable
24 consequence of, and within the zone of risk concealed by, Defendants'
25 misrepresentations and omissions of material facts concerning their illegal
26 promotion of Subsys for off-label use, illegal kickback payments, and the related
27 efforts to lie to third-party payers to obtain insurance coverage for off-label Subsys
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1 prescriptions alleged herein. Moreover, the November 5, 2015 disclosure revealed
2 new information that was previously concealed by Defendants' misstatements,
3 omissions and fraudulent course of conduct. This disclosure partially (but
4 incompletely) revealed some of the relevant truth concealed and/or obscured by
5 Defendants' prior misstatements and omissions surrounding Subsys. Thus, the
6 November 5, 2015 disclosure also partially (but incompletely) revealed the
7 materialization of the known foreseeable risks surrounding Defendants' illegal
8 promotion of Subsys off-label, illegal kickback payments, and the related efforts to
9 defraud third-party payers into approving insurance coverage for off-label Subsys
10 prescriptions that Defendants deliberately and/or recklessly concealed from
11 investors.

12 421. As a direct and proximate result of these partial corrective disclosures
13 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
14 price of Insys common stock declined by \$0.95 per share, or 3.60%, from a closing
15 price of \$26.38 on November 4, 2015 to a closing price of \$25.43 on November 5,
16 2015, on heavy trading volume, thereby removing a portion of the artificial
17 inflation in the price of Insys common stock.

18 422. Despite this partial disclosure relating to Subsys, Insys common stock
19 price remained artificially inflated due to Defendants' failure to fully disclose their
20 illegal off-label promotion of Insys, illegal kickback payments, and related effort to
21 lie to third-party payers to secure insurance coverage for off-label Subsys
22 prescriptions.

23 423. As set forth in ¶¶326-327, a seventh partial disclosure occurred on
24 December 3, 2015. On that day, *SIRF* published an article reporting that: (i)
25 Defendant Babich had been forced out of his position as CEO of the Company in
26 November 2015 as a result of the various government investigations into Insys'
27 sales practices, illegal kickback payments; and (ii) based on firsthand accounts
28

1 from former Insys employees, the IRC had changed its tactics in order to continue
2 to evade law enforcement and mislead third-party payers. Analysts issued reports
3 relating to this disclosure as alleged above in ¶328.

4 424. The disclosure of both the reason for Defendant Babich's sudden
5 resignation and the illegal activities of the IRC during the Class Period was a
6 foreseeable consequence of, and within the zone of risk concealed by, Defendants'
7 misrepresentations and omissions of material facts concerning their illegal
8 promotion of Subsys for off-label use, illegal kickback payments, and the related
9 efforts to lie to third-party payers to obtain insurance coverage for off-label Subsys
10 prescriptions alleged herein. Moreover, the December 3, 2015 *SIRF* article
11 revealed new information that was previously concealed by Defendants'
12 misstatements, omissions and fraudulent course of conduct. These disclosures
13 partially (but incompletely) revealed some of the relevant truth concealed and/or
14 obscured by Defendants' prior misstatements and omissions concerning Subsys,
15 including the IRC's efforts to defraud third-party payers into approving Subsys
16 prescriptions. Thus, the December 3, 2015 *SIRF* article also partially (but
17 incompletely) revealed the materialization of the known foreseeable risks
18 surrounding Defendants' illegal promotion of Subsys off-label, illegal kickback
19 payments, and the related efforts to defraud third-party payers into approving
20 insurance coverage for off-label Subsys prescriptions that Defendants deliberately
21 and/or recklessly concealed from investors.

22 425. As a direct and proximate result of these partial corrective disclosures
23 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
24 price of Insys common stock declined by \$5.93 per share, or 18.54%, from a
25 closing price of \$31.99 on December 2, 2015 to a closing price of \$26.06 on
26 December 3, 2015 on heavy trading volume, thereby removing a portion of the
27 artificial inflation in the price of Insys common stock.

1 426. Despite this partial disclosure relating to Subsys, Insys common stock
2 price remained artificially inflated due to Defendants’ failure to fully disclose their
3 illegal off-label promotion of Insys, illegal kickback payments, and related effort to
4 lie to third-party payers to secure insurance coverage for off-label Subsys
5 prescriptions.

6 427. As set forth in ¶330, an eighth partial disclosure occurred on January
7 25, 2016. On that day, *SIRF* published an article providing additional new material
8 information regarding the breadth of the IRC’s efforts to mislead third-party payers
9 into covering the costs of Subsys prescriptions, as well as the difficulties the IRC
10 was then experiencing in obtaining PBM approvals of off-label Subsys
11 prescriptions because PBMs had apparently become attuned to Insys’ efforts to
12 deflect their questions with prepared evasive answers, such as those contained
13 within “the spiel.” The article further noted that the IRC’s decreased effectiveness
14 in misleading third-party payers was beginning to decrease Subsys prescriptions.

15 428. The additional material information revealed in the January 25, 2016
16 *SIRF* article regarding the IRC’s Class Period activities (including internal
17 documents and an audio recording of an IRC meeting), as well as the disclosure of
18 reduced PBM approval rates due to heightened scrutiny by PBMs and government
19 investigators, was a foreseeable consequence of, and within the zone of risk
20 concealed by, Defendants’ misrepresentations and omissions of their illegal
21 promotion of Subsys for off-label use, illegal kickback payments, and the related
22 efforts to lie to third-party payers to obtain insurance coverage for off-label Subsys
23 prescriptions alleged herein. Moreover, the January 25, 2016 *SIRF* article revealed
24 new information that was previously concealed by Defendants’ misstatements,
25 omissions and fraudulent course of conduct.

26 429. These disclosures partially (but incompletely) revealed some of the
27 relevant truth concealed and/or obscured by Defendants’ prior misstatements and
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1 omissions concerning Subsys, including the IRC's efforts to defraud third-party
2 payers into approving Subsys prescriptions. Thus, the January 25, 2016 *SIRF*
3 article also partially (but incompletely) revealed the materialization of the known
4 foreseeable risks surrounding Defendants' illegal promotion of Subsys off-label,
5 illegal kickback payments, and the related efforts to defraud third-party payers into
6 approving insurance coverage for off-label Subsys prescriptions that Defendants
7 deliberately and/or recklessly concealed from investors.

8 430. As a direct and proximate result of these partial corrective disclosures
9 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
10 price of Insys common stock declined by \$1.07 per share, or 4.74%, from a closing
11 price of \$22.65 on January 22, 2016 to a closing price of \$21.58 on January 25,
12 2016, on heavy trading volume, thereby removing a portion of the artificial
13 inflation in the price of Insys common stock.

14 431. Despite this partial disclosure relating to Subsys, Insys common stock
15 price remained artificially inflated due to Defendants' failure to fully disclose their
16 illegal off-label promotion of Insys, illegal kickback payments, and related effort to
17 lie to third-party payers to secure insurance coverage for off-label Subsys
18 prescriptions.

19 432. As set forth in ¶332, a ninth partial disclosure occurred on April 11,
20 2016. On that day, Insys announced that Subsys net revenues for 1Q16 would be
21 \$61 million to \$62 million – revenues significantly lower than consensus
22 expectations of \$86 million for the same period. Analysts issued reports
23 expressing surprise in reaction to this disclosure as alleged above in ¶¶333-336.

24 433. Materially lower Subsys net revenues were a foreseeable consequence
25 of, and within the zone of risk concealed by, Defendants' misrepresentations and
26 omissions of material facts concerning their illegal promotion of Subsys for off-
27 label use, illegal kickback payments, and the related efforts to lie to third-party
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1 payers to obtain insurance coverage for off-label Subsys prescriptions alleged
2 herein. Moreover, the April 11, 2016 disclosure revealed new information that was
3 previously concealed by Defendants' misstatements, omissions and fraudulent
4 course of conduct. These disclosures revealed the remaining undisclosed relevant
5 truth concealed and/or obscured by Defendants' prior misstatements and omissions
6 surrounding Subsys, including the negative impact on Company revenues that
7 resulted from the IRC's decreased ability to obtain third-party payer approval for
8 Subsys prescriptions. The substantially decreased Subsys sales revenues that the
9 Company announced on April 11, 2016 constituted a materialization of the known
10 foreseeable risks surrounding Defendants' illegal promotion of Subsys for off-label
11 use, illegal kickback payments, and the related efforts to defraud third-party payers
12 into approving insurance coverage for off-label Subsys prescriptions that
13 Defendants deliberately and/or recklessly concealed from investors.

14 434. As a direct and proximate result of these corrective disclosures and/or
15 materializations of foreseeable risks concealed by Defendants' fraud, the price of
16 Insys common stock declined by 19.37%, from a closing price of \$17.66 on April
17 8, 2016 to a closing price of \$14.24 on April 11, 2016 on heavy trading volume,
18 thereby removing a portion of the artificial inflation in the price of Insys common
19 stock.

20 435. As set forth in ¶343, a tenth and final partial disclosure occurred on
21 December 8, 2016 when the U.S. Government announced the arrests of and
22 criminal charges, including nationwide racketeering, against Babich, Burlakoff,
23 Gurry, Simon, Lee, and Rowan. The new information, and supporting internal
24 Insys documents obtained in the U.S. Government's investigation, revealed to
25 investors on December 8, 2016 is alleged in detail herein. In sum, investors
26 learned that Insys was engaged in a multi-year nationwide criminal scheme,
27 orchestrated and executed by the Company's highest-ranking executives, to
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1 increase revenues from selling Subsys, the source of at least 98% of Insys' Class
2 Period Revenues, through the very illegal payment of kickbacks to prescribers and
3 insurance fraud alleged herein.

4 436. As a direct and proximate result of these partial corrective disclosures
5 and/or materializations of foreseeable risks concealed by Defendants' fraud, the
6 price of Insys common stock declined by \$1.27 per share, or 11.87%, from a
7 closing price of \$10.70 per share on December 7, 2016 to a closing price of \$9.43
8 per share on December 8, 2016 on heavy trading volume, thereby removing the
9 remaining portion of the artificial inflation in the price of Insys common stock.

10 437. The material misrepresentations and omissions detailed in Section
11 IV.C above had the effect of creating and/or maintaining artificially inflated prices
12 for Insys common stock throughout the Class Period. Lead Plaintiff and other
13 Class members purchased or otherwise acquired Insys common stock at prices that
14 were artificially inflated by Defendants' misrepresentations and omissions of
15 material fact alleged herein. Those misrepresentations and omissions of material
16 fact that were not followed by an upward movement in the price of Insys common
17 stock served to maintain the price of Insys common stock at an artificially inflated
18 level.

19 438. Defendants' wrongful conduct, as alleged herein, directly and
20 proximately caused the damages suffered by Lead Plaintiff and other Class
21 members. Throughout the Class Period, Defendants made materially false and
22 misleading statements and omissions of material fact concerning the reasons for
23 the Company's consistently increasing revenues from Subsys, which included (i) a
24 deliberate and sustained campaign, including illegal kickback payments to current
25 and prospective Subsys prescribers, to promote Subsys for prescription to and use
26 by patients other than those suffering from BTCP – the only FDA approved patient
27 population for the drug; and (ii) the IRC's deliberate falsification of patient
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1 diagnoses designed to mislead medical insurers, including Medicare, into
2 approving payment for the drug to treat BTCP, even though only a small
3 percentage of those for whom the drug was prescribed actually suffered from such
4 pain. The risk of decreased sales of Subsys that gradually materialized through the
5 partial disclosures of information alleged in this Section fully materialized with the
6 Company's April 11, 2016 announcement of significantly decreased Subsys sales
7 for 1Q16 – a risk that was both foreseeable and within the zone of risk created by
8 Defendants' material misrepresentations and omissions that concealed Insys'
9 widespread off-label marketing campaign, illegal kickback payments, and the
10 related fraudulent activity within the Company's IRC.

11 439. Had Defendants disclosed complete, accurate, and truthful
12 information concerning these matters during the Class Period, Lead Plaintiff and
13 other Class members would not have purchased or otherwise acquired Insys
14 common stock, or would not have purchased or otherwise acquired their shares of
15 Insys common stock at the artificially inflated prices that they paid.

16 440. It was entirely foreseeable to Defendants that misrepresenting and
17 concealing these material facts from the public would artificially inflate the price
18 of Insys common stock during the Class Period. It was also foreseeable that the
19 ultimate disclosure of this information, and/or the materialization of the risks
20 concealed by Defendants' material misstatements and omissions, would cause the
21 price of Insys common stock to decline as the inflation caused by Defendants'
22 earlier materially false and misleading statements and omissions of material fact
23 was removed from the stock price.

24 441. Accordingly, Defendants' conduct, as alleged herein, proximately
25 caused foreseeable losses to Lead Plaintiff and to the other members of the Class
26 who purchased or otherwise acquired Insys common stock during the Class Period.
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1 442. The economic loss, *i.e.*, damages, suffered by Lead Plaintiff and other
2 Class members directly resulted from Defendants' materially false and misleading
3 statements and omissions of material fact alleged herein, which artificially inflated
4 the price of the Company's common stock, and the subsequent significant decline
5 in the value of Company's common stock when the truth was revealed and/or the
6 risks previously concealed by Defendants' material misstatements and omissions
7 materialized.

8 443. As a result of the previously misrepresented and concealed material
9 information and risks that Defendants disclosed or that were otherwise revealed on
10 the dates alleged above in this Section, and the corresponding substantial declines
11 in the price of Insys common stock when the market absorbed this information,
12 Lead Plaintiff and other Class members have suffered economic loss.

13 **G. Class Members are Entitled to a Presumption of Reliance**

14 444. Lead Plaintiff and other members of the Class are entitled to rely upon
15 the presumption of reliance established by the fraud-on-the-market doctrine in that,
16 among other things:

17 (a) Insys common stock traded in an efficient market;

18 (b) Defendants made public misrepresentations and/or failed to
19 disclose material facts during the Class Period;

20 (c) the facts that Defendants misrepresented and/or failed to
21 disclose were material;

22 (e) the material misrepresentations and/or omissions alleged herein
23 would tend to induce a reasonable investor to misjudge the value of Insys
24 common stock; and

25 (f) without knowledge of the misrepresented and/or omitted facts,
26 Lead Plaintiff and other members of the Class purchased or otherwise
27 acquired Insys common stock between the time that Defendants made
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1 material misrepresentations and/or omitted material facts and the time that
2 the concealed risks materialized or the true facts were disclosed.

3 445. At all relevant times, the market for Insys common stock was open
4 and efficient for the following reasons, among others:

5 (a) as a registered and regulated issuer of securities, Insys filed
6 periodic public reports with the SEC, in addition to the Company's frequent
7 voluntary dissemination of information;

8 (b) Insys regularly communicated with public investors via
9 established market communication mechanisms, including through regular
10 disseminations of press releases on the national circuits of major newswire
11 services and through other wide-ranging public disclosures, such as
12 communications with the financial press, securities analysts, and other
13 similar reporting services;

14 (c) Insys was followed by numerous securities analysts, including,
15 among others, Piper Jaffray, Jefferies, and RBC Capital Markets, who wrote
16 reports that were distributed to the sales force and certain customers of their
17 respective brokerage firms and that were publicly available and entered the
18 public marketplace; and

19 (d) Insys common stock met the requirements for listing, and was
20 listed and actively traded on highly efficient markets, including the
21 NASDAQ, where the Company's common stock traded and trades under the
22 ticker symbol "INSY."

23 446. As a result of the foregoing, the market for Insys common stock
24 promptly digested current information regarding Insys from all publicly available
25 sources, and the prices of Insys common stock reflected such information.

26 447. Based upon the materially false and misleading statements and
27 omissions of material fact alleged herein, Insys common stock traded at artificially
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1 inflated prices during the Class Period. Lead Plaintiff and the other members of
2 the Class purchased Insys common stock relying upon the integrity of the market
3 price of Insys common stock and other market information relating to Insys.

4 448. Under these circumstances, all purchasers of Insys common stock
5 during the Class Period suffered similar injuries through their purchases at
6 artificially inflated prices, and a presumption of reliance applies.

7 449. Further, at all relevant times, Lead Plaintiff and other members of the
8 Class reasonably relied upon Defendants to disclose material information as
9 required by law and in the Company's SEC filings. Lead Plaintiff and the other
10 members of the Class would not have purchased or otherwise acquired Insys
11 common stock at artificially inflated prices if Defendants had disclosed all material
12 information as required. Thus, to the extent that Defendants concealed or
13 improperly failed to disclose material facts with regard to the Company and its
14 business, Lead Plaintiff is entitled to a presumption of reliance in accordance with
15 *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

16 **H. The Statutory Safe Harbor and Bespeaks Caution Doctrine Are**
17 **Inapplicable**

18 450. The statutory safe harbor under the Private Securities Litigation
19 Reform Act of 1995, 15 U.S.C. § 78u-5 and the bespeaks caution doctrine
20 applicable to forward-looking statements do not apply to any of the
21 misrepresentations and omissions alleged in this Complaint.

22 451. None of Defendants' historic or present-tense statements alleged
23 herein was a forward-looking statement because none was based upon an
24 assumption underlying or relating to any plan, projection, or statement of future
25 economic performance, as they were not stated to be such assumptions underlying
26 or relating to any projection or statement of future economic performance when
27 made, nor were any of the projections or forecasts made by Defendants expressly
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1 related to, or stated to be dependent on, those historic or present-tense statements
2 when made.

3 452. To the extent that any of the materially false or misleading statements
4 alleged herein, or any portions thereof, can be construed as forward-looking, these
5 statements were not accompanied by meaningful cautionary language identifying
6 important factors that could cause actual results to differ materially from those in
7 the statements. As alleged above in detail, given the existing facts contradicting
8 Defendants' public statements, the generalized risk disclosures made by
9 Defendants were not sufficient to insulate Defendants from liability for their
10 materially false and misleading statements.

11 453. Defendants are also liable for any false or misleading forward-looking
12 statement alleged herein, or portion thereof, because at the time each forward-
13 looking statement was made, the speaker actually knew the forward-looking
14 statement was false or misleading, or the forward-looking statement was
15 authorized and approved by an executive officer of Insys who actually knew that
16 the forward-looking statement was false.

17 **V. CLASS ACTION ALLEGATIONS**

18 454. Lead Plaintiff brings this action as a class action pursuant to Rule 23
19 of the Federal Rules of Civil Procedure on behalf of himself and all other persons
20 who purchased or otherwise acquired Insys common stock during the Class Period
21 (the "Class") and who were damaged thereby. Excluded from the Class are: (i)
22 Defendants; (ii) present and former directors or executive officers of the Company,
23 and members of their immediate families (as defined in 17 C.F.R. § 229.404,
24 Instructions (1)(a)(iii) and (1)(b)(ii)); (iii) any of the foregoing individuals' or
25 entities' legal representatives, heirs, successors, or assigns; and (iv) any entity in
26 which any Defendant has a controlling interest, or which is related to or affiliated
27 with, any Defendant.
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1 455. The members of the Class are so numerous that joinder of all
2 members is impracticable. While the exact number of Class members is unknown
3 to Lead Plaintiff at this time and can only be ascertained through appropriate
4 discovery, Lead Plaintiff believes that there are at least thousands of members of
5 the proposed Class. In fact, according to the Company's Form 10-Q filed with the
6 SEC on May 5, 2016, as of May 1, 2016, Insys had more than 71.5 million shares
7 of stock outstanding, which are likely owned by thousands of persons. The
8 disposition of their claims in a class action will provide substantial benefits to the
9 parties and the Court. Record owners and other members of the Class may be
10 identified from records maintained by Insys or its transfer agent, and Class
11 members may be notified of the pendency of this action by a combination of
12 published notice and notice sent by first-class mail, using the techniques and form
13 of notice similar to that customarily used in class actions arising under the federal
14 securities laws.

15 456. There is a well-defined community of interest in the questions of law
16 and fact involved in this case. Questions of law and fact common to the members
17 of the Class predominating over any questions that may affect Class members
18 individually include:

- 19 (a) whether Defendants' actions as alleged herein violated the
20 Exchange Act;
- 21 (b) whether Defendants omitted and/or misrepresented material facts;
- 22 (c) whether Defendants' statements omitted material facts necessary in
23 order to make the statements made, in light of the circumstances
24 under which they were made, not misleading;
- 25 (d) whether Defendants knew or were deliberately reckless in not
26 knowing that their statements were false and misleading;
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- 1 (e) whether the price of Insys common stock was artificially inflated
2 and/or distorted before and/or during the Class Period due to the
3 misrepresentations and/or omissions of material facts alleged
4 herein;
- 5 (f) whether Class members' reliance may be presumed pursuant to the
6 fraud-on-the-market presumption and/or the *Affiliated Ute*
7 presumption; and
- 8 (g) whether and to what extent Class members sustained damages as a
9 result of the conduct alleged herein, and the appropriate measure of
10 damages.

11 457. Lead Plaintiff's claims are typical of the claims of the other members
12 of the Class, as all members of the Class purchased or otherwise acquired Insys
13 common stock during the Class Period and similarly sustained damages as a result
14 of Defendants' wrongful conduct as alleged herein.

15 458. Lead Plaintiff will fairly and adequately protect the interests of the
16 members of the Class. Lead Plaintiff has retained counsel competent and
17 experienced in class action securities litigation to further ensure such protection,
18 and intends to prosecute this action vigorously. Lead Plaintiff has no interests that
19 are adverse or antagonistic to the interests of other Class members.

20 459. A class action is superior to other available methods for the fair and
21 efficient adjudication of this controversy. Because the damages suffered by each
22 individual member of the Class may be relatively small, the expense and burden of
23 individual litigation make it impracticable for Class members to seek their own
24 redress for the wrongful conduct alleged herein. Lead Plaintiff knows of no
25 difficulty that will be encountered in the management of this litigation that would
26 preclude its maintenance as a class action.

1 **VI. CAUSES OF ACTION**

2 **COUNT I**
3 **Violation of Section 10(b) of the Exchange Act and Rule 10b-5**
4 **Promulgated Thereunder Against All Defendants**

5 460. Lead Plaintiff repeats and realleges each and every allegation set forth
6 above as if fully set forth herein. This Count is brought against all Defendants
7 pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5
8 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, on behalf of Lead
9 Plaintiff and all other members of the Class.

10 461. During the Class Period, Insys and the Individual Defendants, , while
11 in possession of material adverse, non-public information, carried out a plan,
12 scheme and course of conduct, which was intended to and, throughout the Class
13 Period, did: (i) deceive the investing public, including Lead Plaintiff and other
14 Class members, regarding the intrinsic value of Insys common stock, as alleged
15 herein; (ii) artificially inflate the price of Insys common stock; and (iii) cause Lead
16 Plaintiff and other members of the Class to purchase shares of Insys common stock
17 at artificially inflated prices that did not reflect their true value. In furtherance of
18 this unlawful scheme, plan and course of conduct, Defendants used the means and
19 instrumentalities of interstate commerce, the United States mails, and the facilities
20 of a national securities exchange, and each of the Defendants took the actions.

21 462. Insys and the Individual Defendants: (i) employed devices, schemes,
22 and artifices to defraud; (ii) made untrue statements of material fact and/or failed to
23 disclose material facts necessary to make their statements not misleading; and (iii)
24 engaged in acts, practices, and a course of business that operated as a fraud and
25 deceit upon the purchasers of the Company's common stock in an effort to
26 maintain artificially high market prices for Insys common stock in violation of
27 Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
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1 463. Defendants are liable for all materially false and misleading
2 statements and omissions made during the Class Period, as alleged above,
3 including the false and misleading statements and omissions included in press
4 releases, conference calls, SEC filings, news media, blog reports, and on Insys'
5 website. By virtue of their high-level positions at the Company during the Class
6 Period, the Individual Defendants were authorized to make public statements, and
7 made public statements during the Class Period on Insys' behalf. The Individual
8 Defendants were privy to and participated in the creation, development, and
9 issuance of the materially false and misleading statements alleged herein, and they
10 and the Company disseminated information to the investing public that they either
11 knew, or were deliberately reckless in not knowing, was materially false and
12 misleading.

13 464. In addition to the duties of full disclosure imposed on Defendants as a
14 result of making affirmative statements and reports to the investing public,
15 Defendants also had a duty to disclose information required to update and/or
16 correct their prior statements, misstatements, and/or omissions, and to update any
17 statements or omissions that had become false or misleading as a result of
18 intervening events. Further, Defendants had a duty to promptly disseminate
19 truthful information that would be material to investors in compliance with the
20 integrated disclosure provisions of the SEC, as embodied in SEC Regulation S-X
21 (17 C.F.R. § 210.01 *et seq.*) and Regulation S-K (17 C.F.R. § 229.10 *et seq.*), as
22 well as other SEC regulations, including accurate and truthful information with
23 respect to the Company's operations, so that the market price of the Company's
24 common stock would be based on truthful, complete, and accurate information.

25 465. Such material misrepresentations and/or omissions were done
26 knowingly or with deliberate recklessness, and without a reasonable basis, for the
27 purpose and effect of concealing from the investing public the relevant truth, and
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1 misstating the intrinsic value of Insys common stock. By concealing material facts
2 from investors, Defendants maintained the Company's artificially inflated common
3 stock prices throughout the Class Period.

4 466. Unaware that the price of Insys common stock was artificially
5 inflated, and relying directly or indirectly on the false and misleading statements
6 and omissions made by Defendants, or upon the integrity of the market in which
7 the Company's common stock trades, and/or on the absence of material adverse
8 information that was known to or recklessly disregarded by Defendants but not
9 disclosed in public statements by Defendants during the Class Period, Lead
10 Plaintiff and the other members of the Class purchased or acquired Insys common
11 stock during the Class Period at artificially inflated prices.

12 467. At the time of Defendants' misrepresentations and omissions, Lead
13 Plaintiff and the other members of the Class were unaware of their falsity, and
14 believed them to be true. Had Lead Plaintiff and other Class members known of
15 the truth concerning Defendants' misconduct and the intrinsic value of Insys
16 common stock, Lead Plaintiff and other members of the Class would not have
17 purchased or acquired their Insys common stock, or, if they had purchased or
18 acquired such common stock during the Class Period, they would not have done so
19 at the artificially inflated prices they paid.

20 468. By virtue of the foregoing, Defendants have violated Section 10(b) of
21 the Exchange Act, and Rule 10b-5 promulgated thereunder. As a direct and
22 proximate result of Defendants' wrongful conduct, Lead Plaintiff and other
23 members of the Class suffered damages in connection with their purchases and/or
24 acquisitions of the Company's common stock during the Class Period.

25 **COUNT II**
26 **Violation of Section 20(a) of**
27 **The Exchange Act Against Defendants Babich, Baker, and Kapoor**
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1 469. Plaintiff repeats and realleges each and every allegation contained
2 above as if fully set forth herein. This Count is brought pursuant to Section 20(a)
3 of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of Lead Plaintiff and all other
4 members of the Class against Defendants Babich, Baker, and Kapoor (collectively,
5 the “Section 20(a) Defendants”).

6 470. During the Class Period, the Section 20(a) Defendants acted as
7 controlling persons of Insys within the meaning of Section 20(a) of the Exchange
8 Act as alleged herein. By virtue of their high-level positions, their ownership
9 interest in Insys, and participation in and/or awareness of the Company’s
10 operations and/or intimate knowledge of the materially false and misleading
11 statements and omissions of material fact in statements filed by the Company with
12 the SEC and/or disseminated to the investing public, the Section 20(a) Defendants
13 had the power to influence and control and did influence and control, directly or
14 indirectly, the decision-making of the Company and its executives, including the
15 content and dissemination of the various statements that Lead Plaintiff contends
16 were materially false and misleading. The Section 20(a) Defendants were
17 provided with or had unlimited access to copies of the Company’s reports, press
18 releases, public filings, and other statements alleged by Lead Plaintiff to be
19 materially misleading prior to and/or shortly after these statements were issued and
20 had the ability to prevent the issuance of the statements or cause the statements to
21 be corrected.

22 471. In particular, each of the Section 20(a) Defendants had direct and
23 supervisory involvement in the day-to-day operations of the Company and,
24 therefore, is presumed to have had the power to control or influence the particular
25 conduct and transactions giving rise to the securities violations alleged herein, and
26 exercised the same.

1 472. As set forth above, Insys and each of the Individual Defendants
2 violated Section 10(b) and Rule 10b-5 by their respective acts, statements, and
3 omissions as alleged in this Complaint. By virtue of their respective positions as
4 controlling persons of Insys, each of the Section 20(a) Defendants is liable
5 pursuant to Section 20(a) of the Exchange Act.

6 473. As a direct and proximate result of the Section 20(a) Defendants'
7 wrongful conduct, Lead Plaintiff and other members of the Class suffered damages
8 in connection with their purchases and/or acquisitions of the Company's common
9 stock during the Class Period.

10 **VII. PRAYER FOR RELIEF**

11 WHEREFORE, Lead Plaintiff, on behalf of himself and the other members
12 of the Class, prays for relief and judgment, including:

- 13 (a) Determining this action to be a proper class action under Rules
14 23(a) and (b)(3) of the Federal Rules of Civil Procedure,
15 appointing Lead Plaintiff as a Class Representative under Rule 23
16 of the Federal Rules of Civil Procedure, and appointing Lead
17 Plaintiff's counsel as Class counsel pursuant to Rule 23(g) of the
18 Federal Rules of Civil Procedure;
- 19 (b) Awarding compensatory damages in favor of Lead Plaintiff and
20 other Class members against all Defendants, jointly and severally,
21 for all damages sustained as a result of Defendants' wrongdoing, in
22 an amount to be determined at trial, including pre-judgment and
23 post-judgment interest, as allowed by law;
- 24 (c) Awarding Lead Plaintiff and the other members of the Class all
25 reasonable costs of prosecuting the litigation, including attorneys'
26 fees and experts' fees; and
- 27
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1 (d) Awarding such other and further relief to Lead Plaintiff as this
2 Court may deem just and proper.

3 **VIII. DEMAND FOR JURY TRIAL**

4 Lead Plaintiff hereby demands a trial by jury on all triable claims.

5
6 DATED: December 22, 2016

Respectfully submitted,

7 **KESSLER TOPAZ**
8 **MELTZER & CHECK, LLP**

9 *s/ Johnston de F. Whitman, Jr.*
10 *Johnston de F. Whitman, Jr. (admitted Pro Hac*
11 *Vice)*
12 *jwhitman@ktmc.com*
13 *280 King of Prussia Road*
14 *Radnor, PA 19087*
15 *Telephone: (610) 667-7706*
16 *Facsimile: (610) 667-7056*

-and-

17 *Jennifer L. Joost (admitted Pro Hac Vice)*
18 *jjoost@ktmc.com*
19 *Rupa Nath Cook (admitted Pro Hac Vice)*
20 *rcook@ktmc.com*
21 *1 Sansome Street, Suite 1850*
22 *San Francisco, CA 94104*
23 *Telephone: (415) 400-3000*
24 *Facsimile: (415) 400-3001*

Lead Counsel for Lead Plaintiff and the Proposed
Class

25 **BONNETT, FAIRBOURN,**
26 **FRIEDMAN & BALINT, P.C.**

27 *Francis J. Balint, Jr.*
28 *Andrew S. Friedman*
2325 E. Camelback Road, Ste. 300
Phoenix, AZ 85016
Telephone: (602) 274-1100
Facsimile: (602) 274-1199
fbalint@bffb.com
afriedman@bffb.com

Liaison Counsel for Lead Plaintiff and the
Proposed Class

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GOLDBERG LAW PC
Michael Goldberg
Brian Schall
13650 Marina Pointe Drive
Suite 708
Marina Del Rey, CA 90292
Telephone: (800) 977-7401
Facsimile: (800) 536-0065
michael@goldberglawpc.com
brian@goldberglawpc.com

Additional Counsel for Lead Plaintiff Clark Miller

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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2016, I electronically transmitted the foregoing document to the Clerk’s Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to those persons who are CM/ECF registrants:

Daniel Slifkin
David M. Stuart
Cravath Swaine & Moore LLP
825 8th Ave.
New York, NY 10019
Tel: 212-474-1000
Fax: 212-474-3700
Email: dslifkin@cravath.com
Email: dstuart@cravath.com

Donald Wayne Bivens
Nicole Elizabeth Sornsin
Snell & Wilmer LLP
1 Arizona Center
400 E Van Buren
Phoenix, AZ 85004-2202
Tel: 602-382-6549
Fax: 602-382-6070
Email: dbivens@swlaw.com
Email: nsornsin@swlaw.com

/s/ Johnston de F. Whitman, Jr